

# Apheresis Technologies and Clinical Applications: The 2005 International Apheresis Registry

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**Abstract:** The developments in apheresis technologies and techniques and their clinical applications worldwide are technologically, sociologically, and economically motivated. In past apheresis surveys the statistics have highlighted both the differences by geographic region in clinical practice and in the types of technologies utilized. While a national view of apheresis is very important, an international view may be more representative overall of this therapeutic modality than national results that are highly dependent on the local economics and the available technologies. These regional differences have provided a basis for scientific and clinical assessment of these apheresis technologies and their clinical outcomes, and have impacted the marketing and business developments of new technologies worldwide. The results of the International Apheresis Registry for 2005 reporting from 22 centers on 5

continents are presented. The survey collected data exclusively via a secure internet website on 1133 patients for a total of 6501 treatments. Unlike our prior registries, information on stem cell infusions was gathered. Information gathered included patient demographics, medical history, treatment diagnoses, treatment specifics (type, methodology, access type, anticoagulants, drugs, and equipment usage), side-effects, clinical response, and payment provider. As in the prior International Apheresis Registries for 1983, 2000, and 2002 the survey results highlight the regional differences in apheresis usage and treatment methodologies, indicating that an international overview of apheresis may be more representative of the impact of this therapeutic modality. **Key Words:** Registry, Survey, Therapeutic apheresis.

Survey statistics of apheresis have shown both the differences by geographic region in clinical practices and in the types of technologies utilized (1–4). In 1983, the first International Apheresis Registry was conducted and reported (1), following a pilot, to demonstrate the feasibility of collecting such data and assessing the data collection methodology (5). The data collected indicated regional differences with regards to the apheresis technologies that were applied and the disease states for which they were used.

In 2001, the results of the 2000 International Apheresis Registry was reported (3), and in 2004 so were

the results of the 2002 International Apheresis Registry (4). This survey was carried out to assess the present state of apheresis, the technologies utilized, and its clinical applications. These results were presented in part at the 6th World Congress of the International Society for Apheresis held March 2–4, 2007, in Yokohama, Japan.

## METHODS

A copy of the electronic questionnaire form is given in the Appendix I. This electronic form is similar to the paper and electronic forms used in the 1983, 2000, and 2002 Registries; this was to allow comparison with the results of these prior years. Unlike our prior registries, information on stem cell infusions was gathered. The form requests patient information including demographics, medical history, specifics of the treatment, response to apheresis, and payment provider for the year 2005. For many of the

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Presented in part at the 6th World Congress of the International Society for Apheresis held March 2–4, 2007 in Yokohama, Japan.

**TABLE 1.** *Geographical distribution*

Region/country	Centers	Patients	Treatments
Europe	5	281	3155
Austria	1	118	1898
Germany	2	84	704
Croatia	1	57	443
Lithuania	1	22	110
Asia	9	504	1935
Turkey	3	231	670
Taiwan	1	90	462
Korea	1	43	321
India	1	41	228
China	1	54	124
Malaysia	1	43	121
Japan	1	2	9
North America	4	263	959
USA	3	260	857
Canada	1	3	102
Australia	1	79	429
New South Wales	1	79	429
Central/South America	3	6	23
Argentina	1	4	15
Brazil	1	1	8
Venezuela	1	1	0
Total	22	1133	6501

questions on the form, drop down menus were used to facilitate answering the question. This data solicitation study was approved by the Institutional Review Board (IRB) of the Cleveland Clinic and was compliant with the Health Insurance Portability and Accountability Act (HIPAA).

In soliciting responses, 805 emails were sent to apheresis center personnel. Through this notification, the individuals were referred to a secure website (<https://clinapps.bio.ri.ccf.org/apheresis/>) through which they were provided instructions on how to enter patient data. Participation in this survey was completely voluntary and participants were informed that no compensation would be provided. In order to complete this survey and summarize the results, the deadline for the submission of all data for the reporting year of 2005 was November 15, 2006. From the opening of the website for the collection of data from January 2006 through to its closure, reminders were sent out periodically to the potential participating directors of centers.

In total, data responses were received from 22 centers (30 persons) on 1133 patients receiving 6501 treatments (see Appendix II). The data will be described according to regions as Asia, Europe, North America, Australia, or Central/South America where the regions are classified as in previous surveys. Table 1 outlines the geographic distribution of the survey responders as the number of responding centers, the number of patients submitted by each center, and the number of treatments given. Within

each region, results are listed in order of the country that submitted the largest number of patients to the country that submitted the smallest number of patients. Categorical variables are summarized as frequency counts, with or without percentages. Continuous variables are summarized as the sample size, mean, standard deviation, and median. All data were analyzed using SAS software (SAS Institute, Cary, NC, USA). Because all questions may not have been answered completely for any patient, the numbers reported do not always total 6501 treatments or 1133 patients.

## RESULTS

Table 2 outlines data on race and gender for which both race and gender were noted on the questionnaire. Male subjects, unlike that in the previous registry (4), outnumbered females (54.9% vs. 45.1%). Caucasian was the predominant treated race of the patients treated, with Asian being the second largest.

Table 3 shows descriptive statistics of age and the months from primary diagnosis to first apheresis treatment. The mean age of patients at the time of their first apheresis treatment was 45 years, similar to that in the previous registry (4). The Central/South American region had the lowest mean age of 21 years for the patient's first treatment while the Australian region had the oldest at 50 years. The mean interval from primary diagnosis to the first apheresis treatment was 14.0 months, varying from a high of 23.8 months for the Australian region to a low of 1.0 months for the Central/South American region. The mean number of months from primary diagnosis to the first apheresis treatment was appreciably lower than the 34.6 months found in 2002 (4) and the 31.6 found in 2000 (3).

Table 4 shows the reason for treatment (i.e. treatment diagnosis) for the 942 patients reported. The percentages represent the percentage of patients within each region. The most common treatment diagnosis categories overall were the nervous system (32.5%), neoplasms (20.1%), and circulatory system (10.6%). Some regional differences are noteworthy. In particular, for the European region, endocrine/nutrition/metabolic/immunity ranked second as a treatment diagnosis and blood/blood-forming organs ranked third in the Australian region. This ranking of the most common treatment diagnosis categories differed somewhat from the 2002 survey (4), which ranked the treatment diagnoses as nervous system, endocrine/nutrition/metabolic/immunity, and then musculoskeletal system.

**TABLE 2.** Race and gender by region for 1124 patients

Gender/race	Europe		Asia		N America		Australia		C/S America		Total	
	N	% <sup>†</sup>	N	% <sup>†</sup>	N	% <sup>†</sup>	N	% <sup>†</sup>	N	% <sup>†</sup>	N	% <sup>‡</sup>
Male											617	54.9
Caucasian	140	100	140	52.8	141	85.5	27	58.7	1	100	449	39.9
Oriental	0	0	114	43.0	2	1.2	3	6.5	0	0	119	10.6
Malaysian	0	0	10	3.8	0	0.0	0	0.0	0	0	10	0.9
Black	0	0	0	0.0	17	10.3	0	0.0	0	0	17	1.5
Australia/Oceania	0	0	0	0.0	0	0.0	13	28.3	0	0	13	1.2
Hispanic	0	0	0	0.0	3	1.8	1	2.2	0	0	4	0.4
Nat Am Indian	0	0	0	0.0	1	0.6	0	0.0	0	0	1	0.1
Other	0	0	1	0.4	1	0.6	2	4.3	0	0	4	0.4
Female											507	45.1
Caucasian	136	100	90	37.8	76	79.2	19	57.6	4	100	325	28.9
Oriental	0	0	115	48.3	1	1.0	2	6.1	0	0	118	10.5
Malaysian	0	0	33	13.9	0	0.0	1	3.0	0	0	34	3.0
Black	0	0	0	0.0	17	17.7	0	0.0	0	0	17	1.5
Australia/Oceania	0	0	0	0.0	0	0.0	9	27.3	0	0	9	0.8
Hispanic	0	0	0	0.0	2	2.1	0	0.0	0	0	2	0.2
Nat Am Indian	0	0	0	0.0	0	0.0	0	0.0	0	0	0	0.0
Other	0	0	0	0.0	0	0.0	2	6.1	0	0	2	0.2

<sup>†</sup>Percentage according to region and gender. <sup>‡</sup>Percentage according to 1124 patients.

**TABLE 3.** Age and interval from diagnosis to apheresis

Variable/region	N	Mean	SD	Median
Age (years)				
Europe	278	48	17	48
Asia	503	43	18	44
N America	262	46	17	47
Australia	79	50	18	12
C/S America	5	21	18	12
Total	1127	45	18	46
Months from primary diagnosis to first apheresis treatment				
Europe	171	21.2	45.2	0.1
Asia	216	6.3	25.9	0.1
N America	63	15.4	25.1	6.5
Australia	37	23.8	48.1	3.5
C/S America	3	1.0	1.0	0.6
Total	490	14.0	36.2	0.2

Table 5 outlines the patients whose primary diagnosis matches the treatment diagnosis. Overall the percent match was 86.5% for 905 patients reported, which was similar to the 84.5% found in the 2002 survey (4).

