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Apheresis Technologies and Clinical Applications: The 2002 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 2002, reporting on 33 centers on four continents, are presented. The survey collected data, predominantly via an internet website, on 811 patients for a total of 11 428 treatments. 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 and 2000, the survey results highlight the regional differences in apheresis usage and treatment specifics, 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 (1–3). 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 (4). The data collected indicated regional differences with regards to the apheresis technologies that were applied and the disease states for which they were used.

This survey, just 2 years after the last survey was conducted, was carried out to assess the present state of the technology usage and to report such results at the 4th World Congress of the International Society for Apheresis held 30 October – 1 November 2003 in Nashville, TN, USA.

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METHODS

A copy of the electronic questionnaire form and the instructions are given in Appendix I. This electronic form is the same as the paper form used in the 1983 and 2000 Registries; this was to allow comparison with the results of these prior years. The form requests patient information including demographics, medical history, specifics of the treatment, response to apheresis, and payment provider for the year 2002. For many of the questions on the form, drop down menus were used to facilitate answering the question.

In soliciting responses, over 325 Emails and over 260 letters were sent to medical directors of apheresis centers. Through this notification, the individuals were referred to a website (https://clinapps.bio.ri.ccf.org/apheresis/) through which they

TABLE 1. *Geographical distribution of survey responders*

Region/country	Centers	Patients	Treatments
Asia	**14**	**355**	**2 217**
Taiwan	1	101	508
Turkey	1	79	340
Malaysia	2	49	206
Japan	8	71	832
India	1	28	205
Korea	1	27	126
Europe	**11**	**287**	**7 353**
Italy	5	118	4494
Croatia	1	68	406
Austria	1	51	1426
Germany	2	33	891
Greece	1	17	136
North America	**6**	**151**	**1 680**
USA	6	151	1680
Central/South America	**3**	**18**	**178**
Brazil	3	18	178
Total	**33**	**811**	**11 428**

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 2002 was 31 July 2003. From the opening of the website for collection data from January 2003 through its close, reminders were sent out monthly to the potential participating directors of centers.

In total, data responses were received from 33 centers (>5%) on 811 patients receiving 11 428 treatments. The data will be described according to regions as Asia, Europe, North America, 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. All data were analyzed using SAS software (SAS Institute, Inc. Cary, NC, USA). If the questionnaires had been filled out completely and accurately by respondents, all the numbers presented in this report would be consistent. However, due to the way the respondents completed the questionnaire, there may appear to be inconsistencies in numbers. This is simply an inherent flaw in this kind of data and not in the analysis.

RESULTS

Table 2 outlines that data on race and gender for which both race and gender were noted on the questionnaire. Female subjects, as in the previous registry (3), outnumbered males (57.3% *vs* 42.7%). Caucasian was the predominant treated race of the patients treated, with Asian being the second largest.

Table 3 shows descriptive statistics of age and months from primary diagnosis to first apheresis treatment: summarized as the number of patients, mean, standard deviation and median. The mean age of patients at the time of their first apheresis treatment was 45 years and comparable to that in the previous registry (3). The Asian region had the lowest mean age of 43 years for the patient's first treatment while the North American region the oldest at 50 years. The mean number of months from primary diagnosis to the first apheresis treatment is 34.6 months varying from a high of 45.5 months for the European region to a low of 19.8 months for the North American region. This mean number of

