ATTACHMENT C

The 2005 Nationwide Blood Collection and Utilization Survey Report

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

AABB conducted the 2005 Nationwide Blood Collection and Utilization Survey under United States Department of Health and Human Services Contract HHSP22320042202TE.

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1. Executive Summary

The Department of Health and Human Services (DHHS) and AABB conducted the fourth nationwide survey of blood services and related activities in July 2005. (Earlier surveys were conducted in 2002, 2000, and 1998.) The purpose of the survey (a 12-page questionnaire) was to assess the amount of blood collected and transfused in the United States (US) in 2004 and to provide data to assist the DHHS in validating its Blood Availability and Safety Information System. The facilities surveyed included all non-hospital-based blood collection centers (blood centers), a sample of hospitals from the American Hospital Association database, and, for the first time, a sample of cord blood banks.

Response rates to the 2005 Nationwide Blood Collection and Utilization Survey (NBCUS) were as follows: blood centers 92.3% (131/142), hospitals 56.8% (1,604/2,825), and cord blood banks 33.3% (3/9). Statistical procedures were used to verify that the sample was representative and to develop weighted national estimates.

Important Trends in the US Blood Supply

The supply of screened allogeneic whole blood (WB) and red blood cell (RBC) units that passed all tests (14,560,000) exceeded transfusions of allogeneic WB/RBCs (13,912,000) by a margin of 648,000 units. The blood supply was sufficient to meet transfusion needs. These data, combined with the lowest rate of units outdated in recent years, suggest that hospitals and blood centers have become more efficient at delivering the appropriate product when needed. Although most hospitals reported few delays or shortages, when shortages or delays occurred, the episodes lasted longer. Among hospitals reporting unmet blood needs, the mean number of days of unmet nonsurgical blood need increased significantly from 2.1 days in 2001 to 19.27 days in 2004 ($p<0.001$).

Blood collection per thousand US population of donor age (18-65 years) was 85.6 in 2004 compared to 88.0 in 2001. This was a decrease of 2.7% from the 2001 rate, but still a larger percentage of the population than was reported in 1999 (80.8/1,000). This suggests that donor centers have been able to retain many of the donors who volunteered after the September 11, 2001 terrorist attacks on New York City and Washington, DC. The US WB/RBC transfusion rate in 2004 was 49.6 units per thousand population, statistically unchanged from 2001. This was a welcome flattening of the seemingly ever-increasing transfusion rate curve for the aging US population (**Figure 11-2**).

Blood Collection

The NBCUS indicates that the total supply of WB/RBC units in 2004 was 15,288,000 units before testing. This is only marginally fewer units (0.2%) than were reported in 2001, when increased collections were attributed to altruistic donation after the September 11, 2001 terrorist attacks. Blood centers were responsible for the collection of 14,305,000 units or 93.6% of the supply; hospitals collected 983,000 units or 6.4% of the total.

The composition of the source of the blood supply in 2004 was different from that of previous years. In 2001, traditional allogeneic collections were responsible for the high number of units collected. In 2004, these numbers remained high, but because of the increased use of red cell apheresis technology in the face of reduced (and, in the case of autologous and directed donations, significantly reduced) traditional blood collections. Red cell apheresis collections increased 202% over 2001, yielding approximately 824,000 RBC units. **Figure 1-1** illustrates the growth in use of red cell apheresis.

Note: Red cell apheresis refers to the use of a machine to collect approximately 2 RBC units in one collection procedure instead of extracting the cells from a single unit of whole blood.

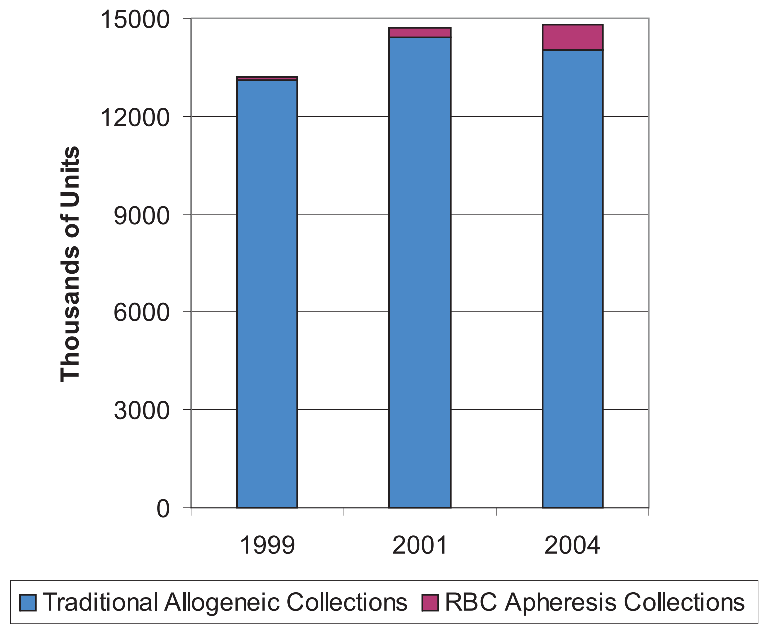

Figure 1-1. Growth in use of RBC apheresis technology.

Blood Transfusion

The number of WB/RBCs transfused in 2004 totaled 14,182,000 units—a small, but not statistically significant, increase of 2% over 2001 totals. Allogeneic units transfused (including the pediatric contribution expressed as adult equivalent units) equaled 13,912,000.

The total number of platelet units provided to patients in 2004 was 9,875,000; this was not significantly different from the 2001 total. However, the proportion of transfused platelets that were collected by apheresis increased 10% from 7,582,000 to 8,338,000 platelet concentrate equivalent units, representing 84.4% of the total platelets transfused. The transfusion of whole-blood-derived platelet concentrates continued a downward trend, decreasing 41.2% from 2,614,000 units in 2001 to 1,537,000 units in 2004 ($p<0.0001$).

2. Key Findings

The results of The 2005 Nationwide Blood Collection and Utilization Survey (NBCUS) provide an update of United States (US) blood services and related activities assessed by the three previous nationwide surveys conducted in 2002, 2000, and 1998. Notable findings from the 2005 NBCUS and comparisons with the 2002 survey results were as follows:

- Allogeneic collections remained statistically the same at 14.8 million units.
- Total WB/RBC transfusions remained statistically the same at 14.2 million units.
- Autologous collections declined significantly by 26% to 458,000 units.
- Red blood cell apheresis collections increased 202% for a total of 824,000 units.
- The total number of all components transfused in 2004 was 29,038,000.
- The total number of transfused units that were irradiated increased by 15.8% while those that were leukocyte-reduced increased by 2.7%.
- Transfusion of prestorage leukocyte-reduced units increased by 7.9%, while the transfusion of poststorage leukocyte-reduced units decreased by 45.3%.
- There was a significant (54%) decline in HPC-M transplant procedures performed.
- There was a 42.9% decrease in the number of outdated whole blood (WB) and red blood cell (RBC) units.
- The transfusion of whole-blood-derived platelet concentrates continued to decline (–41.2%), while the use of apheresis platelets increased by 10%. Overall, transfusion of platelets remained essentially the same at 9.9 million units.
- Almost all blood centers (99.2%) and hospitals (89.6%) have emergency preparedness plans for blood services.
- A total of 135 hospitals reported the cancellation of elective surgery on one or more days because of blood inventory shortages. This affected 546 patients, significantly fewer than in 2001.
- The mean age of RBC units at transfusion was 17 days.
- The mean age of whole-blood-derived platelet units was 3.16 days at transfusion; for an apheresis platelet unit, the mean was 3.08 days.
- The average cost of RBC units increased by 30.8%. A statistically significant increase in the cost since 2001 was measured for all four components assessed.
- The WB/RBC collection rate per thousand US donor population was 85.6 units in 2004, compared to 88.0 in 2001. The WB/RBC transfusion rate remained the same at 49.6 units per thousand US population overall.
- The margin between test-negative allogeneic WB/RBC units collected and those transfused in the US in 2004 was 648,000 units, compared to approximately 920,000 in 2001.

3. Introduction and Methods

This report presents the results of the fourth Nationwide Blood Collection and Utilization Survey (NBCUS), conducted in 2005. The survey was funded by the Department of Health and Human Services and conducted by AABB (Bethesda, MD). Previous surveys were conducted in 1998, 2000, and 2002 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 services activities in the United States (US) in 2004; to provide comparisons with previous measurements; to provide data to validate a real-time national blood supply and utilization monitoring system; and to characterize business practices in the blood collection, transfusion medicine, and cellular therapy 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 12-page questionnaire, cover letter, and postage-paid return envelope were mailed in July 2005 to the 2,976 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 second mailing of the survey questionnaire was sent to 2,492 nonresponders six weeks afterwards. Those facilities that did not respond by the initial September deadline were contacted by e-mail, telephone, or both. Data collection concluded on October 31, 2005.

Data coding, keying, and verification were performed by Research Triangle International (RTI, Research Triangle Park, NC). Validation of survey data was achieved by comparison with 2001 survey data and by direct contact with individual respondents as necessary.

Sampling Frame

The sampling frame for the 2005 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 in the 50 states. This list also contains hospitals that are members of AABB. The second source is the American Hospital Association (AHA) database.

To construct the sampling frame from the AHA database, several criteria were used. Only those hospitals providing general medical and surgical service, children's general medical and surgical service, and obstetrics and gynecology services were considered eligible population members. Two new service categories, oncology and cardiology, were investigated and were included in the frame if the hospitals responded to the 2002 AHA hospital survey. To ensure comparability with previous surveys of domestic institutions, the following types of treatment facilities were excluded from the AHA sampling frame: military and federal facilities, such as Department of Justice facilities, Indian Health Service facilities, and non-US facilities. Veterans Affairs treatment facilities were included in the sampling frame. Finally, hospitals reporting fewer than 100 inpatient surgeries per year were also excluded.

To prepare the AABB database for sampling, hospitals were matched to the AHA database and the AHA identification numbers were assigned to avoid duplication. All US hospitals with 100 or more annual surgeries included on the AABB member list were included in the sampling frame, regardless of whether they met exclusion criteria that were used for the AHA database, because it was established that these hospitals collect and/or transfuse blood. Within the AABB database, the facilities were categorized into four groups: blood collection centers, hospitals that collect and transfuse blood, hospitals that transfuse blood only, and cord blood banks. The final list of eligible facilities contained a total of 4,202 blood centers, hospitals, and cord blood banks.

Sample Selection

The NBCUS sampling frame consisted of all the blood centers on the AABB list and all eligible hospitals on the AABB list. This initial list of treatment facilities was supplemented with hospitals from the AHA database to ensure a total sample of 3,000 facilities. The AHA hospital database was 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 in all strata with more than 2,400 surgeries were sampled at a rate of 100%. If the treatment facility was a nonrespondent to the 2002 AHA survey and the inpatient surgeries were estimated (due to nonresponse) to be fewer than 2,400, then these hospitals were excluded from the sample, but remained as eligible population members. Nonrespondents with the higher surgical volumes were kept in the sample. After these exclusions, the strata for 1,000-1,399 surgeries and 1,400-2,399 surgeries were sampled at rates of 86% and 88%, respectively. The number of hospitals selected in the 100-999 stratum was equal to the sample size needed to result in a total sample of just over 3,000. **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—collectively for blood centers and by surgical volume for hospitals. After eliminating ineligible institutions (42 hospitals that had ceased operations, changed status, or chosen to have an affiliate make the report), the combined response rate was 58.4%.The response rate for blood centers was 92.3% (131/142). The response rate for sampled hospitals was 56.8% (1,604/2,825). Response rates by surgical volume classes ranged between 50.8% and 66.6%. The total number of individual survey responses from the hospital sample was 1,604.

Edit and Imputation Procedures

RTI ensured the internal consistency of the 2005 NBCUS data by developing machine edit specifications to check the logic and internal consistency of the data before imputation. Most missing data were imputed using a model-based

Table 3-1. Sampling Frame Counts and Sampling Rates

Type of Facility	Total Population	Sample	Sampling Rate (%)
Hospitals			
100–999 surgeries/year	1,564	510	32.6
1,000–1,399 surgeries/year	365	314	86.0
1,400–2,399 surgeries/year	682	603	88.4
2,400–4,999 surgeries/year	854	854	100.0
5,000–7,999 surgeries/year	337	337	100.0
≥8,000 surgeries/year	249	249	100.0
Blood Centers	142	142	100.0
Cord Blood Banks	9	9	100.0
Total Facilities	4,202	3,018	71.8

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

Type of Facility	No. Eligible	Respondents	Response Rate (%)
Hospitals	2,825	1,604	56.8
100–999 surgeries/year	502	255	50.8
1,000–1,399 surgeries/year	312	163	52.2
1,400–2,399 surgeries/year	599	329	54.9
2,400–4,999 surgeries/year	841	483	57.4
5,000–7,999 surgeries/year	332	221	66.6
≥8,000 surgeries/year	239	153	64.0
Blood Centers	142	131	92.3
Cord Blood Banks	9	3	33.3
Total Facilities	2,976	1,738	58.4

Table 3-3. Raw Sampling Weights

Type of Facility	No. in Stratum	No. Sampled in Stratum	Raw Sampling Weight
Hospitals			
100–999 surgeries/year	1,564	510	3.0647
1,000–1,399 surgeries/year	365	314	1.1624
1,400–2,399 surgeries/year	682	603	1.1310
2,400–4,999 surgeries/year	854	854	1.0000
5,000–7,999 surgeries/year	337	337	1.0000
≥8,000 surgeries/year	249	249	1.0000
Blood Centers	145	145	1.0000
Cord Blood Banks	9	9	1.0000
Total Facilities	4,051	3,022	

regression method for continuous variables for both hospitals and blood centers. However, for nonresponding blood centers, key variables were imputed using data from the prior NBCUS survey (conducted in 2002) and the *Directory of Community Blood Centers* (published by AABB in 2003) in lieu of regression imputation. 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 raw 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 raw weight for hospitals was calculated as follows:

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

The “number sampled” in the denominator includes all units sampled, including those 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 raw 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 hospitals in the sample. The numerical adjustment was computed as the reciprocal of the response rate in the stratum. This WCA was calculated as follows:

$$\text{WCA} = \frac{\text{Sum of the Raw Weights for All Sampled Members of the Weighting Class}}{\text{Sum of the Raw Weights for All Responding Members of the Weighting Class}}$$

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

The final sampling weight was then calculated as the product of the raw weight and the WCA. The final sampling weights appear in **Table 3-5** together with the raw sampling weights from **Table 3-3** and the WCA from **Table 3-4**. A final sampling weight of 1.000 was applied to the blood centers to obtain national estimates, even though their WCA was calculated to be 1.0840. Given the high response rate for blood centers, the WCA was considered to be negligible.