Table 6 outlines the top 10 treatment diagnoses and number of patients treated by region and in total. Particularly noteworthy are the differences by region and the dominance of the Asian, European, and North American regions in the top or highest ranked treatment diagnosis of myasthenia gravis. Multiple myeloma was the distant second ranked diagnosis and Guillain-Barré the third ranked predominantly due to the number of cases reported from the Asian

**TABLE 4.** Treatment diagnosis for 942 patients

Category	Europe		Asia		N America		Australia		C/S America		Total		
	N	%	N	%	N	%	N	%	N	%	N	%	
Nervous system	89	36.2	168	33.8	30	26.1	18	22.8	1	20.0	306	32.5	
Neoplasma	34	13.8	93	18.7	24	20.9	38	48.1	0	0.0	189	20.1	
Circulatory system	14	5.7	65	13.1	17	14.8	2	2.5	2	40.0	100	10.6	
Blood/blood-forming organs	28	11.4	36	7.2	8	7.0	14	17.7	1	20.0	87	9.2	
Endocrine/nutrition/metabolic/immunity	42	17.1	16	3.2	6	5.2	2	2.5	0	0.0	66	7.0	
Musculoskeletal system	2	0.8	46	9.3	0	0.0	1	1.3	0	0.0	49	5.2	
Digestive system	0	0.0	31	6.2	1	0.9	0	0.0	0	0.0	32	3.4	
Genitourinary system	6	2.4	17	3.4	8	7.0	1	1.3	0	0.0	32	3.4	
Symptoms/signs	16	6.5	3	0.6	10	8.7	1	1.3	1	20.0	31	3.3	
Injury/poisoning	5	2.0	17	3.4	2	1.7	0	0.0	0	0.0	24	2.5	
Skin & subcutaneous tissue diseases	8	3.3	0	0.0	0	0.0	2	2.5	0	0.0	10	1.1	
Congenital anomalies	0	0.0	0	0.0	9	7.8	0	0.0	0	0.0	9	1.0	
Respiratory system	1	0.4	2	0.4	0	0.0	0	0.0	0	0.0	3	0.3	
Infectious/parasitic diseases	1	0.4	1	0.2	0	0.0	0	0.0	0	0.0	2	0.2	
Mental disorders	0	0.0	2	0.4	0	0.0	0	0.0	0	0.0	2	0.2	
Total		246	100	497	100	115	100	79	100	5	100	942	100

**TABLE 5.** Patients whose primary diagnosis matches the treatment diagnosis

Region	$N_{\text{total}}$	# Match	% Match
Europe	245	199	81.2
Asia	497	442	88.9
N America	79	69	87.3
Australia	79	71	89.9
C/S America	5	2	40.0
Total	905	783	86.5

and European regions. Also in the 2002 survey (4) myasthenia gravis was ranked as the top treated diagnosis.

Table 7 outlines the top 10 treatment diagnoses by the number of treatments. By far, the largest numbers of treatments were for myasthenia gravis, followed by hypercholesterolemia, and then thrombotic thrombocytopenic purpura (TTP). The majority of treatments for myasthenia gravis came from the Asian and European regions, while more than 95% of the treatments for hypercholesterolemia were reported from the European region. The differences in ranking between the treatment diagnosis (Table 6) and the treatment diagnosis according to the number of treatments (Table 7) suggest that the differences in the treatment requirements by disease categories are related to the treatment requirements for the disease, response to apheresis, and payment provider.

Table 8 shows the total number of each type of treatment and the number of patients who received each treatment. Plasmapheresis (PP) procedures as plasma exchange (PE) and plasma treatment were the most common treatment modalities with over 82% of the reported treatment on 67% of all patients. This is down from the previous registry (4) where the percentage was 93.3%. In this registry we first collected data on stem cell infusion, which represented only 4.3% of patient treatments but 25.6% of all patients. The European region reported the highest number of treatments per patient of 11.8 (the mean of all regions was 6.0) where about 65% of all the procedures were by plasma treatment or whole blood adsorption, as well as the highest numbers of such treatments in any region by far. The Asian region also reported that over 43% of its treatments were by plasma treatment. No plasma treatment or whole blood adsorption procedures were reported in the North American, Australian, and Central/South American regions.

Table 9 shows the number (also shown in Table 8) and percentage of patients who received each type of treatment. Plasma exchange and plasma treatment accounted for 67.3% of the types of treatments for

the patients reported. Stem cell infusion, for which data was first collected in this registry, was used in 25.7% of the patients. Only 4.1% of the patients were treated by cytopheresis or lymphoplasmapheresis. Only the European and Asian regions reported patient whole blood adsorption and plasma treatment procedures suggesting the limited availability of such treatment technologies outside these regions. Technology availability in the different regions influences the type of treatment provided to the patients, as well as the disease states treated.

Table 10 shows the frequencies and percentages of the number of treatments noted for each patient. Most patients received 1–5 treatments for plasma exchange, plasma treatment, or cytopheresis. For whole blood adsorption reported only from the Asian and European regions, and most often from the European region, most patients received greater than 10 treatments. For stem cell infusions, single infusions were assumed as data was not collected.

Table 11 describes the average volume of plasma exchange, plasma treatments, whole blood adsorption, and lymphoplasmapheresis and average number of cells for cytopheresis, lymphoplasmapheresis, and stem cell infusions. The mean volume exchanged was 3.0 L. For plasma treatment, the mean total treated volume was 3.8 L for the Asian and European regions, the only regions reporting this form of treatment. For the European region, the mean plasma treatment volume was 6.6 L, more than twice the mean volume used in plasma exchange. The average volume treated with whole blood adsorption was 6.7 L, which was mainly reflective of the larger number of patients reported in the European region and their high average treatment volume of 7.1 L. The average volume processed in lymphoplasmapheresis was 4.0 L, but the number of patients reported was only two. The average number of cells removed in cytopheresis was  $11.4 \times 10^{11}$  and for lymphoplasmapheresis  $5.0 \times 10^{10}$ . For stem cell infusions the average number of cells were  $9.5 \times 10^6/\text{kg}$ , with the North American region reporting the highest of  $20.3 \times 10^6/\text{kg}$ , nearly more than double all the other regions reporting.

Table 12 shows the number of treatments per replacement solution and the number of patients who received them. Patients may have received more than one type of solution, therefore the categories are not mutually exclusive. Albumin solution was the most common replacement solution by nearly two times more than fresh frozen plasma, the next most common replacement solution. These were followed by electrolyte solution and then plasma expander solution. In contrast to the previous survey (4), the

TABLE 6. Top 10 treatment diagnoses according to number of patients for 942 patients

Rank	Europe	Asia	N America	Australia	C/S America	Total
1	Myasthenia gravis (54)	Myasthenia gravis (118)	TTP (14)	non-Hodgkin's lymphoma (15)	Vasculitis/non-cutaneous (2)	Myasthenia gravis (189)
2	Hypercholesterolemia (28)	Other circulatory system disease (34)	Myasthenia gravis (13)	Chronic relapsing polynuropathy (9)	Cerebral flow alteration (1)	Multiple myeloma (59)
3	Symptoms/signs (16)	Multiple myeloma (32)	Symptoms/signs (10)	Hyperviscosity syndrome (8)	Hyperviscosity syndrome (1)	Guillain-Barré syndrome (54)
4	Guillain-Barré syndrome (15)	Guillain-Barré syndrome (29)	Congenital anomalies (9)	Multiple myeloma (8)	Symptoms/signs (1)	TTP (51)
5	Leukemia (13)	Systemic lupus erythematosus (26)	Guillain-Barré syndrome (8)	Chronic myelogenous leukemia (7)	-	Leukemia (43)
6	MS (12)	TTP (23)	Multiple myeloma (8)	Other dis. blood/blood-forming organs (6)	-	non-Hodgkin's lymphoma (39)
7	TTP (12)	Leukemia (22)	Leukemia (6)	Hodgkin's disease (4)	-	Other circulatory system dis. (37)
8	Multiple myeloma (11)	Rheumatoid arthritis (19)	Cryoglobulinemia (4)	Myasthenia gravis (4)	-	Hypercholesterolemia (34)
9	Other skin/subq tissue dis. (8)	non-Hodgkin's lymphoma (16)	Chronic relapsing polynuropathy (3)	Guillain-Barré syndrome (2)	-	Symptoms/signs (31)
10	Hemolytic-uremic syndrome (7)	Hyperviscosity syndrome (15)	Hemolytic anemia (3)	Leukemia (2)	-	Hyperviscosity syndrome (29)
	Hypertriglyceridemia (7)	Myeloma kidney (3)	MS (3)	TTP (2)	-	

dis., disease(s); MS, multiple sclerosis; subq, subcutaneous; TTP, thrombotic thrombocytopenic purpura.