TABLE 2. *Patients by race and gender by region for 742 patients*

Gender/Race	Asia	Europe	North America	Central/South America	Total	(% of 742 patients)
Male	**156**	**119**	**32**	**10**	**317**	**(42.7)**
Caucasian	55 (35.3)	119 (100)	31 (96.9)	10 (100)	215	(29.0)
Asian	93 (59.6)	0 (0.0)	1 (3.1)	0 (0.0)	94	(12.7)
Malaysian	8 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	8	(1.1)
Black	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0	(0.0)
Australia/Oceania	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0	(0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0	(0.0)
Female	**195**	**165**	**57**	**8**	**425**	**(57.3)**
Caucasian	59 (30.3)	161 (97.6)	45 (78.9)	8 (100)	273	(36.8)
Asian	95 (48.7)	2 (1.2)	1 (1.8)	0 (0.0)	98	(13.2)
Malaysian	40 (20.5)	0 (0.0)	0 (0.0)	0 (0.0)	40	(5.4)
Black	0 (0.0)	1 (0.6)	10 (17.5)	0 (0.0)	11	(1.5)
Australia/Oceania	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	1	(0.1)
Other	1 (0.5)	0 (0.0)	1 (1.8)	0 (0.0)	2	(0.3)

Percentage according to region and gender in parentheses.

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

Variable/region	N	Mean	SD	Median
Age (years)				
Asia	352	43	18	44
Europe	284	44	18	45
North America	151	50	19	51
Central/South America	18	46	20	41
Total	805	45	18	46
Months from primary diagnosis to first apheresis treatment				
Asia	263	32.9	47.4	12.1
Europe	210	45.5	71.1	12.0
North America	114	19.8	45.1	0.3
Central/South America	18	27.2	47.3	2.8
Total	605	34.6	57.0	7.5

months from primary diagnosis to the first apheresis treatment is 3 months longer than that for the 2000 Registry (3). There were wide variances with the median being 7.5 months with the Asian and European regions high at 12.1 and 12.0 months, respectively, to a low of 0.3 months for the North American region.

Table 4 shows the reason for treatment (i.e. treatment diagnosis) for 800 patients. The percentages represent the percentage of patients within each region. The most common treatment diagnosis categories overall were the nervous system (31.2%), endocrine/nutrition/metabolic/immunity (15.6%) and musculoskeletal system (12.0%). These treatment diagnostic categories were also the top three reported previously (3). Regional differences were quite noteworthy. For the Asian region, the top three treatment diagnoses were the nervous system, musculoskeletal system, and the digestive system. For Europe the top three treatment diagnoses were endocrine/nutrition/metabolic/immunity, the nervous system, and the musculoskeletal system. For North America, the top three treatment diagnoses were the nervous system, the circulatory system, and endocrine/nutritional/metabolic/immunity. For the Central/South America region the top three treatment diagnoses were diseases of blood and blood-forming organs and equally the nervous system and endocrine/nutrition/metabolic/immunity.

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

Region	N total	# match	% match
Asia	351	321	91.4
Europe	280	223	79.6
North America	149	115	77.2
Central/South America	18	15	83.3
Total	**798**	**674**	**84.5**

Table 5 shows the number and percentage of patients whose primary diagnosis matches their treatment diagnosis category. As noted in Table 5, 84.5% of all treatments carried out were for diagnosis categories identified as the primary diagnostic category. The Asian region had the highest matching treatment with the primary diagnostic category of 91.4%. This region also had the longest median time from primary diagnosis to the first apheresis treatment of 12.1 months. The North American region had the lowest matching treatment with the primary diagnostic category of 77.2% and the shortest median time from primary diagnosis to the first apheresis treatment of 0.3 months.

Table 6 outlines the top 10 treatment diagnoses and number of patients treated by region and in total. As noted previously (3), particularly noteworthy are the differences by region and the dominance of the Asian region in the top ranked treatment diagnosis of myasthenia gravis. Thrombotic thrombocytopenic