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 58.4%, as stated above. The response rate for blood centers was 92.3% (131/142). The overall response from eligible sampled hospitals that reported for themselves was 56.8% (1,604/2,825). Response rates by surgical volume classes ranged from 50.8% to 66.6%. An additional 60 medical treatment facilities submitted data through other reporting institutions (35), a common practice among centralized transfusion services and hospital affiliates. Of these, 18 were in the original sample and 42 were not. Three of the nine (33.3%) facilities classified as public cord blood banks also responded. Therefore, the actual number of facilities (including blood cen-

Table 3-4. Weighting Class Adjustments

Type of Facility	No. Eligible in Weighting Class	No. Eligible and Responded in Weighting Class	Weighting Class Adjustment
Hospitals			
100–999 surgeries/year	502	255	1.9272
1,000–1,399 surgeries/year	312	163	1.9202
1,400–2,399 surgeries/year	599	329	1.8207
2,400–4,999 surgeries/year	841	483	1.7412
5,000–7,999 surgeries/year	332	221	1.5023
≥8,000 surgeries/year	239	153	1.5621
Blood Centers	142	131	1.0840
Cord Blood Banks	9	3	3.0000
Total Facilities	2,976	1,738	

Table 3-5. Final Sampling Weights

Type of Facility	Raw Weight	Weighting Class Adjustment	Final Sampling Weight
Hospitals			
100–999 surgeries/year	3.0647	1.9272	5.9063
1,000–1,399 surgeries/year	1.1624	1.9202	2.2321
1,400–2,399 surgeries/year	1.1310	1.8207	2.0592
2,400–4,999 surgeries/year	1.0000	1.7412	1.7412
5,000–7,999 surgeries/year	1.0000	1.5023	1.5023
≥8,000 surgeries/year	1.0000	1.5621	1.5621
Cord Blood Banks	1.0000	3.0000	3.0000
Blood Centers	1.0000	1.0840	1.0000

ters, hospitals, and cord blood banks) for which survey data were received was 1,798.

The 2005 response rates for blood centers and for hospitals overall were each within 1% of the 2002 survey rates and, thus, were not significantly different. However, the actual number of hospitals that responded to the current survey was greater than in 2002 by 298 (1,604 vs 1,306). The additional facilities were distributed across all geographic regions.

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). The total number of blood centers included in the national estimates for collection and processing was 138. Of these, 129 self-reported or centrally reported for each center individually. Data for two centers were aggregated with those of two other centers that had assumed ownership of them. Data for nine additional blood centers were imputed from previous surveys in which those centers had participated.

Characterization of Respondents

The majority of blood centers self-identified as such. However, 21 centers selected the centralized transfusion service option to describe themselves. This option, added to the survey categories for the first time this year, reads "A local or regional blood center that collects blood from donors and supplies blood, components, and crossmatched blood products to participating facilities (such as a centralized transfusion service)."

Another classification option added to the current survey reads "An independent facility that collects, processes, manufactures, stores, or distributes cellular therapy products." Three cord blood banks that are members of AABB selected this option. Hospital respondents for the most part self-classified as either a transfusion service (1,318) or a hospital-based blood bank and transfusion service that collects blood (278).

The survey also captured the current corporate status of respondents. Multiple responses were permitted. The majority of the blood centers self-

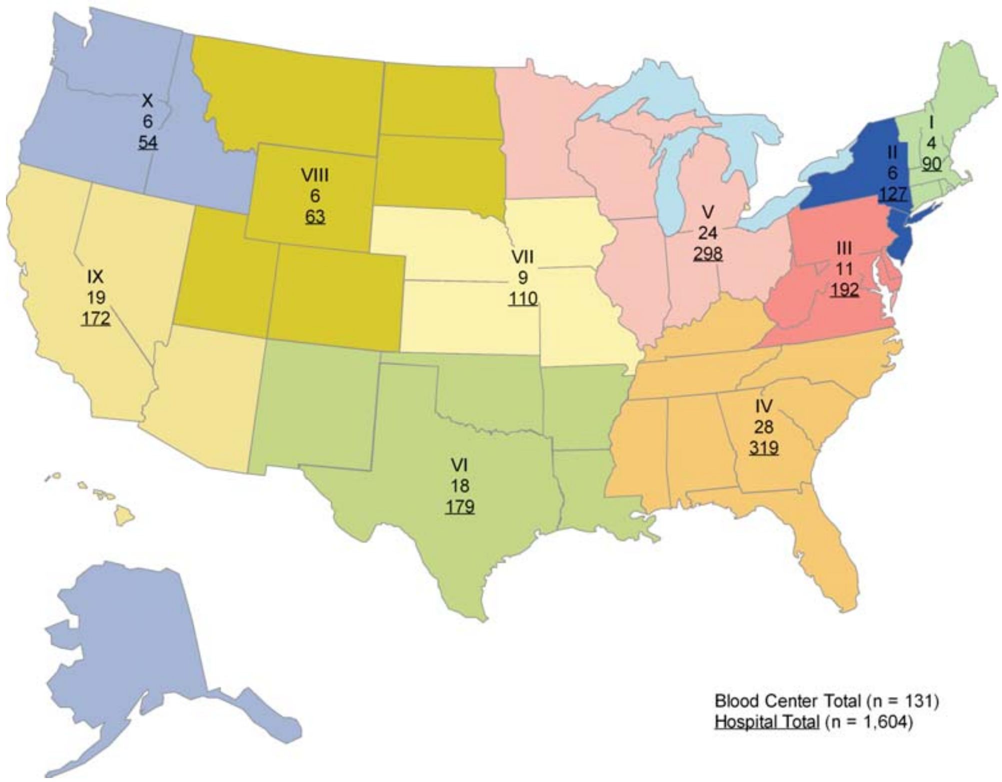

Figure 3-1. Distribution of blood center and hospital respondents by USPHS region.

classified as independent (121/129, 93.8%). Also selected were university (2), government (3), owned by a corporation or other entity (4), and affiliated with another institution (5). Hospital respondents were largely independent (649/1,604, 40.5%) or owned by a corporation or other entity (605/1,604, 37.7%). Also indicated were affiliations with another institution (12.3%), government (10.0%), and university (3.4%).

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

Blood Center Nonrespondents

Eleven blood centers did not respond to the survey. Data for key collection variables were available from the previous survey and other AABB resources for seven non-responding centers and were used in lieu of statistical imputation. The remaining four centers are known to have relatively low collection volumes. Collectively, the non-respondents were estimated to account for 4.0% of total US blood center collections.

Limitations of the Survey

The weights described here account for simple survey response. However, more complex issues surrounding response exist in this survey.

Several respondents (including both blood centers and hospitals) reported for other treatment facilities in the sample. These other treatment facilities were both contained within the same sampling stratum and located in other strata, and several respondents reported for treatment facilities that were not in the original sample. When group-reporting information was available, the facilities that reported the information combined the data for all facilities so that it was not possible to separate those data to ensure that the most appropriate weights were assigned.

For the 2005 survey, a data control system was designed to collect information on the following group-reporting categories:

- The sampled treatment facility reported for itself only.
- The sampled treatment facility reported for other sampled treatment facilities only.
- The sampled treatment facility chose another sampled treatment facility to report the data.
- The sampled treatment facility reported for itself and other sampled treatment facilities.
- The sampled treatment facility reported for itself and other sampled and nonsampled treatment facilities.

Useful information was captured using the control system. However, because of the complex issue of different types of treatment facilities (including health systems, individual hospitals, satellite facilities, and affiliated hospitals) that report together, information necessary to adjust the weights with absolute accuracy could not be captured. Additional information describing the relationship between sample members and those for whom they report, as well as reporting practices, will be essential to accounting for these complex issues. In other words, stricter definitions of the eligible population and reporting requirements are needed for future surveys.

4. Blood Collected and Processed in the United States

Total Collections

The total supply of blood collected in the United States in 2004 was 15,288,000 units before laboratory testing (**Table 4-1**). Blood centers collected 14,305,000 units, or 93.6% of the total. The balance of 983,000 units (6.4%) was collected by hospitals. The total supply in 2004 was virtually unchanged (–0.2%). However, the composition of the supply in 2004 was different than that of 2001. While traditional allogeneic collections were responsible for the high number of units collected in 2001, in 2004 these high numbers were maintained by the increased use of red cell apheresis technology in the face of reduced (and, in the case of autologous and directed donations, significantly reduced) traditional blood collections. On a positive note, the gain seen in blood donation activity following the terrorist attacks of September 11, 2001, has not been lost in the subsequent years.

Whole Blood Collections

Donations of WB in 2004 totaled 14,464,000 and were reported according to the type of donation. Community donations, excluding directed donations, accounted for 90.8% of the supply; directed donations accounted for 0.8%; and autologous donations accounted for 3.0%. Another 824,000 units (5.4%) were red blood cells (RBCs) collected by apheresis, which is discussed below.

Community donations totaled 13,890,000, of which 94.4% were collected by blood centers, and 5.6% by hospitals. The percentage decrease in community donations between 2001 and 2004 was 2.6% ($p=0.8036$). Directed donations declined by 31.3%, to 116,000 units ($p=0.0285$). Hospitals reported 31.0% of directed donations, a portion of which were eventually crossed over to the community supply.

Autologous, or self-directed units, totaled 458,000, a decrease of 26.0% in comparison with 2001 ($p<0.0003$). Hospitals collected 31.7% of all autologous units.

Red Blood Cells Collected by Apheresis

In addition to WB collections, 824,000 RBC units were collected by apheresis, which typically yields a double volume of cells. Apheresis procedures in 2004 yielded a 202% increase in RBC units in comparison to the 273,000 collected in 2001, which is statistically significant ($p<0.0001$). RBCs collected in this manner contributed 5.4% of the total WB/RBC supply in 2004. This total included autologous collections (2.2% of the apheresis total) as well as directed donations (0.4% of the total).

The expanded use of this technology occurred largely in blood centers, which accounted for 96.7% of reported

Table 4-1. Estimated 2004 Activities of US Blood Centers and Hospitals for Whole Blood (WB) and Red Blood Cells (RBCs) (expressed in thousands of units)

Activity	Blood Centers	Hospitals		2004 Combined Total	% of Total Collections/ Transfusions	2001 Total	% Change 2001-2004
		Total	±95% CI				
Collections							
WB Allogeneic (excluding directed)	13,115	775	150	13,890	90.8	14,259	–2.6
WB Autologous	313	145	14	458*	3.0	619	–26.0
WB Directed	80	36	10	116*	0.8	169	–31.3
RBC Apheresis	797	27	10	824*	5.4	273	200.4
Total Supply	14,305	983	146	15,288	100.0	15,320	–0.2
Rejected on Testing	255	15	3	270	1.8	245	10.3
Available Supply	14, 050	968	144	15,019	98.2	15,076	–0.4
Transfusions							
Allogeneic (excluding directed)	551	13,169	319	13,720	96.7	13,361	2.7
Autologous	13	258	18	270*	1.9	359	–24.6
Directed (to designated patient)	1	131	38	132	0.9	95	39.4
Pediatric	2	57	11	60	0.4	84	–29.2
Total Transfusions	568	13,614	329	14,182	100.0	13,898	2.0
Outdated WB/RBCs	166	337	15	503*	3.3	880	–42.9

*significantly different from 2001 data.

units. In 2001, 63 blood centers and 17 hospitals reported such collections. By 2004, 115 blood centers had adopted this technology, while only 30 hospitals reported collecting RBCs by apheresis. The mean number of units collected by blood centers was 6,834 and for hospitals was 885. The minimum number of units collected by any facility reporting this activity was 10 and the maximum was 50,201.

Note: For the current analysis, blood centers were consulted to determine the most accurate red cell yield from an RBC apheresis procedure. From this input, it was decided that, on average, *an RBC apheresis procedure yields 1.9 units of RBCs, rather than 2.0 units. Therefore, a factor of 1.9 was used in the conversion of RBC apheresis collection procedures to RBC units produced in 2004. The previous survey used a factor of 2.0.*

Whole Blood and Red Blood Cell Units Released for Distribution

Blood centers and collecting hospitals reported the total number of WB/RBC units released for distribution in 2004, and provided a breakdown of released units by ABO group and Rh type. The unweighted results, shown in **Table 4-2**, indicate that 53.7% of units released were group O units, with O-negative blood accounting for 6.8% of all units. Another 21.6% were group A units, with most of these being A-positive units. Groups B and AB comprised 11.8% of units released for transfusion. The group and type of the remaining 13% of units were not reported. Hospitals were less likely to categorize their distribution data by group and type. However, because blood centers release the greater proportion of units for distribution, they are responsible for approximately 10% of the total for which group and type went unreported.