TABLE 7. Top 10 treatment diagnoses according to number of treatments for 5809 treatments

Rank	Europe	Asia	N America	Australia	C/S America	Total
1	Hypercholesterolemia (861)	Myasthenia gravis (514)	TTP (182)	Chronic relapsing polynuropathy (109)	Vasculitis, non-cutaneous (12)	Myasthenia gravis (1315)
2	Myasthenia gravis (573)	TTP (195)	Myasthenia gravis (158)	TTP (73)	Hyperviscosity syndrome (8)	Hypercholesterolemia (900)
3	TTP (156)	Guillain-Barré syndrome (138)	Factor VIII inhibitor of antibodies (158)	Myasthenia gravis (70)	Symptoms/signs (3)	TTP (606)
4	MS (125)	Rheumatoid arthritis (115)	Multiple myeloma (49)	Hyperviscosity syndrome (52)	Cerebral flow alteration (1)	Guillain-Barré syndrome (272)
5	Symptoms/signs (102)	Kidney transplant complications (85)	Symptoms/signs (43)	Other skin/subq tissue disease (25)	-	Chronic relapsing polynuropathy (197)
6	Hypertipidemia (95)	Other circulatory system dis. (84)	Guillain-Barré syndrome (42)	non-Hodgkin lymphoma (15)	-	MS (154)
7	Guillain-Barré syndrome (84)	Systemic lupus erythematosus (73)	Thrombocytopenia (31)	Leukemia (11)	-	Symptoms/signs (154)
8	Other dis. blood/blood-forming organs (55)	Other GU system disease (68)	Other circulatory system disease (27)	Motor neuron dis. (9)	-	Multiple myeloma (138)
9	Hemolytic-uremic syndrome (50)	Other nervous system disease (50)	Hemolytic anemia (24)	Multiple myeloma (9)	-	Factor VIII inhibitor of antibodies (125)
10	Thrombocytopenia (45)	RPGN (50)	Hypercholesterolemia (23)	Guillain-Barré syndrome (8)	-	Kidney transplant complications (118)

dis., disease(s); GU, genitourinary; MS, multiple sclerosis; RPGN, rapidly progressive glomerulonephritis; subq, subcutaneous; TTP, thrombotic thrombocytopenic purpura.

**TABLE 8.** *Treatments*

Treatment	Europe	Asia	N America	Australia	C/S America	Total
Plasma exchange only	979 (145)	953 (205)	802 (87)	391 (36)	20 (3)	3145 (476)
Plasma treatment only	1391 (64)	840 (190)	0 (0)	0 (0)	0 (0)	2231 (254)
Whole blood adsorption only	658 (26)	13 (3)	0 (0)	0 (0)	0 (0)	671 (29)
<i>LDL hemoperfusion</i>	271 (10)	12 (2)	0 (0)	0 (0)	0 (0)	283 (12)
<i>Endotoxin hypoperfusion</i>	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
<i>Other type</i>	387 (16)	0 (0)	0 (0)	0 (0)	0 (0)	387 (16)
Cytapheresis only	35 (7)	49 (23)	13 (8)	3 (3)	3 (1)	103 (42)
Lymphoplasmapheresis only	26 (2)	0 (0)	0 (0)	0 (0)	0 (0)	26 (2)
Stem cell infusion only	21 (21)	80 (80)	144 (144)	33 (33)	0 (0)	278 (278)
<i>Autologous</i>	19 (19)	58 (58)	126 (126)	32 (32)	0 (0)	235 (235)
<i>Prep-chemo</i>	18 (18)	56 (56)	0 (0)	29 (29)	0 (0)	103 (103)
<i>Prep-G-CSF</i>	1 (1)	0 (0)	0 (0)	3 (3)	0 (0)	4 (4)
<i>Prep-unspecified</i>	0 (0)	2 (2)	126 (126)	0 (0)	0 (0)	128 (128)
<i>Allogenic</i>	2 (2)	22 (22)	18 (18)	1 (1)	0 (0)	43 (43)
<i>Prep-chemo</i>	0 (0)	15 (15)	0 (0)	0 (0)	0 (0)	15 (15)
<i>Prep-chemo &amp; RT</i>	0 (0)	4 (4)	0 (0)	0 (0)	0 (0)	4 (4)
<i>Prep-G-CSF</i>	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)	3 (3)
<i>Prep-unspecified</i>	0 (0)	3 (3)	18 (18)	0 (0)	0 (0)	21 (21)
Plasma exchange & whole blood ads <sup>†</sup>	45 (2)	0 (0)	0 (0)	0 (0)	0 (0)	45 (2)
Plasma exchange & autologous stem cells	0 (0)	0 (0)	0 (0)	2 (1)	0 (0)	2 (1)
All treatments	3155 (267)	1935 (501)	959 (239)	429 (73)	23 (4)	6501 (1084)

<sup>†</sup>Whole blood adsorption for all 45(2) was LDL hemoperfusion. Number of treatments (number of patients treated).

Average number of treatments/patient: 11.8 Europe; 3.9 Asia; 4.0 N America; 5.9 Australia; 5.8 C/S America; 6.0 total. ads, adsorption; G-CSF, granulocyte colony stimulating factor; LDL, low-density lipoprotein; RT, radiation therapy.

percentage of treatments using electrolyte solution were the highest.

Table 13 summarizes the equipment types reported, Table 14, the plasma membrane separators, Table 15 the plasma treatment methods of membrane filtration (cascade filtration), sorption, or other means, Table 16 the plasma membrane treatment products, and Table 17 the sorptive plasma treatment products. Significant regional differences exist in the small amount of data collected in this survey and regional differences are reflective of the technologies available in the various regions. Only the Asian and European regions reported treatments by membrane plasma separation, plasma sorption and plasma membrane treatment.

Table 18 shows the number of treatments per blood access method and the number of patients who received each method. Venous access methods

were by far the most dominant methods, whether by central vein, peripheral vein, or femoral vein; however, regional differences were notable. Notable also was the use of arterial puncture in the Asian region only.

Table 19 reports the anticoagulant and drug usages. Anticoagulation by citrate and heparin were the predominant forms. The use of the anticoagulant drug nafamostat mesilate was reported only in the Asian region and only for one patient. As noted in the Japanese Registries (6,7), this drug is widely used in a large number of centers for anticoagulation. Of all patients, 66.2% were reported as taking no steroids or immunosuppressives for their therapy and nearly one-fourth (23.7%) of the patients were on steroids only. Differences in drug regimes in the different regions most likely are related to treatment diagnosis differences in their patient populations.

**TABLE 9.** *Number and percentage of patients receiving each type of treatment*

Treatment	Europe	Asia	N America	Australia	C/S America	Total
Plasma exchange only	145 (54.3%)	205 (40.9%)	87 (36.4%)	36 (49.3%)	3 (75.0%)	476 (43.9%)
Plasma treatment only	64 (24.0%)	190 (37.9%)	0 (0%)	0 (0%)	0 (0%)	254 (23.4%)
Whole blood adsorption only	26 (9.7%)	3 (0.6%)	0 (0%)	0 (0%)	0 (0%)	29 (2.7%)
Cytapheresis only	7 (2.6%)	23 (4.6%)	8 (3.3%)	3 (4.1%)	1 (25.0%)	42 (3.9%)
Lymphoplasmapheresis only	2 (0.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Stem cell infusion only	21 (7.9%)	80 (16.0%)	144 (60.3%)	33 (45.2%)	0 (0%)	278 (25.6%)
Plasma exchange & whole blood ads	2 (0.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (0.2%)
Plasma exchange & stem cells	0 (0%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	1 (0.1%)
Number of patients	267	501	239	73	4	1084

ads, adsorption.

**TABLE 10.** Number of treatments given per patient

No. of treatments	Europe		Asia		N America		Australia		C/S America		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
<b>Plasma exchange</b>												
1-5	85	57.8	162	79.0	40	46.0	15	40.5	1	33.3	303	63.3
6-10	38	25.9	29	14.2	27	31.0	8	21.6	2	66.7	104	21.7
>10	24	16.3	14	6.8	20	23.0	14	37.8	0	0.0	72	15.0
(No. of patients)	(147)		(205)		(87)		(37)		(3)		(479)	
<b>Plasma treatment</b>												
1-5	8	12.5	106	84.2	0	—	0	—	0	—	168	66.1
6-10	11	17.2	27	14.2	0	—	0	—	0	—	38	15.0
>10	45	70.3	3	1.6	0	—	0	—	0	—	48	18.9
(No. of patients)	(64)		(190)		(0)		(0)		(0)		(254)	
<b>Whole blood adsorption</b>												
1-5	4	14.3	2	66.7	0	—	0	—	0	—	6	19.3
6-10	2	7.1	1	33.3	0	—	0	—	0	—	3	9.7
>10	22	78.6	0	0.0	0	—	0	—	0	—	22	71.0
(No. of patients)	(28)		(3)		(0)		(0)		(0)		(31)	
<b>Cytapheresis</b>												
1-5	5	71.4	21	91.3	8	100	3	100	1	100	38	90.5
6-10	1	14.3	2	8.7	0	0	0	0	0	0	3	7.1
>10	1	14.3	0	0.0	0	0	0	0	0	0	1	2.4
(No. of patients)	(7)		(23)		(8)		(3)		(1)		(42)	
<b>Lymphoplasmapheresis</b>												
1-5	1	50.0	0	—	0	—	0	—	0	—	1	50.0
>10	1	50.0	0	—	0	—	0	—	0	—	1	50.0
(No. of patients)	(2)		(0)		(0)		(0)		(0)		(2)	
<b>Stem cell infusion</b>												
1-5	21	100	80	100	144	100	34	100	0	—	279	100
(No. of patients)	(21)		(80)		(144)		(34)				(279)	

Table 20 shows the number of occurrences of each side-effect or complication during the treatment and up to 2 h after its cessation. Citrate-related complications were among the highest (citrate-induced, paresthesia, and hypocalcemia); this relates to the predominant use of citrate reported and the dominance of centrifugal equipment used, which is typically used with citrate anticoagulation. Blood access difficulties and hypotension were also reported frequent complications of the procedures. This differs from the 2002 registry (4), where blood access difficulties and hypotension were the most frequent side-effects or complications reported. No deaths were reported in this survey year.