TABLE 4. *Treatment diagnosis for 800 patients*

Category	Asia	Europe	North America	Central/South America	Total
Nervous system	132 (37.5)	62 (22.1)	53 (35.6)	3 (16.7)	250 (31.2)
Endocrine/nutrition/metabolic/immunity	29 (8.2)	72 (25.6)	21 (14.1)	3 (16.7)	125 (15.6)
Musculoskeletal system	55 (15.6)	41 (14.6)	0 (0.0)	0 (0.0)	96 (12.0)
Circulatory system	17 (4.8)	13 (4.6)	31 (20.8)	1 (5.6)	62 (7.8)
Diseases of blood and blood-forming organs	17 (4.8)	16 (5.7)	18 (12.1)	7 (38.9)	58 (7.2)
Digestive system	49 (13.9)	5 (1.8)	0 (0.0)	2 (11.1)	56 (7.0)
Genitourinary system	13 (3.7)	16 (5.7)	13 (8.7)	1 (5.6)	43 (5.4)
Neoplasms	15 (4.3)	8 (2.8)	10 (6.7)	0 (0.0)	33 (4.1)
Injury/poisoning	3 (0.8)	14 (5.0)	0 (0.0)	0 (0.0)	17 (2.1)
Skin and subcutaneous tissue disease	2 (0.6)	15 (5.3)	0 (0.0)	0 (0.0)	17 (2.1)
Infectious/parasitic disease	15 (4.3)	1 (0.4)	0 (0.0)	0 (0.0)	16 (2.0)
Symptoms/signs	0 (0.0)	11 (3.9)	2 (1.3)	0 (0.0)	13 (1.6)
Respiratory system	3 (0.8)	4 (1.4)	0 (0.0)	1 (5.6)	8 (1.0)
Pregnancy and childbirth	2 (0.6)	3 (1.1)	1 (0.7)	0 (0.0)	6 (0.8)
Total	**352 (100.0)**	**281 (100.0)**	**149 (100.0)**	**18 (100.0)**	**800 (100.0)**

Precentage in parenthesis.

TABLE 6. *Top ten treatment diagnoses according to number of patients for 800 patients*

Rank	Asia	Europe	N America	Central/South America	Total
1	Myasthenia gravis (78)	Myasthenia gravis (44)	TTP (28)	Hemolytic-uremic syndrome (4)	Myasthenia gravis (148)
2	Systemic lupus erythematosus (34)	Hypercholesterolemia (40)	Myasthenia gravis (24)	Crohn's disease (2) Cryoglobulinemia (2)	TTP (52)
3	Ulcerative colitis (34)	Hyperlipidemia (13) Other skin and subcutaneous tissue disease (13)	Guillan-Barré syndrome (12)	Myasthenia gravis (2) Other diseases of the blood (2)	Systemic lupus erythematosus (46)
4	Chronic relapsing polyneuropathy (22)		Waldenstrom's syndrome (11)		Hypercholesterolemia (45)
5	Guillan-Barré syndrome (22)	Rheumatoid arthritis (12) Systemic lupus erythematosus (12)	Myeloma kidney (9)		Guillan-Barré syndrome (42)
6	Rheumatoid arthritis (16) TTP (16)		Multiple sclerosis (7) Chronic relapsing polyneuropathy (7)	Chronic relapsing polyneuropathy (1) Hyperviscosity syndrome (1) Immune complex disease (1) Myeloma kidney (1) Other respiratory system disease (1) TTP (1)	Chronic relapsing polyneuropathy (37)
7		Symptoms/signs (11)			Ulcerative colitis (35)
8	Other infectious/ parasitic disease (15)	Guillan-Barré syndrome (8)	Cryoglobulinemia (6) Hemolytic-uremic syndrome (6)		Rheumatoid arthritis (28)
9	Multiple myeloma (12)	Chronic relapsing polyneuropathy (7) Scleroderma (7) TTP (7)			Multiple myeloma (20)
10	Liver disease (10)		Leukemia (5)		Hemolytic-uremic syndrome (16)

TTP, Thrombotic thrombocytopenic purpura.

purpura was the second top ranked treatment diagnosis overall due to the high prevalence of this treatment diagnosis in the North American region. The overall treatment diagnosis of hypercholesterolemia (fourth highest overall) was primarily related to the number of patients treated for this diagnosis in the European region (89% of total) and the overall treatment diagnosis of systemic lupus erythematosus was primarily related to the number of patients treated for this diagnosis in the Asian region (74% of total)