Non-Red-Blood-Cell Components Processed

Non-RBC component units collected or processed include platelets from whole blood, platelets from apheresis, plasma from apheresis, cryoprecipitate, and granulocytes. The total number of non-RBC components produced for transfusion in 2004 was 11,559,000 (apheresis platelets counted as platelet doses, *not* as platelet concentrate equivalents).

Platelets

Platelet concentrates were derived from 4,202,000 WB units, an increase of 0.9%

Table 4-2. WB/RBC Units Released for Distribution by Blood Group and Type by Blood Centers and Collecting Hospitals

Blood Group/Type	Unweighted Units Released (in thousands of units)	% of Total
O+	5,880	46.9
O–	846	6.8
A+	2,406	19.2
A–	299	2.4
B+	887	7.1
B–	196	1.6
AB+	327	2.6
AB–	61	0.5
Unknown	1,624	13.0
Total Units	12,527	100.0

Table 4-3. Estimated 2004 Activities of US Blood Centers and Hospitals for Non-Red-Blood-Cell Components (expressed in thousands of units)

Activity	Blood Centers	Hospitals* Total	Hospitals* ±95% CI	2004 Total	2001 Total	% Change 2001-2004
Collection Production						
Apheresis Platelets†	8,252	909	366	9,161 (1,527)	8,734	4.9
WB-Derived Platelet Concentrates	3,930	272	104	4,202	4,164	0.9
Total Platelets	12,182	1,180	398	13,362	12,898	3.6
FFP/Apheresis Plasma‡	4,265	386	100	4,651	4,437	4.8
Cryoprecipitate	1,133	31	21	1,164	1,067	8.9
Transfusions						
Apheresis Platelets†	353	7,985	626	8,338 (1,390)	7,582	10.0
WB-Derived Platelet Concentrates	33	1,504	205	1,537§	2,614	–41.2
Total Platelets	386	9,489	655	9,875	10,196	–3.1
FFP/Apheresis Plasma	214	3,875	269	4,089	3,926	4.1
Cryoprecipitate‖	32	858	58	890	898	–0.9
Outdated Non-RBC Components	599	480	50	1,079§	1,346	–19.8

*weighted data, includes 95% confidence interval (CI)
†platelet concentrate equivalent units (apheresis packs); includes splits
‡for transfusion; includes apheresis plasma
§significantly different from 2001 data
‖for transfusion only

from the 2001 volume (**Table 4-3**). Platelets were prepared from 30.3% of all allogeneic WB collected, essentially unchanged from 2001. Blood centers processed 3,930,000 units (93.5%), while hospitals produced 272,000 (6.5%).

An estimated 1,164,000 apheresis platelet procedures were completed, yielding 1,527,000 platelet doses. This volume indicates a split rate of 31.2% 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 9,161,000 platelet concentrate units. This was statistically unchanged in comparison with 2001. Blood centers collected 90.1% of apheresis platelets, while hospitals were responsible for 9.9%.

Plasma

A total of 4,651,000 units of plasma from apheresis procedures were produced for transfusion. This volume is an increase of 4.8% from the 2001 volume but statistically unchanged (p=0.6941). Blood centers produced 91.7% of the plasma (4,265,000 units) and hospitals produced the remaining 8.3% (386,000 units). A total of 111,000 plasmapheresis procedures were reported. In addition, 7,804,000 units of plasma were produced that were intended for further manufacture, with 96% coming from blood centers.

Cryoprecipitate

A total of 1,164,000 units of cryoprecipitate were prepared. This was an increase of 9.1% over 2001, but not statistically significant (p=0.0730). Blood centers accounted for 97.3% of cryoprecipitate produced.

Granulocytes

Granulocytes, which are prepared from both apheresis and whole-blood-derived buffy coat units, totaled 13,000 units produced. Blood centers reported 94.4% of this total, which includes 6,050 non-directed apheresis donations, and 334 directed apheresis donations.

5. Blood Transfused in the United States

Whole Blood and Red Blood Cells Transfused

Transfusions of whole blood (WB) and red blood cells (RBCs) of all donation types totaled 14,182,000 units, a 2% increase from 2001, which is not statistically significant (p=0.5379) (see **Table 4-1**). Allogeneic units, including pediatric units expressed as adult equivalent units, accounted for 98% of units transfused, or 13,912,000 units. There was a small increase (2.7%, not statistically significant) in the transfusion of allogeneic units (community, directed, and pediatric combined) in comparison with 2001. The percent of available allogeneic units utilized was 97.7%, in contrast to 93.7% and 92.5% in 2001 and 1999, respectively. Blood centers claimed responsibility for 4.0% (568,000) of transfused units, primarily through contractual arrangements with hospitals.

The number of autologous units transfused, 270,000, represented 59% of the 458,000 units donated preoperatively by patients in 2004. Autologous units accounted for 1.9% of all units transfused in 2004. Autologous transfusions, which declined steadily between 1992 and 1999 and were statistically unchanged from 1999 to 2001, declined significantly again (p<0.0001) between 2001 and 2004. Only 487 units (0.04%) were reported to have been crossed over to the community supply in 2004.

Directed donations, the donation of allogeneic blood for a designated patient other than the donor, accounted for 132,000 units transfused. Another 144,000 units were reported to have been crossed over to the community supply. The overall utilization of directed units was greater than 100% vs 88.2% in 2001. Although it appears that there are more directed units transfused and outdated than collected, many red cell apheresis procedures are directed donations and are not attributed as such in the collection figures.

In the last survey, an attempt was made to capture more detailed information regarding the usage of WB/RBC units—specifically, the number of units ordered for surgical procedures (total sent to operating and recovery rooms). The data were not weighted. In 2004, 261 (16.3%) hospitals answered the question, compared with 179 (15.7%) in 2001. The responses totaled 297,000 units ordered, as compared with 350,000 reported in 2001. This total was then calculated as a percentage of the total units transfused at the responding institutions. The overall percentage of transfused WB/RBCs ordered for surgical procedures at the reporting hospitals was 27.9% (compared with 39.5% in 2001).

Whole Blood and Red Blood Cell Recipients

The 2005 NBCUS captured the number of patients who received WB/RBCs of each donation type. The reported number of recipients of allogeneic units (including directed) was 1,688,345 per

4,569,584 units transfused by 1,073 medical treatment facilities. This represents 2.7 units per recipient, a small decline from 2.9 units per recipient in 2001. Autologous recipients received an average of 1.5 units each compared to 1.6 units in 2001. Finally, for recipients of pediatric units, the ratio was 2.3 units per recipient (2.4 units per recipient in 2001).

Extrapolating the ratio of 2.7 for WB/RBC recipients to total WB/RBCs transfused yields a national estimate of 5.3 million total WB/RBC recipients in 2004. This represents an increase in recipients of 8.6% (4.9 million recipients in 2001).

Non-Red-Blood-Cell Components Transfused

National estimates for non-RBC components transfused in 2004 are presented in **Table 4-3.**

An estimated total of 9,875,000 platelet units were transfused to patients in 2004, a decrease of 3.2% in comparison with 2001; this decrease is not statistically significant. The transfusion of apheresis platelets increased by 10.0% from 7,582,000 to 8,338,000 platelet concentrate equivalent units; this increase is not statistically significant.

The transfusion of whole-blood-derived platelet concentrates continued on a significantly downward trend ($p<0.001$), declining 41.2% to 1,537,000 from the previous survey estimate of 2,614,000. This has been the trend in platelet usage since 1994.

Note: The AABB standard requiring testing for bacterial contamination of platelets was implemented on March 1, 2004.

The combined total of fresh frozen plasma (FFP), and apheresis plasma resulted in 4,089,000 units transfused, an increase of 4.1% over the 2001 volume of 3,926,000 (not statistically significant). Reporting institutions indicated the volumes of transfused plasma that had been processed by a variety of methods as shown in **Figure 5-1**. The weighted results, for which overlap is possible, are as follows:

- FFP represented 82.5% of plasma transfused (3,398,000 units).
- Plasma frozen within 24 hours after phlebotomy comprised 14.7% of plasma transfused (604,000 units); this amount is significantly higher than in 2001 ($p<0.05$).
- Jumbo plasma accounted for 1.8% (73,000 units) of plasma transfused.
- Pediatric-sized plasma units represented 0.9% (39,000 units) of plasma transfused.

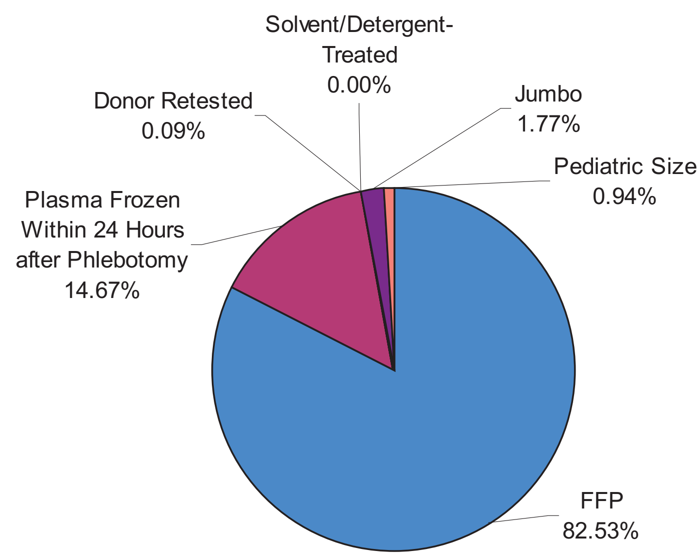

Figure 5-1. Types of plasma transfused in 2004.

The median volume of plasma transfused during a single transfusion episode was 300 mL (n=1,441).

Donor retested and solvent/detergent-treated plasma showed marked and significant decreases in use and each represented less than 1% of the plasma transfused in 2004—3,639 and 19 units reported, respectively. The manufacturer of solvent/detergent-treated plasma ceased production in 2002.

Cryoprecipitate transfusions decreased slightly by 0.9% to 890,000 units. Only an additional 15,000 units were reportedly issued for fibrin sealant, compared with 44,000 units in 2001, a 65.9% decline (p=0.005), following a 61.4% decline in the 2001 survey (from 114,000 units). Other uses of cryoprecipitate were not assessed.

Granulocytes, prepared from both apheresis and whole-blood-derived buffy coat units, resulted in a total of 2,174 units transfused. This represents a 42% decrease from 2001 levels (3,744 units transfused).

The total number of units transfused in the United States in 2004, both RBC and non-RBC components, was 29,038,000. The increase of 119,000 (0.4%) in comparison with 2001 is not statistically significant. With the exception of the significantly lower number of transfusions of whole-blood-derived platelet concentrates, transfusion activity remained consistent between 2001 and 2004.

Platelet Dosage

Institutions reporting platelet transfusions were requested to indicate the number of therapeutic doses of each type of platelet product (see **Figure 5-2**). These data were not weighted.

Hospitals reported the transfusion of 681,000 doses of apheresis platelets (n=1,393) and 184,000 whole-blood-derived platelet concentrates (n=1,327). Blood centers reported the transfusion of 44,000 apheresis platelet doses (n=20) and 10,000 whole-blood-derived platelet concentrates (n=17). The combined totals were 725,000 doses of apheresis platelet products and 194,000 whole-blood-derived platelet concentrates. This represents a ratio of 3.7:1 in contrast to the 2.2:1 ratio reported in 2001.

Hospitals reporting whole-blood-derived platelet concentrate doses also indicated the most common dosage of that product used in their institutions (see **Figure 5-3**). Similar to 2001 results, data show that 50.3% of hospitals reported six concentrates,

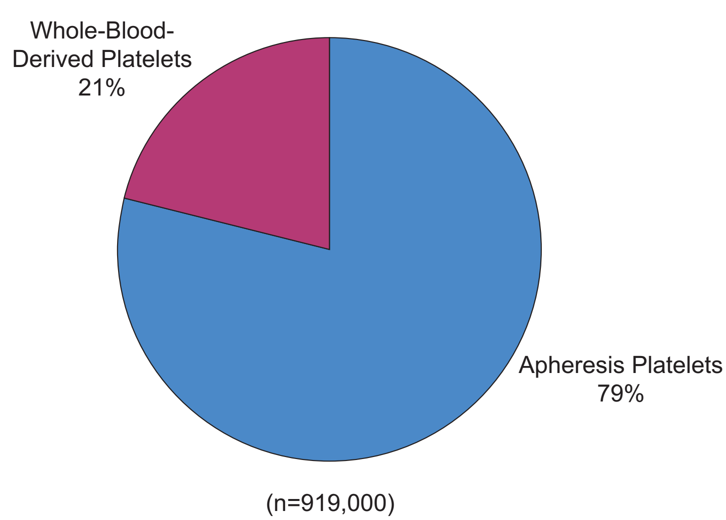

Figure 5-2. Therapeutic platelet doses transfused in 2004.