The reported response to apheresis and payment provider, noted in Table 21, show that nearly 75% (74.8%) of the patients showed improvement, whereas 10.4% indicated that their condition remained the same, and 9.7% were reported as not assessable. These results were nearly comparable to the last survey (4), with the exception of the higher percentage of responses that were not assessable. Response to apheresis was determined objectively, at least in part, in 82.5% of cases. 71.8% of the patients received support from the government for their treat-

ment, which was similar to that reported in the last survey (4) of 71.2%. The Australian and Central/South American regions reported receiving support from the government at 100%, whereas the North American region reported only 36.7% government payment and the European region 51.4%. The North American region reported the highest private insurance payment of 55.1% and the Asian region the highest self/family payment provider of 12.1%. The European region reported the highest hospital/institution payment provider of 18.1%.

## DISCUSSION

Apheresis registries are a collection of information on apheresis patients, procedures, techniques, and outcomes for a specific disease or device application. Apheresis registries may be specific for data collection on a designated disease and/or a specific protocol or product specific for data collection on a specific device trial, national for data collection within a specific country, or international for data collection across countries and continents. A brief description of various registries recently published will be given and then a discussion will be made on this Interna-

**TABLE 11.** Treatment volume and cells

Variable/region	N	Mean	SD	Median
Plasma exchange – average volume (liters)				
Europe	142	3.2	0.7	3.0
Asia	204	2.9	0.7	3.0
N America	84	3.2	0.9	3.1
Australia	36	2.9	0.6	2.8
C/S America	3	2.2	0.7	2.0
Total	469	3.0	0.8	3.0
Plasma treatment – average volume (liters)				
Europe	64	6.6	1.2	7.2
Asia	190	2.9	4.8	2.7
N America	0	–	–	–
Australia	0	–	–	–
C/S America	0	–	–	–
Total	254	3.8	4.5	3.0
Whole blood adsorption – average volume (liters)				
Europe	28	7.1	3.2	7.8
Asia	3	3.0	1.7	2.1
N America	0	–	–	–
Australia	0	–	–	–
C/S America	0	–	–	–
Total	31	6.7	3.3	7.0
Cytapheresis – average number of cells ( $\times 10^{11}$ )				
Europe	7	15.6	25.8	5.0
Asia	5	5.6	5.5	3.0
N America	0	–	–	–
Australia	0	–	–	–
C/S America	0	–	–	–
Total	12	11.4	20.0	5.0
Lymphoplasmapheresis – average number of cells ( $\times 10^{10}$ )				
Europe	2	5.0	0.0	5.0
Asia	0	–	–	–
N America	0	–	–	–
Australia	0	–	–	–
C/S America	0	–	–	–
Total	2	5.0	0.0	5.0
Lymphoplasmapheresis – average volume (liters)				
Europe	2	4.0	0.0	4.0
Asia	0	–	–	–
N America	0	–	–	–
Australia	0	–	–	–
C/S America	0	–	–	–
Total	2	4.0	0.0	4.0
Stem cell infusion – average number of cells ( $\times 10^6/\text{kg}$ )				
Europe	20	8.8	6.7	7.5
Asia	79	11.2	12.2	8.0
N America	3	20.3	22.2	14.0
Australia	34	4.9	1.8	4.0
C/S America	0	–	–	–
Total	136	9.5	10.5	7.0

tional Apheresis Registry. Specific discussion will be made to the most recent reports of registries from Canada, France, Germany, Hungary, Italy, Japan, Philippines, the United States of America (USA), Venezuela, the Rheopheresis Registry, and the World Apheresis Registry (see Tables 22–24).

The Canadian Apheresis Registry of 2002 (8) reported on 42 centers with 898 cases. Canada then had a population of 30 million inhabitants. Treating 30 disease types, 8561 procedures were reported.

Note was made that the plasma exchange cost is CDN \$950. The most frequent disease types treated were hematological (55%), neurological (40%) and others, such as collagen-vascular and renal. The top diseases treated by numbers are TTP/hemolytic-uremic syndrome (HUS) (2477), myasthenia gravis (1309), Waldenstrom's macroglobulinemia (633), chronic inflammatory demyelinating polyneuropathy (586), cryoglobulinemia (321), myeloma (228), acute Guillain-Barré syndrome (185), hypercholesterolemia (174), Goodpasture's syndrome (160), and transplant rejection (117). The methods of apheresis included centrifugation and plasma exchange, the method of anticoagulation by citrate, and substitution fluids used included albumin (11 135 L), cryosupernatant plasma (5144 L), and fresh frozen plasma (2059 L). Reported side-effects were 12% of procedures, of which 0.4% had severe reactions.

The French Apheresis Registry of 2003 (9) reported on 91 centers with 942 patients having 9837 procedures. The population of France was 60 million in 2003. Centrifugal techniques were predominant (62%) with plasma treatment increasing over time (24.8%, of which 11.3% were whole blood treatment). Reportedly, vascular access was predominately (>54%) by peripheral vein. Substitution fluids were albumin substitutes (31.9%), albumin (27.7%), plasma (20.6%), or no substitution fluids (19.8%). Anticoagulation was by citrate (61.7%) with heparin (22.0%) used predominantly with filtration, and low molecular weight heparin (8.7%). Reported complications were 1.9%, with hypotension most common (0.4%). Reporting for 2003, the most frequent diseases treated were hematology (>30%) followed by neurology (about 30%). Over the years there had reportedly been a decline in neurological diseases treated and an increase in hematological diseases treated. These are followed by dermatology, vasculitis, and endocrinology in the range of 10–13% each. Reporting for 2004 were 97 centers with 1021 patients having 10 700 procedures, up from 2003. They noted increased numbers of treatments for TTP and HUS (189 patients with 2315 sessions) and familial hypercholesterolemia (114 patients with 2440 sessions, of which 1330 were on whole blood and 1107 by adsorption).

Germany has no official apheresis registry (10). Its population was 82 million at the time of reporting. For blood component collections, the Paul Ehrlich Institute reports, but it does not report manufacturers of devices, side-effects, or other specific details. The German Society for Transfusion Medicine and Immunohematology collects data on hemapheresis procedures and their side-effects on a voluntary basis.

**TABLE 12.** Replacement solution

Solution	Europe	Asia	N America	Australia	C/S America	Total
Albumin solution	535 (91)	839 (209)	510 (62)	319 (35)	20 (3)	2223 (400)
Fresh frozen plasma	383 (61)	506 (108)	268 (33)	78 (3)	0 (0)	1235 (205)
Electrolyte solution	28 (9)	442 (85)	0 (0)	0 (0)	0 (0)	470 (94)
Plasma expander solution	0 (0)	132 (34)	0 (0)	0 (0)	0 (0)	132 (34)
Purified protein fraction	0 (0)	0 (0)	3 (1)	0 (0)	0 (0)	3 (1)
Plasma products	0 (0)	4 (1)	1 (1)	0 (0)	0 (0)	5 (2)
Other	87 (20)	27 (5)	100 (17)	25 (8)	6 (1)	245 (51)
<i>SD plasma (Octaplas)</i>	67 (9)	0 (0)	0 (0)	0 (0)	0 (0)	67 (9)
<i>Albumin &amp; plasma expander</i>	0 (0)	0 (0)	60 (7)	0 (0)	0 (0)	60 (7)
<i>Red blood cells</i>	5 (5)	0 (0)	0 (0)	19 (7)	6 (1)	30 (13)
<i>Albumin &amp; normal saline</i>	0 (0)	23 (3)	0 (0)	0 (0)	0 (0)	23 (3)
<i>Fresh frozen plasma &amp; albumin</i>	14 (5)	0 (0)	0 (0)	0 (0)	0 (0)	14 (5)
<i>Normal saline</i>	0 (0)	0 (0)	0 (0)	6 (1)	0 (0)	6 (1)
<i>Cryosupernatant</i>	0 (0)	4 (1)	0 (0)	0 (0)	0 (0)	4 (1)
<i>Saline &amp; plasma expander</i>	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
<i>Not specified</i>	0 (0)	0 (1)	40 (10)	0 (0)	0 (0)	40 (11)

Number of treatments (number of patients treated). SD, solvent/detergent.