Table 7 outlines the top treatment diagnoses by the number of treatments. By far, the largest number of treatments was for hypercholesterolemia primarily related to reporting from the European region. When combined with the treatment diagnosis of hyperlipidemia (primarily from the European region) the number of treatments for these combined categories were over four times that of the treatment diagnosis myasthenia gravis receiving the second largest number of treatments. The data from the Asian, European and North American regions made myasthenia gravis the treatment diagnosis receiving the second highest number of treatments. 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 95.8% of the reported treatment on 93.8% of all patients. The European region reported the highest number of treatments per patient of 25.8 where about 70% of all the procedures were by plasma treatment and also the highest number of total treatments or 64.3% of the total number of treatments reported. The Asian region reported the highest

TABLE 7. *Top 10 treatment diagnoses according to number of treatments for 11 172 treatments*

Rank	Asia	Europe	North America	Central/South America	Total
1	Myasthenia gravis (364)	Hypercholesterolemia (3722)	TTP (434)	Hemolytic-uremic syndrome (67)	Hypercholesterolemia (3853)
2	Ulcerative colitis (276)	Hyperlipidemia (612)	Other endocrine/ nutrition/metabolic/ immunity (423)	Other diseases of the blood (26)	Myasthenia gravis (1021)
3	TTP (172)	Myasthenia gravis (500)	Myasthenia gravis (144)	Crohn's disease (24)	TTP (702)
4	Chronic relapsing polyneuropathy (153)	Other skin and subcutaneous tissue disease (244)	Cryoglobulinemia (85)	TTP (18)	Hyperlipidemia (625)
5	Hypercholesterolemia (131)	Systemic lupus erythematosus (194)	Myeloma kidney (70)	Myasthenia gravis (13)	Other endocrine/ nutrition/metabolic/ immunity (532)
6	Systemic lupus erythematosus (123)	Grave's disease (146)	Waldenstrom's syndrome (68)	Cryoglobulinemia (11)	Chronic relapsing polyneuropathy (335)
7	Rheumatoid arthritis (110)	Scleroderma (130)	ITP (66)	Chronic relapsing polyneuropathy (6)	Systemic lupus erythematosus (317)
8	Guillan-Barré syndrome (102)	Chronic relapsing polyneuropathy (122)	Guillan-Barré syndrome (65)	Myeloma kidney (5)	Ulcerative colitis (282)
9	Other respiratory system disease (69)	Kidney transplant complications (108)	Chronic relapsing polyneuropathy (54)	Immune complex disease (3)	Guillan-Barré syndrome (253)
				Other respiratory system disease (3)	
10	Other infectious/ parasitic disease (40) Other endocrine/ nutrition/metabolic/ immunity (40)	Rheumatoid arthritis (102)	Multiple myeloma (51)		Other skin and subcutaneous tissue disease (244)

TTP, Thrombotic thrombocytopenic purpura; ITP, ideopathic thrombocytopenic purpura.

number of patients treated, 43.7% of the total number of patients reported. No plasma treated procedures and patients treated by such were reported in the North American 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. There were two patients in Europe and two in Asia for whom no treatment is recorded, which is why the number of patients in both of these tables is 807 instead of 811. Plasmapheresis procedures were used on 93.8% of the patients. In comparison to an earlier survey (1) the percent of patients receiving plasma treatment versus plasma exchange has increased significantly indicating, not only the availability of plasma treatment technologies, but also their acceptability. Only the Asian and European regions reported plasma treatment only and patients treated by plasma treatment, suggesting the higher availability of plasma treatment technologies in these regions. These data indicate that the availability of plasma treatment technologies in the

TABLE 8. *Number of treatments*

Treatment	Asia	Europe	North America	Central/South America	Total
Plasma exchange only	950 (185)	2017 (175)	1660 (142)	130 (15)	4 757 (517)
Plasma treatment only	835 (132)	5100 (104)	0 (0)	0 (0)	5 935 (236)
Cytapheresis only	428 (35)	7 (3)	20 (9)	0 (0)	455 (47)
Lymphoplasmapheresis only	0 (0)	0 (0)	0 (0)	24 (2)	24 (2)
Plasma exchange & plasma treatment	4 (1)	223 (2)	0 (0)	24 (1)	251 (4)
Plasma exchange & cytapheresis	0 (0)	6 (1)	0 (0)	0 (0)	6 (1)
All treatments	2217 (353)	7353 (285)	1680 (151)	178 (18)	11 428 (807)
Average number of treatments/patient	6.3	25.8	11.1	9.9	14.2

Number of patients who received treatment in parentheses.