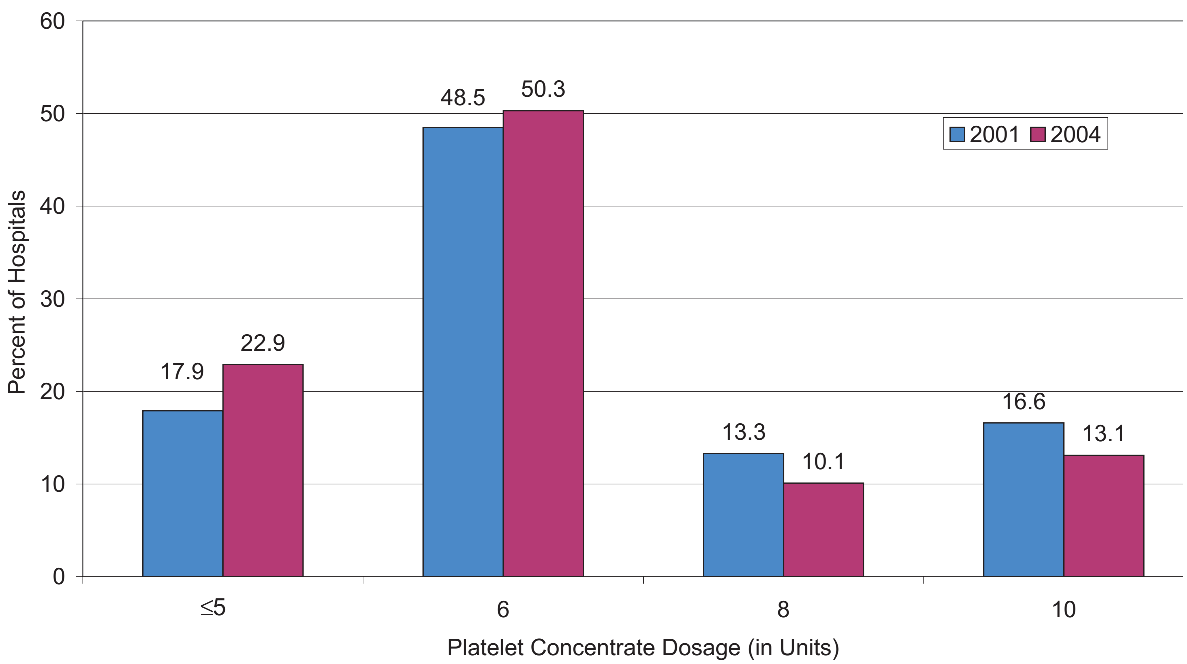

Figure 5-3. Most common platelet concentrate dosage reported by hospitals.

while 13.1% reported 10, 10.1% reported eight, and 22.9% reported five or fewer (n=731). In this survey, the use of five or fewer concentrates was increasingly popular in all hospitals except those performing fewer than 1,000 surgeries per year.

Outdated Units

The national estimate for all whole blood and blood component units outdated by blood centers and hospitals in 2004 was 1,551,000 units. Significantly fewer units outdated in 2004 than in 2001 ($p<0.001$). Blood centers were responsible for 47.8% of all outdates. Allogeneic, nondirected RBC outdates were shared evenly between blood centers and hospitals in 2004, while hospitals were responsible for more of the directed and autologous outdates. Most non-RBC components, with the exception of whole-blood-derived platelets, were outdated by hospitals.

Outdated WB and RBCs totaled 503,000 units, of which 266,000 were allogeneic, nondirected RBCs. The remaining outdates were: autologous (203,000), whole blood (24,000), and directed (10,000) units. 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 923 while the mean for hospitals was 33, a reduction for both medical treatment facilities (3,100 and 114, respectively, in 2001). As shown in **Table 5-1**, outdated WB/RBCs accounted for 3.2% (503,000) of all WB/RBC units processed in 2004.

Survey respondents provided a breakdown of ABO group and Rh type for approximately half of all WB/RBCs outdated, as shown in **Figure 5-5**. The

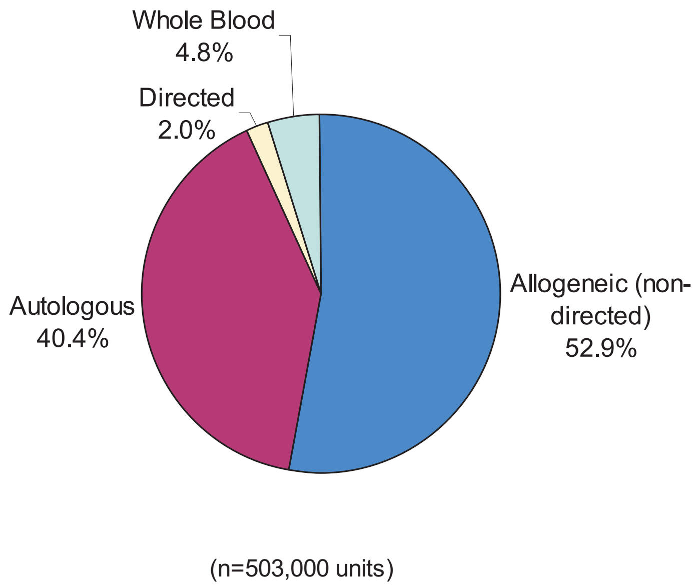

Figure 5-4. WB/RBC unit outdates by collection type.

largest portion of outdated units was AB-positive; when combined with A-positive units, this accounted for slightly more than one-third of the total WB/RBC outdates. O-positive and B-positive units accounted for an additional 16%; Rh-negative units also accounted for 16% of outdated units. An additional 73,000 (31.3%) units were not identified by ABO group or Rh type.

The total number of WB/RBC outdated units was significantly fewer than the 2001 total by 42.9% (p<0.0001). The percentage of outdated WB/RBCs, 3.2%, was lower than the 5.8% and 5.3% reported in 2001 and 1999, respectively. The percentages of directed and autologous units outdates (9% and 44.2%, respectively) were unchanged from 2001.

As has been the case in previous surveys, whole-blood-derived platelet concentrates accounted for the greatest percentage of total outdates, 48.2% (762,000/1,582,000). These 762,000 unused units represented a 29% decline in the volume of outdates reported in 2001. Outdated platelets from WB accounted for 18.1 % of all whole-blood-derived platelets processed in 2004.

Table 5-1. Outdated Components as a Percentage of the Total Volume of Each Type Processed for Transfusion in 2004

	WB/RBCs	Whole-Blood-Derived Platelets	Apheresis Platelets	Plasma	Cryoprecipitate	All Components
Outdated	503,000	762,000	212,000	75,000	31,000	1,582,000
Processed	15,571,000	4,202,000	1,527,000	4,651,000	1,164,000	27,115,000
Percent Outdated	3.2%	18.1%	13.9%	1.6%	2.7%	5.8%

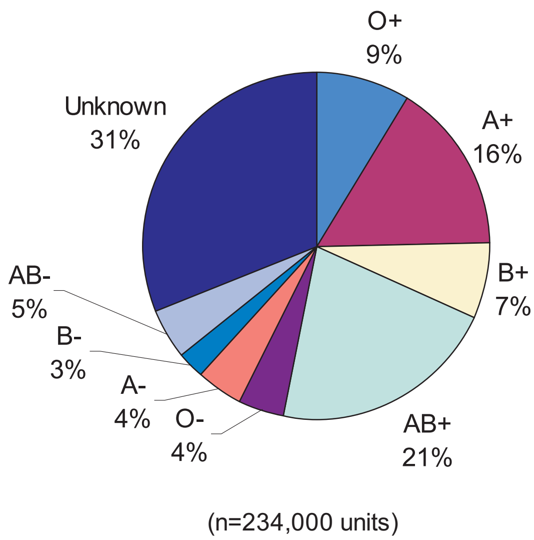

Figure 5-5. Percentage of WB/RBC outdates by blood group and type.

Apheresis platelets contributed 212,000 units, or 13.4% of total outdates. This amount represented 13.9% of apheresis platelets processed, which is significantly lower than the number reported in 2001.

Outdated plasma units totaled 75,000, only 1.6% of the plasma units processed for transfusion. FFP contributed 66,000 units to the total and apheresis plasma accounted for 9,000 units.

The number of outdated cryoprecipitate units was 31,000, 2.7% of the total cryoprecipitate processed. Apheresis platelets, plasma, and cryoprecipitate combined accounted for 20% of all outdated units.

Overall, the proportion of outdated units was much lower in 2004 than in previous years, suggesting that product utilization has become more efficient at meeting specific demand.

Intraoperative Autologous Blood Recovery

Intraoperative blood recovery refers to blood recovery and return procedures conducted during surgery. Such procedures may result in a reduction of the demand for allogeneic blood in some patients. In 2004, a total of 95,000 of these procedures were conducted nationally, an amount estimated on the basis of data reported by 150 hospitals. In 2001 the estimated number of these procedures was 180,000. It is possible that the prevalence of this procedure went underreported in the 2005 survey. Data regarding the use of intraoperative blood recovery may have been maintained by different hospital groups (eg, operating room personnel) than the blood bank staff; therefore, all data may not have been reported to those completing the survey. Future surveys will explore how to better ascertain the procedure's actual prevalence. In 2004, this activity is more likely to be reported by hospitals performing more than 2,400 surgeries per year than by smaller hospitals and blood centers.

6. Component Modification

Irradiation

Irradiation of blood components is intended to prevent graft-vs-host disease and is performed primarily in hospitals. The survey measured the number of facilities in 2004 that had a policy to irradiate all components before transfusion. Of 1,723 survey respondents, 29 (1.7%) indicated that there was such a policy in place at their institution. These 29 respondents were hospitals, and 23 (79.3%) perform 2,400 or more surgeries per year. Of the 129 blood centers, 128 responded negatively and 1 response was missing.

Table 6-1 summarizes the types and numbers of blood component units irradiated in blood centers and hospitals in 2004 (including all facilities that irradiate some components, not just the 29 hospitals that irradiate all components). A total of 2,657,000 component units, including pediatric aliquots, were irradiated; 736,000 in blood centers and 1,922,000 in hospitals. Overall, 10.0% of component units produced in 2004 were irradiated. Of these, 1,473,000 were whole blood (WB) or red blood cell (RBC) units and 1,184,000 were all other components combined. The percentage of all units irradiated in 2004, 10.0, was a decrease of 0.5% from the percentage irradiated in 2001 (10.5%).

Table 6-1. Blood Components Modified by Irradiation in All Facilities in 2004

Blood Component	Irradiated	% of Total Components Irradiated
All Facilities		
WB/RBCs	1,473,000	9.8
Other Component Units	1,184,000	10.3
Total Components	2,657,000	10.0
Blood Centers		
WB/RBCs	413,000	2.9
Other Component Units	323,000	3.0
Total Components	736,000	3.0
Hospitals		
WB/RBCs	1,060,000	7.1
Other Component Units	861,000	7.5
Total Components	1,922,000	7.2

Leukocyte Reduction

Blood components are leukocyte-reduced (LR) to remove leukocyte-associated infectious agents and to avoid alloimmunization in transfusion recipients. Leukocyte reduction may occur during collection or at some time before components are placed in

Table 6-2. Blood Components Modified by Prestorage and Poststorage Leukocyte Reduction in All Facilities in 2004

Blood Component	Prestorage Leukocyte-Reduced Units	Poststorage Leukocyte-Reduced Units	Total Leukocyte-Reduced Units	% of Total Units Leukocyte Reduced
All Facilities				
WB/RBCs	10,346,000	885,000	11,231,000	74.8
WB-Derived Platelets	996,000	168,000	1,165,000	27.7
Apheresis Platelets	1,491,000	11,000	1,502,000	98.4
Other Component Units	16,000	1,000	17,000	0.3
Total Components	12,849,000	1,066,000	13,915,000	52.4

inventory and is considered prestorage LR. Leukocyte reduction is considered poststorage LR when it occurs after the unit is placed into inventory, primarily by filtration at the patient's bedside. In 2004, a total of 13,915,000 units, including pediatric aliquots, were LR components—12,849,000 (92.3%) prestorage LR units and 1,066,000 (7.7%) poststorage LR units (**Table 6-2**). Blood centers produced 12,770,000 units (91.8%) and hospitals produced 1,145,000 units (8.2%). Of those units produced by blood centers, 12,094,000 (94.7%) were prestorage LR units, while only 676,000 (5.3%) were poststorage LR units.

The components most frequently undergoing leukocyte reduction were WB/RBCs (74.8%) and apheresis platelets (98.4%). The 9.6% increase in LR components

Table 6-3. Number of Irradiated and Leukocyte-Reduced Blood Component Units Processed in All Facilities in 2004 and 2001 (expressed in thousands of units)

	Blood Centers			Hospitals			All Facilities		
Modification	2001	2004	% Change	2001	2004	% Change	2001	2004	% Change
Total, All Units	11,513	13,506	17.3	3,935	3,066	–22.1	15,448	16,572	7.3
Irradiated	644	736	14.3	2,103	1,921	–8.7	2,746	2,657	–3.2
Leukocyte-Reduced Total	10,870	12,770	17.5	1,832	1,145	–37.5	12,702	13,915	9.6
prestorage	10,413	12,094	16.1	743	755	1.6	11,157	12,849	15.2
poststorage	456	676	48.2	1,089	390	–64.2	1,545	1,066	–31.0

Table 6-4. Estimated Number of Blood Component Units Modified by Irradiation or Leukocyte Reduction and Transfused by All Facilities in 2004

Blood Component	Irradiated Units	Prestorage Leukocyte-Reduced Units	Poststorage Leukocyte-Reduced Units	Total Leukocyte-Reduced Units	% of Total Units Irradiated	% of Total Units Leukocyte-Reduced
All Facilities						
WB/RBCs	1,222,000	9,142,000	454,000	9,596,000	8.6	67.7
WB-Derived Platelets	413,000	780,000	146,000	926,000	26.9	60.3
Apheresis Platelets	536,000	1,140,000	15,000	1,155,000	38.6	83.1
Other Component Units	139,000	343,000	4,000	347,000	2.8	7.0
Total Components	2,310,000	11,405,000	619,000	12,024,000	10.5	54.4
Blood Centers						
WB/RBCs	62,000	187,000	3,000	190,000	0.4	1.3
WB-Derived Platelets	52,000	68,000	20	68,000	3.4	4.4
Apheresis Platelets	22,000	52,000	0	52,000	1.6	3.7
Other Component Units	6,000	10,000	0	10,000	0.1	0.2
Total Components	142,000	317,000	3,000	320,000	0.6	1.4
Hospitals						
WB/RBCs	1,160,000	8,955,000	451,000	9,406,000	8.2	66.3
WB-Derived Platelets	361,000	712,000	146,000	858,000	23.5	55.8
Apheresis Platelets	514,000	1,088,000	15,000	1,103,000	37.0	79.4
Other Component Units	133,000	333,000	4,000	337,000	2.7	6.8
Total Components	2,168,000	11,088,000	616,000	11,704,000	9.8	53.0

since 2001 can be attributed to LR WB/RBCs (80%) and apheresis platelets (20%).