**TABLE 13.** Equipment type

Equipment	Europe	Asia	N America	Australia	C/S America	Total
Asahi Plasauto	0 (0)	12 (1)	0 (0)	0 (0)	0 (0)	12 (1)
Gambro BCT COBE Spectra, Spectra LRS	264 (48)	301 (39)	1112 (262)	523 (79)	0 (0)	2200 (428)
Baxter (Fenwal) CD 3000/3000 Plus	0 (0)	46 (24)	0 (0)	0 (0)	0 (0)	46 (24)
Kuraray	0 (0)	533 (124)	0 (0)	0 (0)	0 (0)	533 (124)
Baxter (Fenwal) Amicus	0 (0)	125 (78)	0 (0)	0 (0)	0 (0)	125 (78)
Baxter (Fenwal) Autopheresis C	85 (18)	0 (0)	0 (0)	0 (0)	0 (0)	85 (18)
Dideco Hemaplex BT900	0 (0)	228 (41)	0 (0)	0 (0)	0 (0)	228 (41)
B Braun Diapact	290 (45)	147 (55)	0 (0)	0 (0)	0 (0)	437 (100)
B Braun Dialog	0 (0)	10 (4)	0 (0)	0 (0)	0 (0)	10 (4)
Excorim (Fresenius)	333 (43)	0 (0)	0 (0)	0 (0)	0 (0)	333 (43)
Freseuius 4008 ADS	177 (9)	12 (2)	0 (0)	0 (0)	0 (0)	189 (11)
Fresenius AS 104, 204	67 (13)	435 (112)	0 (0)	0 (0)	21 (4)	523 (129)
Fresenius Comtec	11 (6)	86 (37)	0 (0)	0 (0)	0 (0)	97 (43)
Haemonetics PCS2 System	15 (5)	0 (0)	0 (0)	0 (0)	0 (0)	15 (5)
Hospal Prisma	58 (20)	0 (0)	0 (0)	0 (0)	0 (0)	58 (20)
Kaneka	26 (5)	0 (0)	0 (0)	0 (0)	0 (0)	26 (5)
Medicap ADA	5 (1)	2 (1)	0 (0)	0 (0)	0 (0)	7 (2)
Otsuka Adamonitor MN6-N	35 (5)	0 (0)	0 (0)	0 (0)	0 (0)	35 (5)
Therakos UVAR XTS	133 (8)	0 (0)	0 (0)	0 (0)	0 (0)	133 (8)
Other	95 (3)	22 (5)	0 (0)	0 (0)	0 (0)	117 (8)
<i>Fresenius Dali</i>	95 (3)	0 (0)	0 (0)	0 (0)	0 (0)	95 (3)
<i>Dideco Excell Pro</i>	0 (0)	8 (1)	0 (0)	0 (0)	0 (0)	8 (1)
<i>Fresenius 4008-H Prometheus System</i>	0 (0)	8 (2)	0 (0)	0 (0)	0 (0)	8 (2)
<i>Not specified</i>	0 (0)	6 (2)	0 (0)	0 (0)	0 (0)	6 (2)

Number of treatments (number of patients treated).

**TABLE 14.** Plasma membrane separator

Type	Europe	Asia	N America	Australia	C/S America	Total
Asahi	0 (0)	129 (44)	0 (0)	0 (0)	0 (0)	129 (44)
Bellco	0 (0)	47 (21)	0 (0)	0 (0)	0 (0)	47 (21)
Cobe	4 (2)	0 (0)	0 (0)	0 (0)	0 (0)	4 (2)
Fresenius	275 (39)	8 (2)	0 (0)	0 (0)	0 (0)	283 (41)
Gambro	302 (47)	0 (0)	0 (0)	0 (0)	0 (0)	302 (47)
Kuraray	0 (0)	693 (149)	0 (0)	0 (0)	0 (0)	693 (149)
Toray	0 (0)	34 (6)	0 (0)	0 (0)	0 (0)	34 (6)
Hospal Prisma TPE set	46 (15)	0 (0)	0 (0)	0 (0)	0 (0)	46 (15)

Number of treatments (number of patients treated).

**TABLE 15.** Plasma treatment method

Method	Europe	Asia	N America	Australia	C/S America	Total
Cascade	0 (0)	709 (143)	0 (0)	0 (0)	0 (0)	709 (143)
Sorption	56 (3)	49 (21)	0 (0)	0 (0)	0 (0)	105 (24)
Other	0 (0)	16 (8)	0 (0)	1 (1)	0 (0)	17 (9)
<i>Fractionated plasma sep/adsorption</i>	0 (0)	8 (2)	0 (0)	0 (0)	0 (0)	8 (2)
<i>PDF</i>	0 (0)	7 (5)	0 (0)	0 (0)	0 (0)	7 (5)
<i>Centrifuge</i>	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
<i>Unspecified</i>	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)

Number of treatments (number of patients treated).

**TABLE 16.** Plasma membrane treatment product

Product	Europe	Asia	N America	Australia	C/S America	Total
Asahi	0 (0)	129 (44)	0 (0)	0 (0)	0 (0)	129 (44)
Fresenius	28 (2)	9 (2)	0 (0)	0 (0)	0 (0)	37 (4)
Kuraray	0 (0)	721 (155)	0 (0)	0 (0)	0 (0)	721 (155)
Toray	0 (0)	11 (2)	0 (0)	0 (0)	0 (0)	11 (2)

Number of treatments (number of patients treated).

Therapeutic apheresis procedures are not formally registered, although most are believed to be performed by nephrologists. For preparative hemapheresis in Germany in 2002, 410 507 transfusion units for fresh frozen plasma (FFP) were produced by plasma-pheresis, 1 090 329 L of apheresis plasma were collected for fractionation, 227 096 transfusion units of platelets were collected by plateletpheresis, 4982 units of red blood cells were collected (4.45 million units were collected by whole blood donation), and

8213 single transplantation units of peripheral blood stem cells. In 2002 the German Community Transfusion Services performed 3078 plasmaphereses, 1292 erythrocytaphereses, 1658 leukocytophereses, 299 immunoadsorptions, and 614 photophereses. It is recognized that many routine preparative and therapeutic procedures are carried out in Germany, and that new treatment therapies are evaluated in pilot studies but require randomized trials to prove efficacy.

**TABLE 17.** Sorptive plasma treatment method

Method	Europe	Asia	N America	Australia	C/S America	Total
Kuraray	0 (0)	15 (4)	0 (0)	0 (0)	0 (0)	15 (4)
Other	151 (6)	14 (4)	0 (0)	0 (0)	0 (0)	165 (10)
Fresenius Dali	95 (3)	0 (0)	0 (0)	0 (0)	0 (0)	95 (3)
Immunosorba	42 (2)	0 (0)	0 (0)	0 (0)	0 (0)	42 (2)
Immunosorba, Protein A	14 (1)	0 (0)	0 (0)	0 (0)	0 (0)	14 (1)
Dideco	0 (0)	8 (1)	0 (0)	0 (0)	0 (0)	8 (1)
Medicap	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)	2 (1)
Unspecified	0 (0)	4 (2)	0 (0)	0 (0)	0 (0)	4 (2)

Number of treatments (number of patients treated).

**TABLE 18.** Blood access method

Method	Europe	Asia	N America	Australia	C/S America	Total
Peripheral veno-venous	731 (87)	480 (135)	140 (43)	209 (48)	6 (1)	1566 (314)
Central venous	617 (84)	842 (206)	863 (206)	187 (29)	15 (3)	2524 (528)
Femoral vein	8 (2)	464 (126)	47 (13)	27 (2)	0 (0)	546 (143)
Arterio-venous fistula/shunt	83 (6)	50 (14)	65 (5)	26 (1)	0 (0)	224 (26)
Arterial puncture	0 (0)	113 (20)	0 (0)	0 (0)	0 (0)	113 (20)
Other	0 (0)	5 (1)	0 (0)	26 (2)	0 (0)	31 (3)
<i>Port-a-cath</i>	0 (0)	0 (0)	0 (0)	26 (2)	0 (0)	26 (2)
<i>Unspecified</i>	0 (0)	5 (1)	0 (0)	0 (0)	0 (0)	5 (1)

Number of treatments (number of patients treated).

TABLE 19. Anticoagulants and drugs

Type	Europe		Asia		N America		Australia		C/S America		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
<b>Anticoagulants</b>												
Citrate only	70	24.9	269	53.4	263	100	73	92.4	5	83.3	680	60.0
Heparin only	93	33.1	196	38.9	0	0	0	0.0	0	0.0	289	25.5
Heparin & citrate	110	39.1	3	0.6	0	0	6	7.6	0	0.0	119	10.5
None	4	1.4	35	6.9	0	0	0	0.0	1	16.7	40	3.5
Other (saline solution)	4	1.4	0	0.0	0	0	0	0.0	0	0.0	4	0.4
Nafamostat mesilate	0	0.0	1	0.2	0	0	0	0.0	0	0.0	1	0.1
No. of patients	281		504		263		79		6		1133	
<b>Drugs</b>												
None	143	50.9	300	59.5	224	85.2	79	100	4	66.7	750	66.2
Steroids only	82	29.2	162	32.1	23	8.7	0	0	1	16.7	268	23.7
Steroids & immunosuppressants	54	19.2	22	4.4	14	5.3	0	0	1	16.7	91	8.0
Immunosuppressive only	2	0.7	20	4.0	2	0.8	0	0	0	0.0	24	2.1
No. of patients	281		504		263		79		6		1133	

N, number of patients, %, percentage of patients.