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

Treatment	Asia	Europe	North America	Central/South America	Total
Plasma exchange only	185 (52.4%)	175 (61.4%)	142 (94.0%)	15 (83.3%)	517 (64.1%)
Plasma treatment only	132 (37.4%)	104 (36.5%)	0 (0.0%)	0 (0.0%)	236 (29.2%)
Cytapheresis only	35 (9.9%)	3 (1.0%)	9 (6.0%)	0 (0.0%)	47 (5.8%)
Lymphoplasmapheresis only	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (11.1%)	2 (0.2%)
Plasma exchange and plasma treatment	1 (0.3%)	2 (0.7%)	0 (0.0%)	1 (5.6%)	4 (0.5%)
Plasma exchange and cytapheresis	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Number of patients	353	285	151	18	807

TABLE 10. *Number of treatments given (percentage of total given treatments)*

Treatment/no. treatments	Asia	Europe	North America	Central/South America	Total
Plasma exchange					
1–5	144 (77.4)	69 (38.8)	68 (47.9)	6 (37.5)	287 (55.0)
6–10	28 (15.0)	50 (28.1)	38 (26.8)	5 (31.2)	121 (23.2)
>10	14 (7.5)	59 (33.2)	36 (25.4)	5 (31.2)	114 (21.8)
No. patients treated	186	178	142	16	522
Plasma treatment					
1–5	84 (63.2)	8 (7.6)	0	0 (0.0)	92 (38.3)
6–10	42 (31.6)	7 (6.6)	0	1 (100.0)	50 (20.8)
>10	7 (5.3)	91 (85.8)	0	0 (0.0)	98 (40.8)
No. patients treated	133	106	0	2	240
Cytapheresis					
1–5	11 (31.4)	4 (100.0)	9 (100.0)	0	24 (50.0)
6–10	19 (54.3)	0 (0.0)	0 (0.0)	0	19 (39.6)
>10	5 (14.3)	0 (0.0)	0 (0.0)	0	5 (10.4)
No. patients treated	35	4	9	0	48
Lymphoplasmapheresis					
>10	0	0	0	2 (100.0)	2 (100.0)
No. patients treated	0	0	0	2	2

different regions may influence the type of treatment provided to the patients.

Table 10 shows the frequencies and percentages of the number of treatments noted for each patient. This summary only includes patients who were noted to have had at least one of the corresponding treatments. Most patients received one to five treatments for plasma exchange, whereas for plasma treatment most patients received six or more treatments. These data were particularly impacted by the European region where 85.8% plasma of the patients (91 patients in total) received greater than 10 plasma treatments.

Table 11 shows the sample size, mean, standard deviation and median for the average volume of plasma exchange, plasma treatments, and lymphoplasmapheresis and average number of cells for cytapheresis and lymphoplasmapheresis. The average mean value exchanged was 2.8 L. For plasma treatment, the mean treated volume was 3.8 L. Particularly noteworthy is the mean volume of 5.6 L in the European region, which is over two times the volume processed for plasma exchange in this region.

TABLE 11. *Treatment volume and cells*

Variable/region	N	Mean	SD	Median
Plasma exchange – average volume (L)				
Asia	186	2.8	0.6	3.0
Europe	173	2.6	0.7	2.5
North America	142	3.0	0.8	3.0
Central/South America	15	3.0	0.6	3.0
Total	516	2.8	0.7	3.0
Plasma treatment – average volume (L)				
Asia	126	2.4	0.8	2.5
Europe	100	5.6	2.2	6.0
North America	1	1.8	–	1.8
Central/South America	227	3.8	2.3	3.0
Cytapheresis – average number of cells ($x10^{11}$)				
Asia	30	0.2	0.0	0.2
North America	3	5.2	2.0	4.7
Total	33	0.7	1.5	0.2
Lymphoplasmapheresis – average number of cells ($x10^{11}$)				
Central/South America	2	0.7	0.1	0.7
Total	2	0.7	0.1	0.7
Lymphoplasmapheresis – average volume (L)				
Central/South America	2	0.5	0.0	0.5
Total	2	0.5	0.0	0.5