Table 6-3 summarizes the changes that occurred between 2001 and 2004 in the numbers of irradiated and LR component units. During the period, the number of units irradiated in blood centers increased by 14.3%, while the number irradiated in hospitals declined by 8.7%.

In contrast to 2001, when hospitals leukocyte-reduced 73% of units after storage, in 2004 only 34.0% (390,000 units) were processed after storage. Another 755,000 total components (66.0%) were leukocyte-reduced by hospitals before storage.

Prestorage LR component units increased by 16.1% in blood centers, and by 1.6% in hospitals. At the same time, poststorage LR units continued to decline in hospitals by 64.2%, while increasing in blood centers by 48.2%. Poststorage LR units declined *overall*, however, by 31.0% in 2004.

Transfusion of Irradiated and Leukocyte-Reduced Components

Table 6-4 summarizes the types and numbers of irradiated and LR blood component units transfused during 2004. A total of 142,000 irradiated units were reported as transfused by blood centers and 2,168,000 by hospitals. In total, 10.5% of all transfused component units were irradiated.

In 2004, some 12,024,000 transfused component units were leukocyte-reduced—320,000 (2.7%) by blood centers and 11,704,000 (97.3%) by hospitals. Of the total units transfused, 95% were prestorage LR units and 5% were poststorage LR units. Substantial proportions of all RBCs and platelets transfused in 2004 were LR units: 67.7% of WB/RBCs; 60.3% of whole-blood-derived platelets, and 83.1% of apheresis platelets.

Table 6-5 summarizes the changes that occurred between 2001 and 2004 in numbers of irradiated and LR component units transfused. The number of irradiated units increased by 15.8%, while LR units increased by 2.7%. At the same time, a continuing shift occurred in the mix of LR units transfused. Transfusion of prestorage LR units increased by 7.9%, while transfusion of poststorage LR units declined by 45.3%, a pattern also observed in 1999 and 2001.

Table 6-5. Number of Irradiated and Leukocyte-Reduced Component Units Transfused in 2004 and 2001 (expressed in thousands of units)

	Total Units			
Modification	2004	2001	Increase/ Decrease	% Change
Total, All Units	14,192	13,576	616	4.5
Irradiated	2,168	1,873	295	15.8
Leukocyte-Reduced Total	12,024	11,703	321	2.7
prestorage	11,405	10,572	833	7.9
poststorage	619	1,131	–512	–45.3

7. Current Issues in Blood Collection and Screening

Screening Test Losses

The overall number of donated whole blood units with positive results on infectious disease screening tests was 270,000, or 1.8% of allogeneic collections, including directed donations. The number of units collected by blood centers and discarded for this reason was 255,000 (1.9%) (n=138 blood centers reporting). Among hospitals, screening test loss was 1.8% of donations or 15,000 units (n=258). Screening test loss was lower in hospitals than reported in 2001, when the test loss totaled 2.5% of donations.

As observed in previous surveys, test losses varied between reporting blood centers in different United States Public Health Service regions. The highest average losses were experienced by centers in regions II, III, and VI. Region VI reported test loss that was significantly higher than the mean. Regions IV, V, VII, VIII, and IX (see **Table 3-6**) experienced testing losses significantly lower than the mean in 2004. The proportions of units lost per individual screening test were not assessed by the 2005 NBCUS.

Therapeutic Phlebotomy

Therapeutic phlebotomy procedures are performed for the benefit of the donor as a patient rather than for blood collection purposes. In August 2001, the US Food and Drug Administration (FDA) approved the use of blood collected from hereditary hemachromatosis patients for transfusion. The FDA has allowed this use provided that 1) the blood collecting facility has a variance from the FDA, 2) the patient meets all regular donor eligibility requirements, and 3) the therapeutic phlebotomy is performed at no cost to the patient. Hereditary hemachromatosis is only one of the indications for therapeutic phlebotomy.

Blood centers reported a total of 28,000 procedures performed at 33 centers. The number of procedures per center ranged from 31 to 3,685, with a median of 471 procedures. Hospital data were weighted to achieve a national estimate of 112,000. The median for hospitals was 41 procedures, with a range of 1 to 1,839. Together, hospitals and blood centers nationwide are estimated to have performed 140,000 therapeutic phlebotomy procedures in 2004. This is not significantly different from the previous survey findings. The larger the surgical volume of the hospital, the more likely the hospital was to offer this service, with the most procedures being performed at hospitals with 8,000 or more surgeries per year.

Disaster Planning

In follow-up to the terrorist attacks of September 11, 2001, the United States instituted many changes in approaches to critical national functions, including blood safety and supply. Several new questions were developed for the 2005 NBCUS, the first survey to be distributed nationally since the attacks.

Medical facilities were asked whether they have an "emergency preparedness plan" for blood. Almost all (99.2%) of the blood centers responded affirmatively. Among the 98.7% of hospitals that responded to the question, 89.6% had emergency preparedness plans. Hospitals across all surgical volume strata were equally likely to have a plan in place. None of the cord blood banks reported having emergency plans for blood.

The survey also asked how many days of group O red blood cell (RBC) inventory were considered to be "critically low." The response to this question varied widely depending on the type of facility, its location, and the services provided. The systemwide mean of 2.4 days of group O RBCs was driven by the hospitals, which had a mean of 2.5 days as the critically low inventory level. The blood center mean of 1.7 days most likely reflected closer proximity to the supply and greater control over access.

Facilities were also asked to report the number of days of group O RBC uncrossmatched inventory that was considered to be "ideal." The overall mean of 5.5 days again varied between hospital and blood center respondents. The hospital mean was 5.5 days of group O RBC uncrossmatched inventory, whereas the blood centers reported a mean of 4.7 days as ideal. Smaller hospitals were more likely to report higher mean numbers of days as ideal than were larger hospitals (see **Figure 7-1**). This may reflect the locations of larger hospitals—urban and proximal to blood centers and blood donating populations.

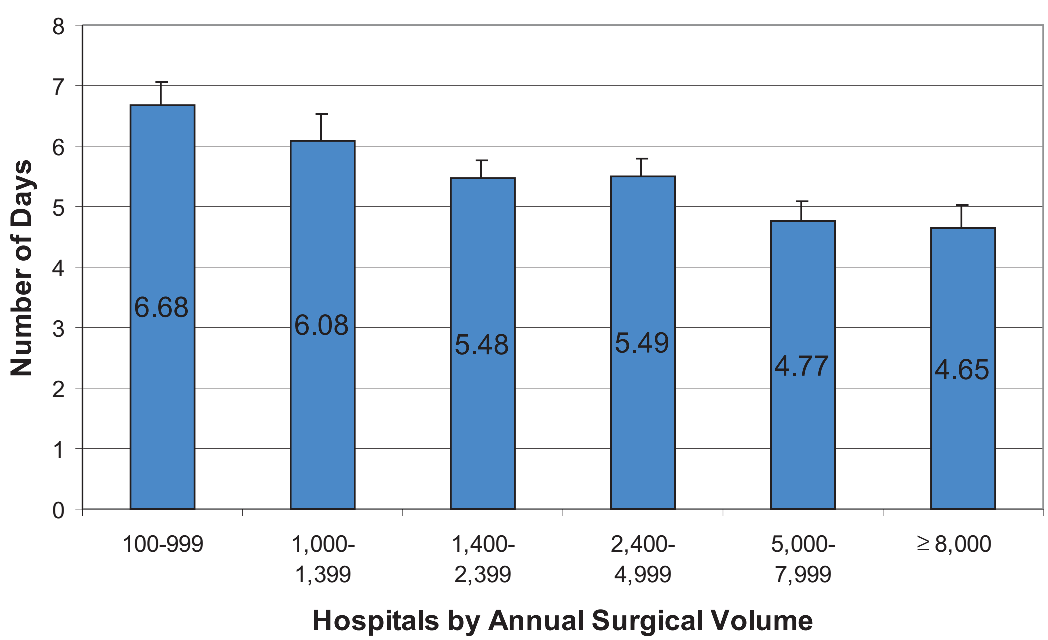

Figure 7-1. Ideal number of days of group O red blood cells in uncrossmatched inventory.

8. Current Issues in Blood Transfusion

Blood Inventory Shortages

The current survey, as well as previous versions, 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 135 hospitals (8.4%) reported that elective surgery was postponed on one or more days in 2004 because of blood inventory shortages. **Table 8-1** provides a characterization of cancellation reports in 2004 in comparison with previous survey years. The percentage of responding hospitals reporting any shortage was a statistically significant decrease from the 2001 data ($p<0.0001$), but comparable to the percentages from 1997 and 1999 data. The range (1 to 39) of days postponed was narrower in 2004 than in the recent surveys, but the mean number of days for all hospitals responding was 3.39, noticeably higher than in years past. This suggests that while shortages were less frequent, when they did occur they were more acute. There were no significant differences in the mean number of days of postponement among hospitals when grouped by surgical volume or by region of the country.

Hospitals indicated separately that the total number of surgical procedures that were postponed was 546 (n=110) compared with 952 in 2001 ($p=0.026$). This is a decrease of 42.6%. The number of surgeries postponed varied significantly between hospitals by surgical volume ($p=0.003$). Hospitals that performed 1,400 to 2,399 surgeries per year appeared to have the greatest proportion of surgeries postponed among those reporting.

Table 8-1. Cancellation of Elective Surgeries by US Hospitals, 1997-2004

Year	>0 Days (%)	Range of Days	Median No. of Days	Mean No. of Days	No. of Patients Affected
1997	8.60	1–21	2.0	0.44	Not determined
1999	7.40	1–150	2.0	0.32	568 (n=83)
2001	12.70	1–63	2.0	0.55	952 (n=116)
2004	8.40	1–39	2.0	3.39	546 (n=110)

Hospitals also indicated the number of days in which nonsurgical blood requests were not met. Of responding hospitals, 16.0% (257/1604) experienced at least one day in which nonsurgical blood needs could not be met vs 18.9% (202/1,066) in 2001 and 16.2% (273/1,588) in 1999. The total number of days reported was 4,953 and the range was 1 to 366 (2004 was a leap year). There is a significant difference between the mean number of days of unmet nonsurgical needs for all respondents between 2001 (2.1) and 2004 (19.27) ($p<0.001$). Eight hospitals reported 365 or 366 days in which nonsurgical blood requests were not met in 2004, whereas only one hospital reported an entire year of unmet need in 2001. This most likely accounted for the large increase in the mean between 2001 and 2004. The hospitals reporting this condition were evenly distributed throughout the country, and only one of these hospitals had reported any days of unmet need in 2001.

Crossmatch Procedures

Transfusing facilities were requested to report the total number of crossmatch procedures, as well as the percentage of procedures performed serologically, using microplate technology, and using gel media, if applicable. The data were not weighted.

A total of 11,221,000 crossmatch procedures were performed in 2004, compared to 10,506,000 in 2001. This increase was not statistically significant. Of the total volume of crossmatches reported, microplate technology accounted for less than 1%, gel media accounted for 18.9%, and serologic methods accounted for 77.8%.

In order to calculate the crossmatch-to-transfusion (C:T) ratio, the total number of allogeneic WB/RBC units (unweighted, not imputed) transfused by the responding medical treatment facilities served as the denominator (7,250,000). The overall C:T ratio was 1.55 procedures per unit in 2004.

When analyzed by surgical volume, the trend established in the 2001 data report continued to be seen in the 2005 NBCUS—C:T ratios increased with increasing hospital size. The C:T ratios ranged from 1.30 in hospitals performing 0 to 999 surgeries per year to 1.63 in hospitals performing more than 8,000 surgeries per year.

RBC Unit Age

The 2005 survey attempted to identify trends in the average age of an RBC unit at the time of transfusion. In this survey, 488 hospitals responded, up from 293 in the last survey. The data were not weighted. The minimum average age reported was 1.5 days, the maximum was 42 days, and the median was 15.0 days. When analyzed by United States Public Health Service (USPHS) region, however, there was one statistically significant difference from the national mean of 17.0: the mean average age of RBC units transfused in region VI (NM, OK, AR, TX, LA) was 14.5 days ($p=0.0013$).

Platelet Product Age

This was the first survey to ask about the average age of transfused platelets. A total of 381 hospitals provided data on the average age of whole-blood-derived platelets at transfusion. The minimum average age was 0.5 day old and ranged to a maximum of 6 days with the median being 3 days. The mean age was 3.16 days. Quite a few more hospitals (918/1,604 or 57%) responded with data on an age for apheresis platelets at the time of transfusion. The minimum average age was again 0.5 day, the maximum was 6 days, and the median was 3 days. The mean age of apheresis platelets at transfusion was 3.08 days.