A national survey of hemapheresis practice in Hungary for the years 2001–2004 was reported primarily to review the costs reimbursed (11). Hungary's population was 10 million; 792–983

patients incurred 2544–3121 treatments for 30 different diseases, of which 26 were treated by plasma exchange and four by cytoapheresis. The reimbursed cost per treatment was 680–860 EUR over the years.

TABLE 20. Side-effects or complications following treatment

Side-effect/complication	Europe	Asia	N America	Australia	C/S America	Total
Hypotension	32 (13)	62 (41)	14 (9)	84 (25)	1 (1)	193 (89)
Blood access difficulties	51 (21)	77 (52)	36 (24)	29 (11)	0 (0)	193 (108)
Bleeding, access site	3 (2)	10 (10)	1 (1)	3 (2)	0 (0)	17 (15)
Bleeding, other site	4 (1)	5 (4)	0 (0)	0 (0)	0 (0)	9 (5)
Shock	1 (1)	4 (4)	0 (0)	0 (0)	0 (0)	5 (5)
Fever/chills	8 (7)	52 (33)	3 (3)	1 (1)	0 (0)	64 (44)
Circuit clotting	28 (19)	1 (1)	0 (0)	0 (0)	0 (0)	29 (20)
Allergic reaction	20 (11)	22 (19)	39 (9)	0 (0)	6 (2)	87 (41)
Hemolysis	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
Pain other than at access site	2 (2)	6 (5)	6 (6)	0 (0)	0 (0)	14 (13)
Respiratory distress	5 (5)	5 (5)	1 (1)	2 (1)	0 (0)	13 (12)
Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
ACE-inhibitor related Sx	0 (0)	0 (0)	0 (0)	2 (1)	0 (0)	2 (1)
Arrhythmia/tachycardia/MI	6 (3)	16 (14)	4 (3)	1 (1)	0 (0)	27 (21)
Citrate-induced reaction	25 (6)	0 (0)	106 (90)	130 (31)	0 (0)	261 (127)
Device-related malfunction	8 (6)	43 (23)	0 (0)	0 (0)	0 (0)	51 (29)
Headache	4 (2)	16 (14)	4 (4)	3 (1)	0 (0)	27 (21)
Hypocalcemia	2 (2)	3 (2)	107 (86)	91 (23)	0 (0)	203 (113)
Hypertension	6 (2)	1 (1)	0 (0)	0 (0)	0 (0)	7 (3)
Nausea	1 (1)	25 (24)	19 (11)	17 (7)	0 (0)	62 (43)
Paresthesia	15 (6)	11 (8)	99 (82)	131 (35)	0 (0)	256 (131)
Other	4 (4)	6 (6)	4 (4)	3 (1)	0 (0)	17 (15)
Cramps	0 (0)	0 (0)	3 (3)	3 (1)	0 (0)	6 (4)
Vomiting	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	3 (3)
Anxiety	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnea	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
Epigastric pain	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hypothermia	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
Hysteric reaction	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pulmonary edema	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
FFP bag rupture	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

Number of episodes (number of patients). ACE, angiotensin converting enzyme; FFP, fresh frozen plasma; MI, myocardial infarction; Sx, signs and symptoms.

**TABLE 21.** Response to apheresis and payment provider

Type	Europe		Asia		N America		Australia		C/S America		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
Response to apheresis												
Improvement	195	70.7	285	79.8	57	81.4	48	60.8	4	80.0	589	74.8
Same	13	4.7	47	13.2	3	4.3	19	24.0	0	0.0	82	10.4
Worsening	1	0.4	9	2.5	2	2.9	4	5.1	0	0.0	16	2.0
Treatment discontinued	7	2.5	5	1.4	4	5.7	8	10.1	0	0.0	24	3.1
Not assessable	60	21.7	11	3.1	4	5.7	0	0.0	1	20.0	76	9.7
(Total no. of patients)	(276)		(357)		(70)		(79)		(5)		(787)	
Response to apheresis (above question) based upon:												
Subjective	83	35.5	18	5.3	15	22.4	11	13.9	0	0	127	17.5
Objective	110	47.0	39	11.4	21	31.3	26	32.9	0	0	196	27.0
Both	41	17.5	284	83.3	31	46.3	42	53.2	5	100	403	55.5
(Total no. of patients)	(234)		(341)		(67)		(79)		(5)		(726)	
Payment provider												
Self/family	1	0.4	61	12.1	0	0.0	0	0	0	0	62	6.8
Private insurance	81	29.3	11	2.2	27	55.1	0	0	0	0	119	13.1
Government	142	51.4	410	81.7	18	36.7	79	100	4	100	653	71.8
Hospital/institution	50	18.1	20	4.0	1	2.0	0	0	0	0	71	7.8
Other	2	0.7	0	0.0	3	6.1	0	0	0	0	5	0.5
(Total no. of patients)	(276)		(502)		(49)		(79)		(4)		(910)	

N, number of patients; %, percentage of patients.

The top diseases treated were myasthenia gravis, acute Guillain-Barré, gammopathies, TTP, and HUS, which represented 60% of total costs per year. The top diseases treated by numbers of treatments for the period were myasthenia gravis (2114), acute Guillain-Barré (1855), gammopathies (1302), TTP (1121), and HUS (498). Also reported was that 1043 autologous stem cell collections were carried out. Note was made that Protein A columns were not available and no specific mention was made of the technologies, replacement fluids, and or anticoagulants used. Further, no mention was made of the side-effects experienced.

The Italian Society for Hemapheresis reported for 2000 on 15 202 therapeutic treatments and 149 741 productive (donor) procedures (12). Italy had a population of 58 million in the year 2000. Of 2820

patients from 102 centers reported there are 5.4 procedures per patient. Methodologies included plasma exchange (49.3%), cytapheeresis (17.8%), cascade plasma filtration (5.0%), low-density lipoprotein (LDL)-apheresis (3.7%), and immunoadsorption (0.1%). Reported side-effects were 6.75%, of which 0.89% was noted as severe. By the number of patients, the diseases treated were cryoglobulinemia (132), Guillain-Barré (105), myasthenia gravis (68), TTP (64), glomerulonephritis (28), hypercholesterolemia (26), and others (486). By the number of procedures, the diseases treated were cryoglobulinemia (934), myasthenia gravis (635), TTP (607), Guillain-Barré (563), hypercholesterolemia (552), glomerulonephritis (137), and others (3176). The authors felt that the data collected are underreported with data predominately lacking from dialysis and intensive

**TABLE 22.** Therapeutic apheresis procedures by country

	Patients	Treatments	Population (million)	Cases/million inhabitants	No. of treatments/million inhabitants
Canada	898	8561	30	30.0	285
France	1021	10 700	60	17.0	178
Germany	–	6941	82	–	85
Hungary	983	3120	10	98.3	312
Italy	1477	15 205	58	25.5	262
Japan	–	11 697	127	–	92
Philippines	194	735	83	2.3	9
USA	–	48 221	252	–	191
Sweden	439	3562	10	43.9	356
Turkey	172	869	67	2.6	13
Venezuela	–	547	26	–	21

TABLE 23. National view of therapeutic apheresis

Reporting year	Population (million)	Cases	Procedures	Diseases by frequency	Diseases by #
Canada 2002	30	898	8561	Hematological, Neurological, Vascular/Renal	TTP, HUS, Myasthenia Gravis, Macroglobulinemias
France 2003/04	60	942/1021	9837/110 700	Hematological, Neurological	TTP, HUS, Familial Hypercholesterolemia
Germany 2002	82	-	6941	Guillain-Barré, Cryoglobulinemia, MG, SLE, TTP	Myasthenia Gravis Guillain-Barré
Hungary 2001-2004	10	792-983	2544-3120	Gammopathies, TTP, HUS	Fam. Hyperchol., SLE, Cryo, Guillain-Barré, MG
Italy 2000/1994-2004	58	2820/1477	15 202/15 285	Guillain-Barré, Cryo, MG, SLE, TTP	Fam. Hyperchol., SLE, Cryo, Guillain-Barré, MG
Japan 1995	127	-	11 697	Fam. Hyperchol., Guillain-Barré, Hepatic failure	Fam. Hyperchol., Ulcerative Colitis, Malign. RA, Fulm. Hepatitis
Philippines 1994-2004	73-83	194	735	Neurological, Hematological, Renal/Metabolic/Immunologic	Polyradiculoneuropathy, MG, TTP
USA 1991	252	-	48 221	Guillain-Barré, Leukemia, T-cell Lymphoma	-
Venezuela 2003	26	-	547	-	-

Cryo, cryoglobulinemia; Fam. Hyperchol., familial hypercholesterolemia; Fulm., fulminant; HUS, hemolytic-uremic syndrome; Malign. RA, malignant rheumatoid arthritis; MG, myasthenia gravis; RPGN, rapidly progressive glomerulonephritis; SLE, systemic lupus erythematosus; TTP, thrombotic thrombocytopenic purpura.