TABLE 12. *Number of treatments per replacement solution*

Solution	Asia	Europe	North America	Central/South America	Total
Albumin solution	395 (110,161)	767 (77,142)	874 (74,74)	40 (9,10)	2076 (270,387)
Fresh frozen plasma	165 (30,88)	125 (16,22)	620 (42,42)	102 (7,7)	1012 (95,159)
Electrolyte solution	599 (118,118)	1984 (17,17)	5 (1,1)	24 (2,2)	2612 (138,138)
Plasma expander solution	1 (1,1)	0 (0)	0 (0)	0 (0)	1 (1,1)
Purified protein fraction	0 (0)	0 (0)	269 (3,3)	0 (0)	269 (3,3)
Plasma products & expander	0 (0,2)	0 (0)	34 (4,4)	0 (0)	34 (4,6)
Other	18 (7,30)	108 (16,16)	249 (28,28)	0 (0)	375 (51,74)

Number of treatments per solution (number of patients treated if # treatments noted, number of patients treated).

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. For this data, a number of respondents indicated that a particular replacement solution was used but they did not indicate the corresponding number of treatments, therefore, two sets of patient numbers are given parenthesis: the first number is the number of patients for whom the number of treatments was recorded, and the second number is the total number patients who received the replacement solution regardless of whether or not the number of treatments was recorded. Electrolyte solution followed closely by albumin solution was the most common replacement solution. In contrast to the previous survey, the percentage of treatments using electrolyte solution were significantly higher. The North American region employed plasma or protein fractions in the majority of its reported treatments in contrast to the Asian and European regions where these products were used more sparingly.

Table 13 and Table 14 show the number of treatments per method of plasma treatment and the number of patients who received each method. These categories are also not mutually exclusive and two numbers of patients are shown; those where the number of treatments was noted and those regardless of whether the number of treatments was noted. The largest number of plasma treatments was by sorption technologies, the data are dominated by the use of this plasma treatment modality used in the European region. Plasma membrane filtration technology was the dominant form of plasma treatment in the Asian region. Notably, the North American region performed very little plasma treatments.

Table 15 shows the number of treatments per blood access method and the number of patients who

TABLE 13. *Number of treatments per method of plasma treatment*

Method	Asia	Europe	North America	Central/South America	Total
Cryofiltration	10 (2,2)	8 (2,3)	11 (2,2)	0 (0)	29 (6,7)
Cascade (double filtration)	730 (122,123)	9 (2,2)	0 (0)	0 (0)	739 (124,125)
Sorption	134 (10,13)	1937 (40,45)	0 (0)	6 (1,1)	2077 (51,59)
Other	149 (43,43)	1993 (53,54)	0 (0)	0 (0)	2142 (96,97)

Number of treatments per method of plasma treatment (number of patients treated if # treatments noted, number of patients treated).

TABLE 14. *'Other' methods of plasma treatment*

Method	Asia	Europe	North America	Central/South America	Total
Total 'other'	149 (43)	1993 (53)	0 (0)	0 (0)	2142 (96)
IgG immunoadsorption	0 (0)	781 (35)	0 (0)	0 (0)	781 (35)
H.E.L.P.	0 (0)	560 (5)	0 (0)	0 (0)	560 (5)
Immunoadsorption	0 (0)	220 (6)	0 (0)	0 (0)	220 (6)
Dideco BT: Centrifuge; HELP:					
LDL precipitation	0 (0)	178 (2)	0 (0)	0 (0)	178 (2)
Plasmafiltration	147 (41)	0 (0)	0 (0)	0 (0)	147 (41)
Plasma-exchange	0 (0)	142 (1)	0 (0)	0 (0)	142 (1)
LDL immunoadsorption	0 (0)	70 (2)	0 (0)	0 (0)	70 (2)
Whole blood adsorption	0 (0)	42 (3)	0 (0)	0 (0)	42 (3)
Not specified	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)

Number of treatments per method of plasma treatment (number of patients treated if # treatments noted).