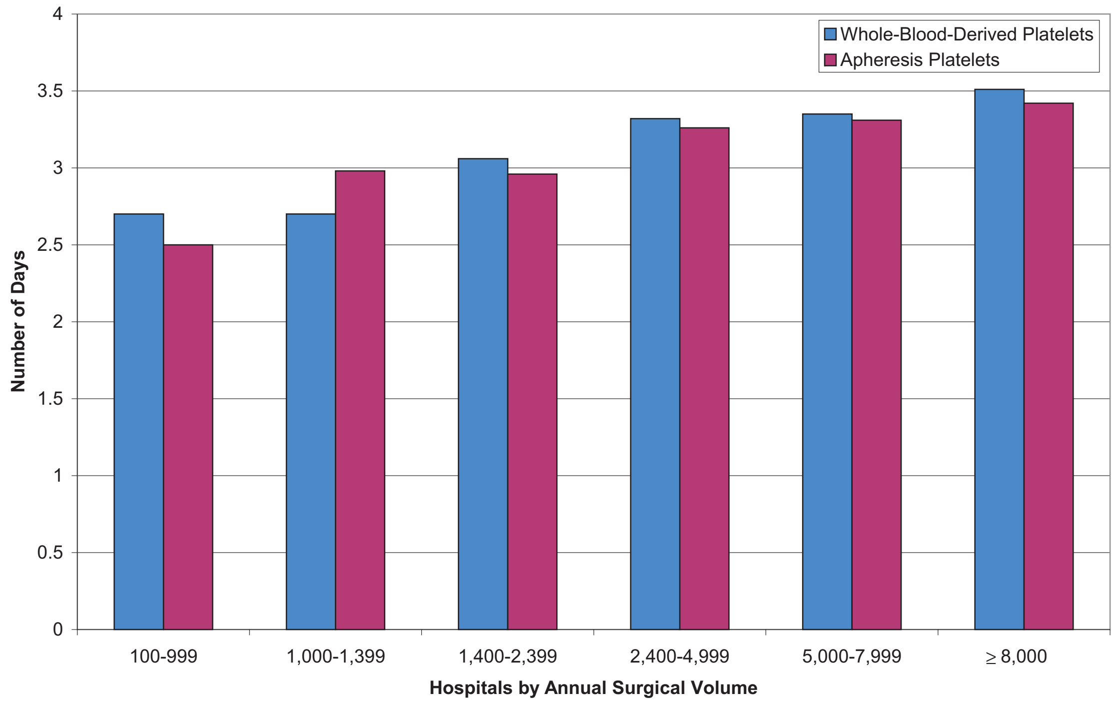

Figure 8-1. Mean platelet age when transfused.

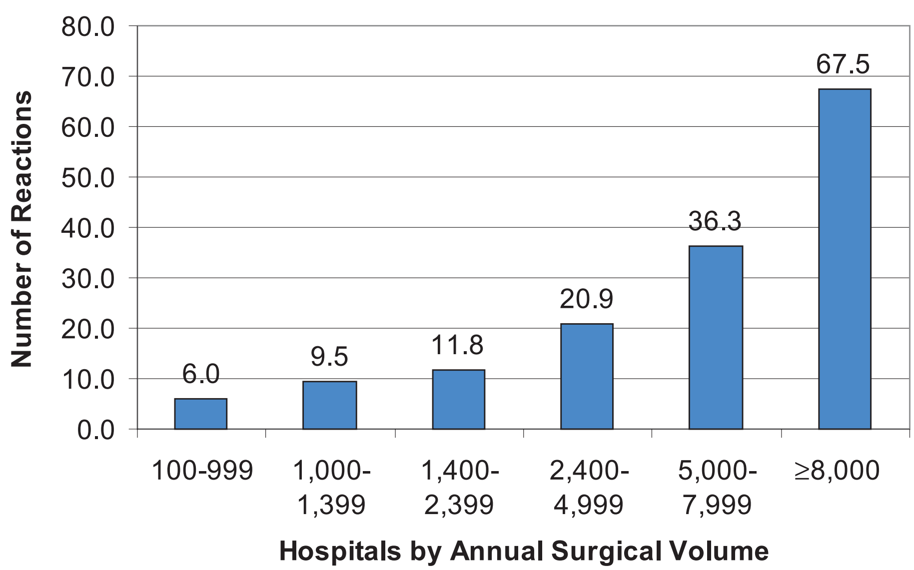

Figure 8-2. Mean number of adverse reactions.

When analyzed by the number of surgeries per year, data from responding hospitals showed a significant trend toward higher mean platelet age in the largest stratum of hospitals, for both whole-blood-derived (p=0.0065) and apheresis (p=0.0006) platelets. See **Figure 8-1**. Means ranged from 2.7 to 3.5 days in whole-blood-derived platelets and from 2.5 to 3.4 days in apheresis platelets. There were no significant differences in platelet age at transfusion by USPHS region.

Adverse Reactions

Approximately 1,322 medical treatment facilities reported a total of 32,128 transfusion-related adverse reactions in 2004. These were defined as events that required diagnostic or therapeutic intervention. The larger the surgical volume of the hospital, the more transfusion-related adverse reactions reported (see **Figure 8-2**). Of these adverse events, 160 were reported as transfusion-related acute lung injury. These were more likely to occur in hospitals performing more than 8,000 surgeries per year. Adverse events related to ABO incompatibility were quite rare, with only 52 occurrences reported in 2004.

9. Component Costs

Hospitals were requested to report the minimum, maximum, and average costs paid per unit in 2004 for each of four specific components. These cost data were not imputed or weighted. The mean of the reported results for each variable is presented in **Table 9-1** and compared with the 2001 value. **Table 9-2** displays the average 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 red blood cells (RBCs) that was O positive, leukocyte-reduced, not irradiated, and not cytomegalovirus negative, was $201.07 (**Table 9-1**). This was higher than the average in 2001 ($153.68); the difference was statistically significant ($p<0.0001$). The values reported by hospitals for this component ranged from a minimum of $5.00 to a maximum of $595.00. When analyzed by United States Public Health Service (USPHS) region, the mean of the average value reported was significantly different from the national average in every region except III, VIII, and X (**Table 9-2**). The average cost was significantly higher than the national mean in the Northeastern and Southwestern states (I, II, and IX). Significantly lower means were found in the Southeastern and Central states (IV, V, VI, and VII; $p<0.0001$). When analyzed by surgical volume, the only stratum that differed statistically from the overall mean was that of hospitals with 1,400-2,399 annual inpatient surgeries, with a mean of $205.45 ($p=0.0461$) (**Table 9-3**).

Fresh Frozen Plasma

The mean cost of a unit of fresh frozen plasma (FFP), type AB, with a volume of approximately 250 mL, averaged $56.29 nationally (**Table 9-1**). The higher cost than the 2001 mean of $52.37 was statistically significant ($p<0.0001$). The values reported by hospitals for this component ranged from a minimum of $20.00 to a maximum of $259.77. When analyzed by USPHS region, the mean of the average values reported was significantly higher in the regions including New York, and the Mountain and Western states (II, VIII, IX, and X). The means reported by regions IV and VII (which include Southeastern and Midwestern states) were significantly lower than the national mean (**Table 9-2**).

Hospitals in the largest surgical volume stratum (≥8,000) reported a mean cost for FFP that was significantly less than the overall mean, $52.19 ($p=0.0080$) (**Table 9-3)**. Not surprisingly, smaller facilities (100-999 surgeries) reported significantly higher FFP costs ($p=0.0257$).

Table 9-1. Mean Dollars Paid per Selected Component Unit by Hospitals in 2004 vs 2001

	Mean Dollar Values								
	Minimum Amount Paid			Maximum Amount Paid			Average Amount Paid		
Component	2001	2004	% Change	2001	2004	% Change	2001	2004	% Change
RBCs, O positive, leukocyte-reduced, not irradiated, not cytomegalovirus negative	143.03	193.20	+35.1	164.13	210.90	+28.5	153.68	201.07	+30.8
FFP, type AB ~ 250 mL	50.62	54.68	+8.0	54.55	57.97	+6.3	52.37	56.29	+7.5
Whole-Blood-Derived Platelet Concentrate, not leukocyte-reduced, not irradiated, 3 days remaining before expiration	52.36	59.49	+13.6	57.54	64.21	+11.6	54.90	63.67	+16.0
Apheresis Platelets with 3-4 $\times 10^{11}$ platelets, leukocyte-reduced	461.44	494.06	+7.1	489.08	527.47	+7.8	475.48	510.05	+7.3

Table 9-2. Average Component Cost by USPHS Region

		Mean Dollar Values							
		RBCs		FFP		Whole-Blood-Derived Platelets		Apheresis Platelets	
USPHS Region	No.	Avg	p Value	Avg	p Value	Avg	p Value	Avg	p Value
I	79	233.63	<0.0001	58.24	0.3207	90.10	<0.0001	516.61	0.4297
II	108	239.06	<0.0001	63.12	<0.0001	56.38	0.0583	551.33	<0.0001
III	156	202.67	0.5385	53.86	0.0716	66.12	0.4174	509.44	0.8894
IV	271	186.24	<0.0001	50.04	<0.0001	63.12	0.8298	490.94	<0.0001
V	264	190.78	<0.0001	55.53	0.4645	62.40	0.5975	494.48	0.0003
VI	160	189.81	<0.0001	55.56	0.5853	59.88	0.2649	529.38	0.0009
VII	96	189.49	0.0007	48.79	<0.0001	54.08	0.1010	456.30	<0.0001
VIII	54	204.98	0.3906	65.83	<0.0001	78.94	0.1474	567.07	<0.0001
IX	148	218.12	<0.0001	65.74	<0.0001	66.75	0.7436	527.52	0.0033
X	45	199.92	0.8159	66.08	0.0002	86.85	0.0052	539.09	0.0060
All Hospitals	1,381	201.07		56.29		63.67		510.05	

Table 9-3. Average Component Cost by Surgical Volume

		Mean Dollar Values							
		RBCs		FFP		Whole-Blood-Derived Platelets		Apheresis Platelets	
Annual Surgical Volume	No.	Avg	p Value	Avg	p Value	Avg	p Value	Avg	p Value
100–999	214	202.47	0.5834	59.06	0.0257	72.01	0.0263	508.11	0.6884
1,000–1,399	139	204.99	0.2101	57.91	0.2813	69.65	0.1423	515.64	0.4082
1,400–2,399	284	205.45	0.0461	57.14	0.4071	66.96	0.2535	514.92	0.2919
2,400–4,999	423	198.38	0.1384	55.63	0.4470	61.39	0.2839	509.71	0.8875
5,000–7,999	189	199.01	0.4497	55.17	0.3752	60.64	0.3306	510.25	0.9982
≥8,000	132	196.71	0.1796	52.19	0.0080	57.17	0.0626	499.30	0.0986

Whole-Blood-Derived Platelets

The national mean cost for a unit of whole-blood-derived platelet concentrate (individual concentrate, not pooled), not leukocyte-reduced or irradiated, with 3 days remaining before expiration, was $63.67 in 2004 (**Table 9-1**). This increase of 16.0% over the 2001 cost was statistically significant (p<0.0001). The reported range varied from $23.00 to $396.95. The higher mean costs for this component in the New England and Northwestern states—regions I and X—(compared with the national mean) were statistically significant (**Table 9-2**). The hospitals in the smallest surgical stratum (100-999) again reported significantly higher costs (p=0.0263).

Apheresis Platelets

The mean cost of a unit of leukocyte-reduced platelets collected by apheresis ($3\text{-}4 \times 10^{11}$ platelets) was $510.05 in 2004 in comparison with $475.48 in 2001, a statistically significant increase of 7.3% (p<0.0001). Reported values ranged from $114.00 to $1,200.00. The mean cost was lower in the Southeastern and Midwestern states (regions IV, V, and VII). Regions that were significantly higher than the mean were II, VI, VIII, IX, and X (which include New York and New Jersey as well as the Mountain, South Central, and Western states as listed in **Table 3-6**). When stratified by surgical volume, there were no statistically significant differences in the cost of this component.

Reimbursement

The Centers for Medicare and Medicaid Services (CMS) hospital outpatient prospective payment system (OPPS) reimbursement rates for the four components assessed are reported in **Table 9-4**. While costs for components increased between 2001 and 2004, outpatient reimbursement decreased for all components during the same period. The reimbursement rate

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

	Reimbursement Code		Reimbursement Rate		
Blood Component	CPT/ HCPCS	APC	2001*	2004†	% Change
Red Blood Cells (leukocyte-reduced)	P9016	0954	$142.17	$119.26	–16.1
Fresh Frozen Plasma (frozen within 24 hours after phlebotomy)	P9017	0955	$113.30	$ 95.00	–16.2
Whole-blood-derived platelets	P9019	0957	$ 49.18	$ 41.44	–15.7
Apheresis platelets (leukocyte-reduced)	P9035	9501/1014	$448.87	$408.81	– 8.9

*Department of Health and Human Services. Update of calendar year 2001 hospital outpatient payment rates and coinsurance amounts effective April 1, 2001. [Available at http://www.cms.hhs.gov/hospitaloutpatientpps/downloads/apr001a.pdf.]

†Department of Health and Human Services. Medicare program; hospital outpatient prospective payment system; payment reform for calendar year 2004; interim final rule. (January 6, 2004). Fed Regist 2004;69:819-44.

CMS = Centers for Medicare and Medicaid Services; CPT = current procedural terminology; HCPCS = health-care common procedure coding system; APC = ambulatory patient classification.

for a unit of leukocyte-reduced RBCs decreased 16.1% between 2001 and 2004, while the mean cost to hospitals increased 30.8%. The smallest decrease was seen in a unit of leukocyte-reduced apheresis platelets, which was reimbursed at a rate of $408.81, 8.9% less than the 2001 rate.