TABLE 24. National view of therapeutic apheresis continued

	Methods	Vascular access	Anticoagulation	Substitution fluids	Side effects
Canada	Centrifugation/Plasma Exchange	-	Citrate	Albumin/Cryosupernatant plasma/FFP	12% 0.4% Severe
France	Centrifugation/Plasma Treatment	Peripheral vein	Citrate/Heparin/LMW Heparin	Albumin substitutes/Albumin/Plasma	1.9% 0.4% Hypotension
Germany	-	-	-	-	-
Hungary	Plasma Ex./Cytapheresis	-	-	-	-
Italy	Plasma Ex./Cytapheresis/Cascade Filtration	AV fistula/Central vein	Heparin/Citrate	-	2.9-6.75% 0.89% Severe
Japan	Membrane Filtration/Adsorption/Centrifugation	-	Nafamostat mesilate/Hep./LMW Heparin/Citrate	FFP	Crystalloids/Albumin/21%
Philippines	Plasma Exchange	-	-	-	-
USA	Centrifugation/PE/Platelepher./Photopheresis	-	-	-	-
Venezuela	Centrifugation/Plasma Exchange	-	-	-	-

AV, arterio-venous; Ex., exchange; FFP, fresh frozen plasma; Hep., heparin; LMW, low molecular weight; PE, plasma exchange; Platelepher. plateletpheresis.

care units. The preference was for plasma exchange, and outcome data were not collected. For the years 1994–2004, the Italian Society for Nephrology reported (13) 15 205 treatments (believed to be 10% of total) on 1477 patients from 44 centers, or 10.5 procedures per patient. Plasma exchange was performed for 56.2% of procedures, of which 50.4% were performed by filtration. Plasma treatment was employed in 40.1% of procedures (14.6% by Protein A immunoadsorption, 12.7% by cascade filtration, and 9.7% by LDL cholesterol dextran sulfate). Cyta-pheresis were performed in only 0.85% of cases by photopheresis, while whole blood treatment was carried out in 2.7%. By the number of patients, the top diseases treated were Guillain–Barré, cryoglobulinemia, myasthenia gravis, systemic lupus, and TTP. By the number of procedures, the top treated diseases were familial hypercholesterolemia, systemic lupus, cryoglobulinemia, Guillain–Barré, and myasthenia gravis. Therapeutic apheresis procedures in Italy are performed primarily in nephrology units. Vascular access in 13.4% was by an arterio-venous fistula and 10.5% by a central venous catheter. Anticoagulation was predominately with heparin (82%), combined heparin and citrate (9.7%), and citrate (4.9%). Reported side-effects were 2.9%, with five deaths reported (4 with PE).

Japan, with a population of 125 million, reported for 1995 on 164 centers (11.6%) for 1961 patients with 15 670 procedures (estimated 26% of all procedures) on 100 disease types (6). The top three disease categories treated were: endocrine, metabolic, nutrition and immunologic; gastrointestinal; and neurological and sensory. In 1995 the top treated diseases by number of patients were familial hypercholesterolemia (173), Guillain–Barré (153), fulminant hepatitis (145), postoperative hepatic failure (144), and endotoxic shock (125). The top treated diseases by number of procedures were familial hypercholesterolemia (2929), ulcerative colitis (1864), malignant rheumatoid arthritis (1050), fulminant hepatitis (947), and rheumatoid arthritis (857). Reporting by percent of centers for 1995, the methods used were adsorption (30–50%), membrane filtration (50–55%), and centrifugation (<5.5%). As anticoagulants, heparin was used in 86% of centers reporting and nafamostat mesilate in 69%. Substitution fluids used by center were crystalloids (40.1%), albumin (31.9%), FFP (20.7%), and FFP plus albumin (6.9%). Reported responses to apheresis for the centers were very effective from 14.4% of centers, and effective from 55.4% of centers. Twenty-one percent of cases had side-effects, or 2.6% of total procedures, with the most frequent being hypotension, shock and hypoc-

alcemia. In 2002 Japan, having a population of 127 million, reported 11 697 procedures, down from 1995 (7). The methods used by centers reporting were centrifugation (6.5%), membrane filtration (63.7%), double filtration (63.1%), direct polymyxin B hemoperfusion (76.6%), cryofiltration (8.1%), direct charcoal hemoperfusion (38.7%), LDL plasma adsorption (51.6%) immunoadsorption (46.8%), bilirubin adsorption (45.2%), leukocytapheresis (40.3%), and granulocytapheresis (43.5%). Anticoagulation used by centers reporting were nafamostat mesilate (91.1%), heparin (83.1%), low molecular weight heparin (37.1%), and citrate (5.6%). Substitution fluids used were fresh frozen plasma (73.4%), albumin (69.0%), FFP and albumin (19.4%), and others (9.7%). Effectiveness reported was for familial hypercholesterolemia 91% and postoperative hepatic failure 26%. Side-effects reported were hypotension at 0.43% of procedures, and urticaria and allergic reactions 0.19%. By procedures most performed in 2002 they reported ulcerative colitis (2263), malignant rheumatoid arthritis (1821), familial hypercholesterolemia (1796), lupus nephritis (813), and other systemic lupus erythematosus (SLE) (766).

Apheresis statistics from the Philippines (73–83 million inhabitants) were reported for the period of 1994–2004 (14). For 8 of 10 centers reporting through the Philippine Society of Hematology and Blood Transfusion, 194 patients were treated with 735 procedures, predominately by plasma exchange (91%). The top disease states treated were neurological (54%), hematological (32%), renal/metabolic (7%), and autoimmune (5%). The most common indications were acute or chronic inflammatory demyelinating polyradiculoneuropathy, myasthenia gravis, TTP, leukocytosis/thrombocytosis, and chronic inflammatory demyelinating polyneuropathy. Limitations reported were economics, reimbursement, available technologies (they do not have adsorption columns, filters or photopheresis machines), and education of apheresis.

In the United States survey by the American Society for Apheresis in 1991 (US population then 252 million), 266 centers (94% from the US) reported on 48 221 therapeutic procedures and 330 702 donor procedures (2). In the US, centrifugal equipment was used predominantly in plasma exchange procedures. Plateletpheresis was the most prevalent donor procedure. The most prevalent diseases treated were Guillain–Barré by plasmapheresis, leukemias by cyta-pheresis, and cutaneous T-cell lymphoma by photopheresis. In 2005 in a report on the status of therapeutic apheresis in the US (15), note was made

that controlled clinical trials drive indications for therapeutic apheresis and technology, and regulatory (FDA) approvals impact the field. It was noted that the US is not technologically advanced, service providers are blood centers and nephrology-based, and there exists a need for trained personnel and education of physicians on clinical indicators.

Venezuela, with a population of 26 million, reported in 2003 that it had 80 apheresis machines, and performed 27 675 donor and 547 therapeutic apheresis procedures (16). Of the therapeutic procedures, 80% were by plasma exchange by centrifugal means for TTP and hemophilia inhibitors, and stem cell harvest (15%). Note was made that the procedure costs are US \$975 and the average annual salary is US \$1910. Adverse events were 3.9%, with hypotension and allergic reaction to plasma the most common.

The World Apheresis Association Registry objectives are to assess apheresis activity with regard to indications, trends over time, and techniques used nationally and internationally to reduce the risks/adverse events and to improve treatment quality. The 2004 report (17) included 28 centers in 11 countries performing 1808 procedures. Fifty-five percent of the patients were women and 45% men, with an average age of 53 years. Acute indications accounted for 80% of the procedures and 12% for chronic indications. Blood access was peripheral for 65% and central for 24%. Citrate anticoagulant was used in greater than 80% of the cases and albumin substitution in greater than 80%. Conclusions made were that centers have various approaches to apheresis, treatment indications and applications depend on the type of apheresis center (blood center, dialysis ward, or apheresis center).

A Rheopheresis RheoNet Registry has been developed to report rheopheresis procedures. Rheopheresis is a membrane plasma filtration procedure to treat microcirculatory disorders such as dry/nonexudative age-related muscular degeneration (AMD) (R Klingel, personal communication). Since August 1999, 439 patients were enrolled (Occulogix, personal communication). a total of 185 patients were enrolled in randomized, double-blind, placebo controlled, 12-center trial. Adverse events were 5.41% (0.51% discontinued and 6.54% with vascular access problems). A 60% improvement in visual activity was reported.

From a review of the national registries particular note can be made that the diagnoses for which apheresis is applied varies country by country most likely as a function of medical evidence, the individual clinician's expertise, and the country's reimbursement policies. The availability of technologies

impacts the procedural methodologies used, including the types of equipment, anticoagulation, and even the diseases treated.

The format of the questionnaire used for this survey was similar to that used for the 1983 (1), 2000 (3), and 2002 (4) surveys. As in the previous survey this survey was conducted through a secure dedicated website.

Of the 805 people solicited, data was received from 30 people representing a 3.7% response rate reporting from 22 centers on 5 continents. We believe that a serious impediment to the collection of data is the voluntary reporting. Certainly providing some incentive other than depending on the ultra-kindness and academic interests of the respondents would be helpful. We are deeply indebted to all the Centers and Collaborative Persons that supported this Registry (See Appendix II for a listing of the participating hospitals and clinics and collaborative persons). The time needed to enter patient data continues to be a major issue for busy physicians and their assistants. Considering the voluntary nature of this survey, we consider the response rate acceptable.

In the review of this survey and its results, one should be considerate of the above noted issues. The geographic distribution of the individual survey responders can have a very important influence on the results reported. Based on the estimated populations in the various regions, the centers reporting from the various countries are not necessarily proportional to the patient numbers reported.