CMS OPPS rates are reported here because they are the only simple measure of Medicare reimbursement for individual blood components. However, most Medicare reimbursement for blood is part of the diagnosis-related group (DRG) payment made for hospital inpatient services. Other payers, besides Medicare, pay for blood under varying mechanisms that are not included in this report.

Summary

In summary, the mean cost of an RBC unit increased by 30.8% between 2001 and 2004. Costs for FFP and apheresis platelets increased by less than 10% in the same period. Whole-blood-derived platelets increased in cost by 16% during the period. The 2005 survey was the first to measure a statistically significant increase in the cost of every component assessed. CMS OPPS reimbursement rates for all components assessed were from 8.9% to 16.2% lower in 2004 than in 2001. Average costs for the components assessed were generally higher in regions I and II (Northeastern states), as well as VIII, IX, and X (Mountain and Western states), and lower in regions IV, V, VI and VII (Southeastern and Central states). Hospitals with 8,000 or more surgeries per year typically pay less than the national mean for blood components; this likely reflects more favorable supplier agreements based on volume purchases.

10. Cellular Therapy Products

Because of ongoing interest in hematopoietic transplantation and novel cellular therapies, the 2005 NBCUS captured data on collection, processing, and infusion of five types of cellular therapy products: hematopoietic progenitor cells collected by apheresis (HPC-A), HPCs derived from marrow (HPC-M), HPCs from cord blood (HPC-C), lymphocytes, and cell products generated in culture.

Cellular Therapy Product Terminology*

Previous		Current	
Term	**Abbr.**	**Term**	**Abbr.**
Peripheral Blood Progenitor Cells	PBPC	Hematopoietic Progenitor Cells-Apheresis	HPC-A
Bone Marrow	BM	Hematopoietic Progenitor Cells-Marrow	HPC-M
Cord Blood	CB	Hematopoietic Progenitor Cells-Cord	HPC-C

* *Circular of Information for the Use of Cellular Therapy Products* (2003).

The survey questions were nearly identical to those in previous surveys so that comparisons could be made and trends identified. This was the first year that public cord blood banks were included in addition to blood centers and hospitals. The majority of independent cord blood banks are private in that the HPC-C units are collected, stored, and processed at the private expense—and for the future potential use—of a family member. However, there are some public or allogeneic cord blood banks and attempts were made to include them in the survey. Nine cord blood banks, all AABB members thought to have some public donation activity, were surveyed and three responded; any unique responses are noted.

Collections

Autologous and allogeneic cellular therapy product collections are illustrated in **Tables 10-1** and **10-2,** and **Figure 10-1**. Collection of HPC-A and HPC-C products made up the largest cohort of cellular therapy products collected in 2004, exceeding the collection of HPC-M, lymphocytes, and cell products generated in culture. The majority of HPC-A products were autologous; however, there was a 26.1% decline in collections since 2001. The change was seen mostly at the blood centers, which showed a 60% decline in autologous HPC-A collections in comparison to 2001 with a single large blood center no longer participating

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	% Change 2001-2004
HPC-A	21	1,459	95	12,624			14,083	–26.1
HPC-M	5	20	30	175			195	–49.5
HPC-C*	1	24	3	91	1	2,234	2,349	442.5
Lymphocytes	3	63	5	502			565	248.8
Cells Generated in Culture	0	0	5	105			105	–73.1
All Products		1,566		13,497		2,234	17,297	–15.4

*autologous HPC-C products represent private cord blood collections

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**	**% Change 2001-2004**
HPC-A	19	744	60	2,554			3,298	–21.7
HPC-M	5	63	49	602			665	–21.7
HPC-C	4	3,331	9	10,590	1	477	14,398	–37.8
Lymphocytes	12	273	36	750			1,023	40.7
Cells Generated in Culture	1	81	1	185			266	2,855.6
All Products		4,492		14,681		477	19,650	–32.1

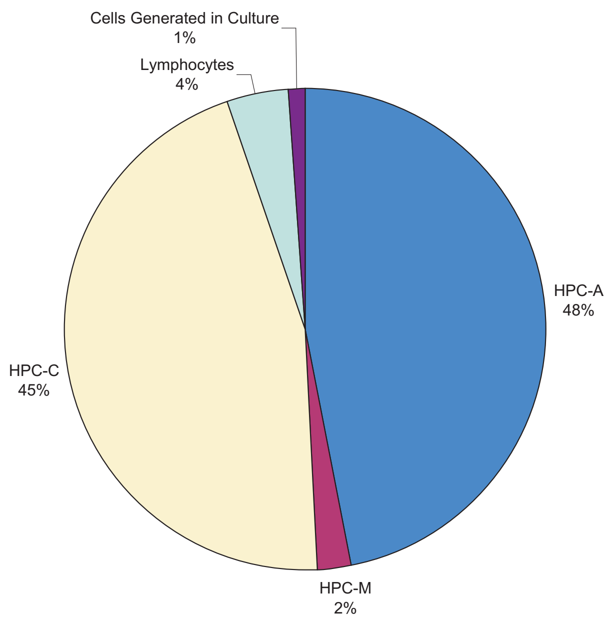

Figure 10-1. Collection of all cellular therapy products.

in cellular therapy activities. Allogeneic HPC-A collections were down 21.7%, from 4,211 to 3,298, although not back to pre-2001 levels. In this case, the decrease can be accounted for by changes in hospital collection volumes.

Changes in medical practice that may contribute to the decrease in the collection totals include: 1) the marrow transplant protocol is no longer recommended for treatment of breast cancer patients; 2) new drugs (including rituximab, an anti-CD20 for treatment for non-Hodgkin's lymphoma, and imatinib mesylate for treatment of chronic myelocytic leukemia) are used as the first line of treatment before transfusion with HPC-A; 3) newer nonmyeloablative protocols (mini-transplants—always allogeneic) often involve less processing and, therefore, fewer collections; and 4) collection efficiency is increased as a result of improved mobilization regimens.

Private (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 significantly. This probably results from the inclusion of cord blood banks—some of which have had mixed public and private activity—in the survey. But overall HPC-C collections were lower than in the previous survey, a consequence of a large decrease in allogeneic collections by blood centers, with the aforementioned large blood center no longer participating in cellular therapy activities. It is also possible that there is underreporting of hospital HPC-C collections when the collection takes place in the obstetrics ward and is not reported to the hospital blood bank. Increased collections were also noted for both autologous and allogeneic lymphocytes and allogeneic cells generated in culture. HPC-M collections continued the declining trend—perhaps because HPC-A collection is so much easier on the donor.

Processing

Processing activity for cellular therapy products is displayed in **Table 10-3** and **Figure 10-2.** Processing of HPC-C units rose by 161.6% since the last survey, with 32,125 collections processed, representing more than 100% of total cord blood collections reported. Again, the inclusion of cord blood banks contributed much to the increase in this area of activity.

Underreporting of cord blood collections is most likely re-

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**	**% Change 2001-2004**
HPC-A	12	1,238	75	13,446			14,684	–24.9
HPC-M	6	88	50	666			754	–44.2
HPC-C	9	6,106	21	3,409	2	22,610	32,125	161.6
Lymphocytes	6	765	34	371			1,136	80.0
Cells Generated in Culture	1	81	6	312			393	–31.7
All Products		8,278		18,204		22,610	49,092	42.8

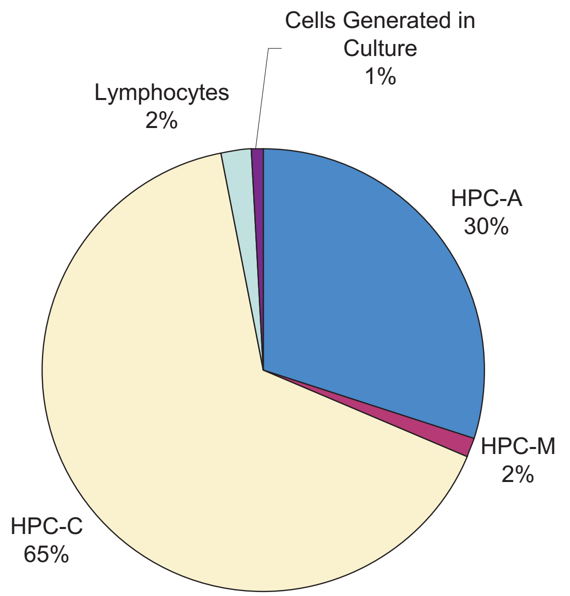

Figure 10-2. Processing of all cellular therapy products.

sponsible for the high percentage of cord blood processing activities reported. There is always less than a 1:1 ratio of collected to processed units, because of inadequate collection, contamination, etc. 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.

Another product type for which processing activity rose is lymphocytes (80%). Lymphocytes are given as part of other transplant protocols to enhance effectiveness of those protocols, and this may contribute to the increase seen. Most of the increase in processing was seen at blood centers. In 2001 there were only two blood centers processing lymphocytes, whereas six centers reported this activity in 2004. Processing activity for all other cell therapy products decreased in 2004. New nonmyeloablative protocols that call for unprocessed HPC-A and HPC-M may account for some of this change, because these protocols often utilize donor lymphocyte infusion.

Infusion

Issue/infusion activity (**Table 10-4** and **Figure 10-3**) decreased in comparison to 2001 for all cell therapy product types except HPC-C (67.3% increase). The declines in infusions of HPC-M (–54%; p=0.0144) and, predictably, the number of recipients of HPC-M (p=0.0089) were substantial. There was also a substantial but not significant decrease in infusions of other cells generated in culture (–71.6%). However, in this survey, two new categories were included under the infusion section: "Other Cellular Products" and "Tissue Products." Other cellular products accounted for 5% of the infusions and 6% of the recipients. Tissue products accounted for 24.5% of the infusions and 22.7% of the recipients, mostly autologous. The number of recipients of cellular therapy products decreased for all products except HPC-C. The increase in HPC-C recipients (65.1%) reflected primarily allogeneic infusions.

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**. HPC-A

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

	Blood Centers		Hospitals		Cord Blood Banks		All Facilities		No. of Recipients			
Product Type	**No.**	**Infusion Episodes**	**No.**	**Infusion Episodes**	**No.**	**Infusion Episodes**	**Infusion Episodes**	**% Change 2001-2004**	**Autol-ogous**	**Allo-geneic**	**Total**	**% Change 2001-2004**
HPC-A	17	806	94	6,474			7,280	–31.5	4,586	1,464	6,050	–23.5
HPC-M	9	89	55	526			615	–54.0	105	466	571	–55.7
HPC-C	10	263	26	312	1	64	639	67.3	4	620	624	65.1
Lymphocytes	7	96	39	398			494	–29.1	46	334	380	–23.4
Cells Generated in Culture	1	1	5	146			147	–71.6	146	1	147	–51.2
Other Cellular Products	1	18	7	625			643		55	586	641	
Tissue Products	0	0	10	3,095			3,095		7	2,391	2,398	
All Products		1,273		11,576			12,913	–4.8	4,949	5,862	10,811	4.2

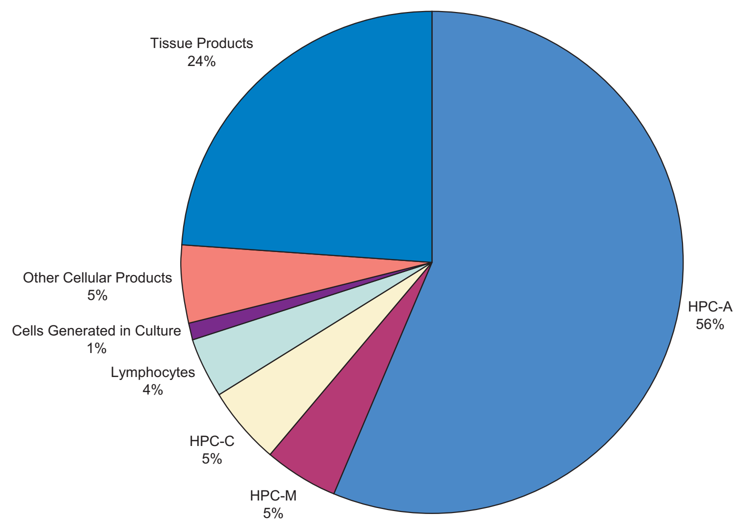

Figure 10-3. Infusion of cellular therapy products.

and HPC-M collection, processing, and infusion activities continue to be more common in hospitals than in blood centers. The number of hospitals collecting autologous HPC-A products exceeds the number collecting allogeneic HPC-A products (95 vs 60), both reduced from the previous survey. Fewer blood centers as well as hospitals reported collecting cord blood in 2004 than in 2001. This may be in response to the number of cord blood banks that have entered the market and the exit of a major blood center from the cellular therapies market.

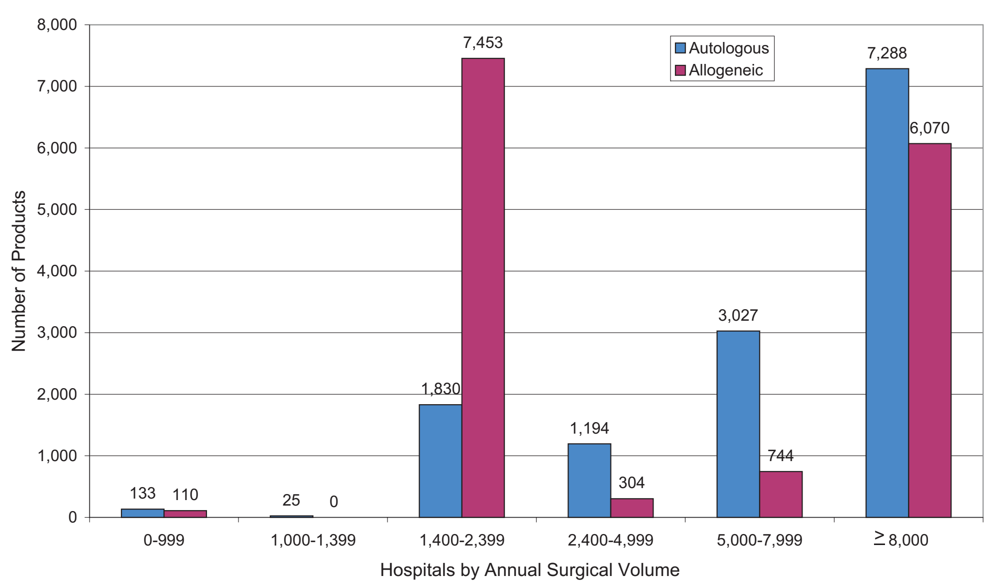

Figure 10-4. Cellular therapy product collections by hospitals (n=101).

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

Surgeries per Year	No. of Facilities	% of Facilities	Collections		
			Autologous	Allogeneic	Total
0-999	3	2.4	133	110	243
1,000–1,399	2	1.6	25	0	25
1,400–2,399	8	6.5	1,830	7,453	9,283
2,400–4,999	29	23.6	1,194	304	1,498
5,000–7,999	26	21.1	3,027	744	3,771
≥8,000	55	44.7	7,288	6,070	13,358
All Hospitals	123	100.0	13,497	14,681	28,178

The reporting in this survey may better reflect the areas of responsibility, with the hospital responsible for the HPC-C collection (possibly under the blood center's protocol) and the blood center or cord blood bank responsible for processing and storage.

Of hospitals reporting collection activity for cellular therapy products, those with higher surgical volumes generally were more likely to have the higher levels of activity, as seen in previous surveys (**Figure 10-4** and **Table 10-5).** The high number of allogeneic collections seen in the category of 1,400 to 2,399 surgeries per year can be accounted for primarily by one large facility.

As seen in previous surveys, cord blood products represent a sizeable proportion of collection (45.4%) and processing (65%) activities among surveyed medical facilities, but only a very small amount of the infusion activity (3.3%). The majority of the cord blood activity is currently 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.

11. Historical Perspectives

The 2005 NBCUS has allowed for the extension of the findings of previous nationwide surveys conducted by the National Blood Data Resource Center in 2002, 2000, and 1998, and earlier assessments conducted by the Center for Blood Research and the National Heart, Lung, and Blood Institute.

Time Trends

Whole blood (WB) and red blood cell (RBC) collections for the past 15 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, largely because of an increased allogeneic donation rate following the September 11 terrorist attacks. In 2004, total collections remained virtually unchanged at 15.3 million units (an actual decline of 0.2%).

Autologous donations, which declined dramatically between 1992 and 1997, appeared to level off at approximately 0.6 million units in the period from 1997 to 2001. In 2004, autologous collections comprised only 0.46 million units, or 3.0% of total collections, the lowest amount that has been measured by contemporary surveys.

Figure 11-2 illustrates the trends in allogeneic WB/RBC collections and transfusions over time, as well as the margin between the two curves, which is discussed below in the section on **Blood Supply Adequacy**. The steep upward rise of the transfusion curve observed since 1994 reached a maximum of 13.9 million in 2004. The total increase in allogeneic transfusions over the past decade was 31.1%. The increase in allogeneic collections over the past decade was only 20.3%, however.

The utilization of platelets overall was statistically unchanged between 2001 and 2004, declining by 3.1%. The continued shift in the mix of platelet types, first observed in 1999, is notable. **Figure 11-3** illustrates the increased use of apheresis platelets (+10.0%) and the decline in transfusion of whole-blood-derived platelet concentrates (–41.2%).

Blood Supply Adequacy

The available supply of both WB/RBCs and non-RBC components was sufficient to meet overall transfusion demands in 2004. Yet, despite the increase in collections achieved since 1997, there is cause for concern regarding the adequacy of the United States (US) blood supply, both currently and in the future.

The shrinking margin between allogeneic WB/RBC supply and demand depicted in **Figure 11-2** is one reason for concern. 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 supply. 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% in-

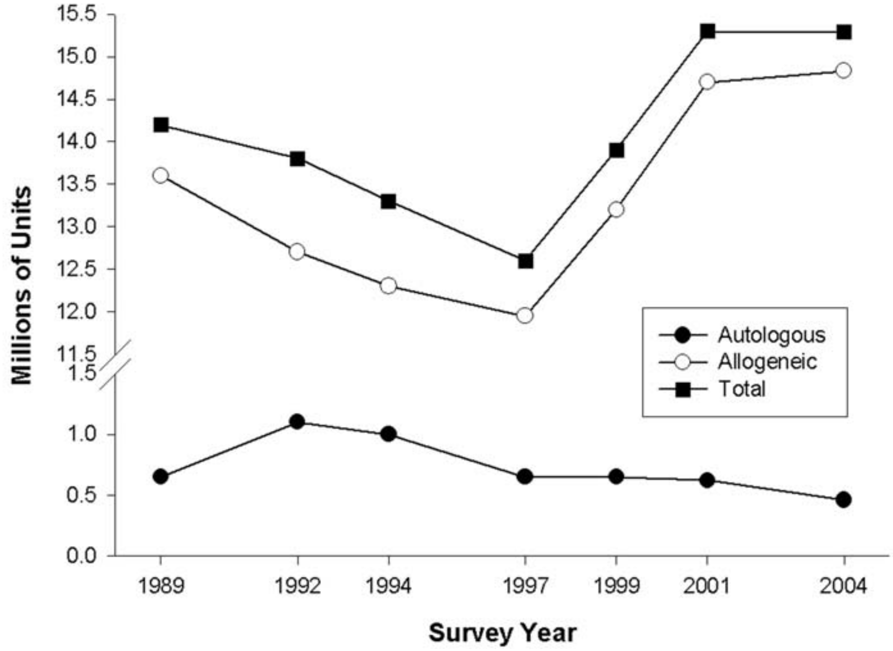

Figure 11-1. Allogeneic, autologous, and total whole blood and red blood cell collections, 1989-2004.

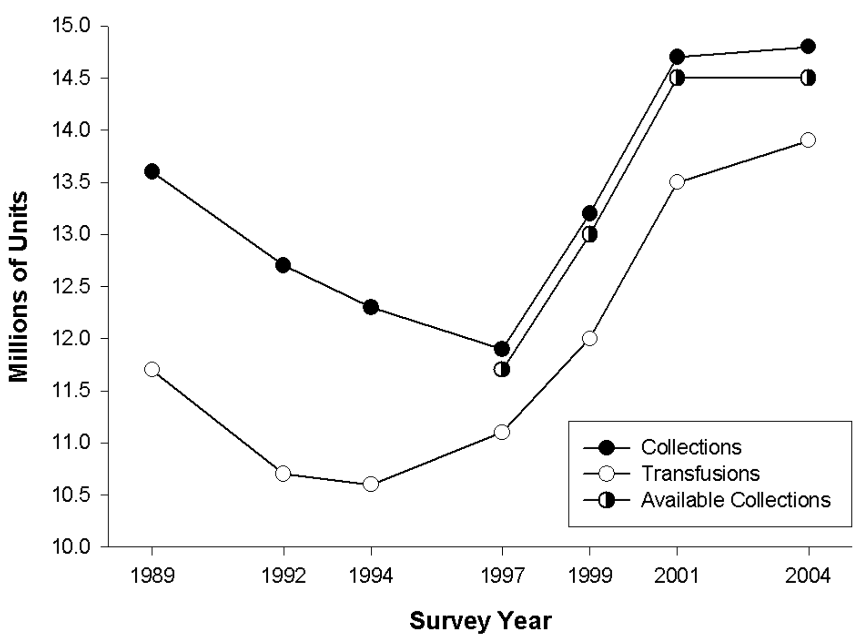

Figure 11-2. Allogeneic whole blood and red blood cell collections and transfusions, 1989-2004.

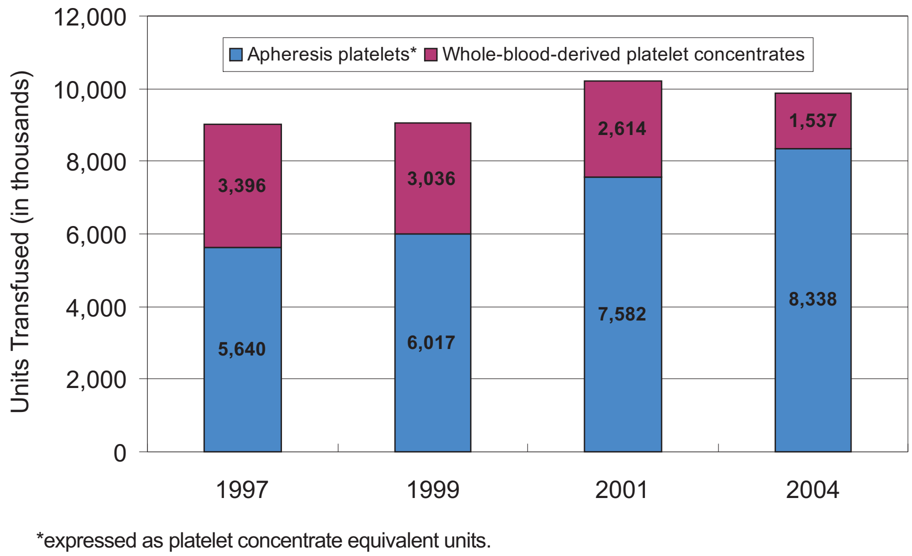

Figure 11-3. Trends in platelet transfusion.

crease in demand. Collections increased significantly ($p<0.0001$) in 2001 largely in response to the extraordinary events of September 11, temporarily boosting the margin to nearly 1.2 million, or 8.0% of supply.

The 2004 data, however, indicate a subsequent reduction in the margin to 6% of supply. This was the result of a leveling of allogeneic units transfused to 13.9 million and a reduction in allogeneic supply to 14.8 million, yielding a margin of 0.9 million units. Thus, as illustrated in **Figure 11-2**, the margin between supply and demand over the 15-year period of 1989 to 2004 was reduced by 52.6%.

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 (not illustrated, but mentioned in the Executive Summary). In 2004, the available supply of screened allogeneic WB/RBC 14,560,000 units exceeded transfusions of allogeneic WB/RBCs (13,912,000) by 648,000 units. This margin was only 4.5%, in comparison with 6.3% in 2001.

In summary, 2004 NBCUS data indicate some leveling of the steep increase in the demand for RBCs previously observed. Collections, however, remained constant in comparison with 2001, resulting in further contraction in the margin between supply and demand. The 2004 margin was the smallest ever measured by this series of contemporary national collection and transfusion surveys.

Through efficient product management, evidenced by reduced outdates and low numbers of hospitals reporting unmet need, the blood community has maintained adequate supply to meet blood product needs. The community must remain vigilant, however, because the margin is smaller than it has ever been. We must be able to ensure that the blood supply is always sufficient for the country's needs.

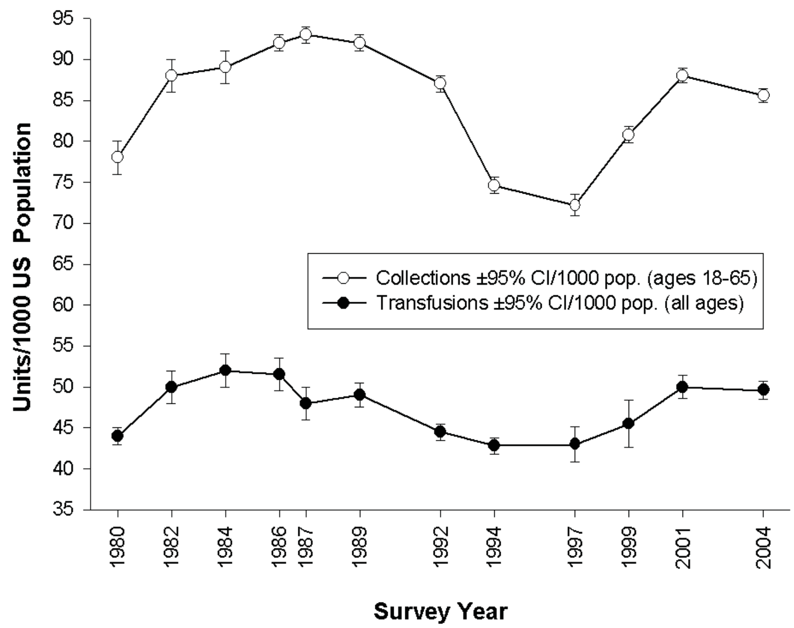

Figure 11-4. Trends in estimated rates of blood collection and transfusion in the United States, 1980-2004.

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 2004. The rate of collection, the upper line, was calculated from the national estimate of total WB and RBC units collected per thousand population aged 18 to 65 for a given survey year. 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. Each rate includes the 95% confidence interval for the estimate. Population figures were obtained from the US Bureau of the Census.

Blood collection per thousand population of donor age was 85.6 units in 2004 compared with 88.0 units in 2001 and 80.8 units in 1999. In comparison with 2001, this was a decline of 2.7%, primarily resulting from the temporary effect of additional donations experienced following the September 11, 2001 terrorist attacks. The US WB/RBC transfusion rate in 2004 was 49.6 units per thousand population, statistically unchanged from the rate in 2001 (50.0), which was the highest rate observed in 15 years.

*Note: Blood collection per thousand total population in 2004 was 53.5. The age-adjusted value of 85.6 was used in **Figure 11-4** for consistency with historical methods.*

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