This survey was based on 1133 patients, the most ever reported in this survey format. The number of treatments was 6501, which is 57% of that reported in 2002 (4). As in 2002, the highest treatment populations were Caucasians, followed by Asians; and, as in the previous registry, the mean age of treatment was 45 years. The top treatment diagnosis category was nervous system disorders, as in previous surveys. The top treatment diseases were myasthenia gravis, multiple myeloma, Guillain-Barré, and TTP. As in previous registries, regional differences were noted. Patient selection most likely is a major influence in the regional differences noted in treatment type, number of treatments per patient, equipment choice, and drug usage. Patient selection relates to multiple factors, including the physician's experience and knowledge of apheresis, technical personnel resources and equipment available, medical evidence of efficacy of the treatment, and reimbursement. The treatment diagnosis and treatment response influence the frequency of treatments. Plasmapheresis accounted for 82.7% of all reported treatments on 67.3% of all patients treated. The largest total

number of treatments were by plasma exchange (48.4%), followed by plasma treatment (34.3%). The average number of treatments per patient was 6.0. In this survey, of the top treated diseases by number of treatments, myasthenia gravis was treated 7.0 times on average per patient, hypercholesterolemia 26.5 times, TTP 11.9 times, and Guillain-Barré 5.0 times per patient.

Only a small percentage of patients were treated by cytapheresis or lymphoplasmapheresis (about 4% and comparable to the previous survey). Replacement solutions varied and most likely relate to the disease state treated and technology applied. Albumin solution was the most frequently used replacement solution. Plasma treatment by membrane filtration and sorption continue to be important forms of therapy, but only in the Asian and European regions where these technologies are widely available. Stem cell infusion data was first collected in this survey on about 26% of the patients reported. Also noteworthy was that whole blood sorption procedures accounted for 10.3% of all procedures.

Blood access continues to be a clinical procedural issue and in this survey citrate-related complications were higher than previously reported. The choice of anticoagulant type is likely to be related to the equipment type used (centrifugal or membrane plasma separation), the site where the apheresis is carried out (blood or dialysis center), and the choice of the physician in charge, which accounts for its regional differences. Drug use relates to treatment diagnosis. Compared to the previous survey, the percentage of patients noted as showing improvement was nearly comparable at 74.8% (78.8% in 2002, 73.1% in 2000, and 64.2% in 1983). Payment provider remained comparable to 2002.

This international survey, in comparison to the national survey results reported, continues to show regional differences. An understanding of these differences, whether related to economics, technology, disease demographics, or other reasons, may contribute to a better understanding of apheresis practices and can lead to the development of better clinical practices worldwide.

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Society for Apheresis. The Center and the authors are particularly thankful and indebted to those medical directors and institutions who so willingly participated in this survey (see Appendix II). We also especially thank the staff of the International Center for Artificial Organs and Transplantation, Traci Coss and Carol Malchesky, and James Liu of the Department of Quantitative Health Sciences at the Cleveland Clinic for supporting this activity. We are appreciative of the financial support of Kaneka and Therakos that permitted updating the on-line data collection program.

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**APPENDIX I: ONLINE DATA ENTRY FORMS FOR THE 2005 INTERNATIONAL APHERESIS REGISTRY**



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# International Apheresis Registry


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▶ Contact

▶ My Account

▶ Sign Out

 There are a total of 6 pages for each patient record that you enter. Please finish all 6 pages. If you can not complete all 6 pages, please save the record on Page 6 by clicking on "Finish This Patient record". It can be retrieved for editing using the Edit Record link in the main page.

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\* - Indicates required fields

**1. Identification Code \*** 20051436

**2a. Patient Record Number \***

**2b. Hospital Name \*** ICAOT

**3. Reporting Year \*** 2005

**4. Sex**

**5. Age**

**6. Race**

**7. Primary Diagnosis**

Please select a disease

If 'other' or 14, 15, 16 specify

**8. Date of Primary Diagnosis**  

**9. Reason for Treatment**

Please select a disease

If 'other' or 14, 15, 16 specify

**10. Date of Treatment Diagnosis**  

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**11. Date of First Apheresis Treatment**

**12. Type of Treatment**

a. Plasma Exchange

Number of treatments

Average volume (liters)

b. Plasma Treatment

Number of treatments

Average volume (liters)

c. Whole blood adsorption

Number of treatments

Average volume (liters)

If 'other' type, please specify:

d. Cytapheresis (therapeutic leukocytapheresis)

Number of treatments

Average number of cells ( $\times 10^{11}$ )

e. Lymphoplasmapheresis

Number of treatments

Average number of cells ( $\times 10^{10}$ )

Average volume (liters)

f. Progenitor (Stem) Cell Infusion

i. Autologous or Allogeneic

Average No. of Cells ( $\times 10^6$ /Kg)

ii. Preparative Regimen of Patient

If 'other' type, please specify:

**13. Type of Equipment**

Type	# of Treatments
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

If 'other' type, please specify:

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**14. Replacement Solution (if used)**

Type	# of Treatments
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

If 'other' type, please specify:

**15. If Plasma Membrane Separation, Type of Separator**

Type	# of Treatments
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

If 'other' type, please specify:

**16. Method of Plasma Treatment (if used)**

Type	# of Treatments
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

If 'other' type, please specify:

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**16a. If Plasma Membrane Treatment, Product**

Type	# of Treatments
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

If 'other' type, please specify:

**16b. If Sorptive Plasma Treatment, Method**

Type	# of Treatments
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

If 'other' type, please specify:

**17. Blood Access Method**

Type	# of Treatments
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

If 'other' type, please specify:

**18. Anticoagulants**

a. Heparin	<input type="text"/>
b. Citrate	<input type="text"/>
c. Nafamostat Mesilate	<input type="text"/>
d. if other, please specify	<input type="text"/>

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**19. Drugs**

a. Steroids

b. Immunosuppressive

**20. Side Effects or Complications during and up to two hours after cessation of treatment**

Type of Effects or Complications	# of Treatments
a. Hypotension	<input type="text"/>
b. Blood access difficulties	<input type="text"/>
c. Bleeding - access site	<input type="text"/>
d. Bleeding - other site	<input type="text"/>
e. Shock	<input type="text"/>
f. Fever/Chills	<input type="text"/>
g. Circuit clotting	<input type="text"/>
h. Allergic reaction	<input type="text"/>
i. Hemolysis	<input type="text"/>
j. Pain other than at access site	<input type="text"/>
k. Respiratory distress	<input type="text"/>
l. Death	<input type="text"/>
m. ACE-inhibitor related symptoms	<input type="text"/>
n. Arrythmia, Tachycardia, Myocardial Infarction	<input type="text"/>
o. Citrate-induced reaction	<input type="text"/>
p. Device-related malfunction	<input type="text"/>
q. Headache	<input type="text"/>
r. Hypocalcemia	<input type="text"/>
s. Hypotension	<input type="text"/>
t. Hypertension	<input type="text"/>
u. Nausea	<input type="text"/>
v. Paresthesia (tingling or numbness)	<input type="text"/>
w. Other, specify	<input type="text"/>

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21a. Response to Apheresis

21b. Above response based upon

22. Payment Provider

If 'Other', specify

23. Person completing form

24. General Comments (maximum 500 characters please)

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## APPENDIX II: COLLABORATING PERSONS AND INSTITUTIONS

Participant	Department, institution	City, country
Mutlu Arat, Meltum Bay, Erol Ayyildiz, Önder Arslan, Osman Ilhan	Ankara University School of Medicine	Ankara, Turkey
Christiane M Saltiel	Banco Metropolitano de Sangre	Caracas, Venezuela
Umut S Bayrakci, Ilknur Kozanoglu	Baskent University Medical Faculty	Ankara, Turkey
Vicki L Graves, Leo J McCarthy	Clarian Health Partners	Indianapolis, IN, USA
Anna P Koo	Cleveland Clinic	Cleveland, OH, USA
Biröl Guvenc, Ferda Tekinturhan	Cukurova University Balcali Hospital	Adana, Turkey
Joselito B Brandao	Hospital Alemao Oswaldo Cruz	Saõ Paulo, Brazil
Norella C Kong	Hospital UKM	Kuala Lumpur, Malaysia
Omar A Trabadelo	Hospital de Hospital de Niños Ricardo Gutierrez	Buenos Aires, Argentina
Jun-Feng Liu	Huashan Hospital	Shanghai, China
Rakesh Srivastava	ISA Institute for Apheresis and Research Center	Delhi, India
Frithjof Blessing, Thomas Bosch	Klinikum Grosshadern	Grosshadern, Germany
Noriaki Shimada	Koto Hospital	Tokyo, Japan
Phillip Wearden	Liverpool Hospital	Liverpool, NSW, Australia
Juergen Rech	Medizinische Klinik III, University of Erlangen-Nuremberg	Erlangen, Germany
Ji-Weon Seo, Eun Young Song, Kyou-Sup Han	Seoul National University Hospital	Seoul, Korea
Jiann-Hong Yeh	Shin Kong Wu Ho-Su Memorial Hospital	Taipei, Taiwan
Carole Y Davis	St Michael's Hospital	Toronto, Ontario
Kes Petar	University Hospital Center Zagreb	Zagreb, Croatia
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