TABLE 15. *Number of treatments per blood access method*

Solution	Asia	Europe	North America	Central/South America	Total
Peripheral veno-venous	589 (82,115)	4417 (105,179)	127 (20,20)	47 (6,6)	5180 (213,320)
Central venous	279 (51,114)	595 (69,89)	860 (88,90)	123 (13,14)	1857 (221,307)
Femoral vein	423 (91,95)	29 (5,6)	131 (19,19)	6 (1,1)	589 (116,121)
Arterio-venous fistula or shunt	199 (21,21)	225 (12,13)	339 (6,6)	0 (0)	763 (39,40)
Arterial puncture	176 (28,28)	0 (0)	0 (0)	0 (0)	176 (28,28)
Other	2 (1,1)	0 (0)	0 (0)	0 (0)	2 (1,1)*

Number of treatments per blood access method (number of patients treated if # treatments noted, number of patients treated). *Both were peripheral vein + central catheter.

TABLE 16. *Number of patients given anticoagulants and drugs (percentage of patients)*

Type	Asia	Europe	North America	Central/South America	Total
Anticoagulants					
Citrate only	103 (34.1)	84 (31.2)	144 (97.3)	18 (100.0)	349 (47.4)
Heparin only	194 (64.2)	118 (43.9)	1 (0.7)	0 (0.0)	313 (42.5)
Heparin and citrate	2 (0.7)	66 (24.5)	0 (0.0)	0 (0.0)	68 (9.2)
Citrate and other	1 (0.3)	0 (0.0)	3 (2.0)	0 (0.0)	4 (0.5)
Other anticoagulant only	2 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.3)
Heparin, citrate and other	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.1)
No. patients	302	269	148	18	737
Drugs					
Steroids only	145 (53.5)	102 (42.7)	66 (51.6)	3 (16.7)	316 (48.2)
Neither	96 (35.4)	59 (24.7)	13 (10.2)	7 (38.9)	175 (26.7)
Both	24 (8.9)	53 (22.2)	35 (27.3)	6 (33.3)	118 (18.0)
Immunosuppressive only	6 (2.2)	25 (10.5)	14 (10.9)	2 (11.1)	47 (7.2)
No. patients	271	239	128	18	656

TABLE 17. *Number of patients treated with 'other' anticoagulants**

Anticoagulant	Asia	Europe	North America	Central/South America	Total
Total 'other'*	3	1	3	0	7
Fragmin	2	0	0	0	2
Protamin chloride antagonization	0	1	0	0	1
Not specified	1	0	3	0	4

*Other anticoagulants could be other anticoagulant alone, or other anticoagulant with heparin and/or citrate.

received each method. Categories are not mutually exclusive and two numbers of patients are shown, the first number is the number of patients for whom the blood access method was recorded and the second number is the total number of patients who received the blood access method regardless of whether or not the number of blood access methods was recorded.

The most prevalent form of blood access in a treatment is peripheral veno-venous followed in a distant second place by central venous, which was the dominant form of access in the North American and Central/South American regions. The dominance of the peripheral veno-venous method relates to its dominance in the European region. In the Asian region arterial punctures were reported for 28 patients.

Table 16 and Table 17 report the anticoagulants and drug used. Anticoagulant data was available on 737 patients and drug data on 656 patients. Anticoagulation by citrate and heparin were the predominant forms. The reporting shows that 48.2% of all patients reported were on steroids only, whereas 26.7% of the patients received neither steroids nor immunosuppressives. Differences in drug regimes in the different regions are most likely related to treatment diagnosis differences in their patient populations.

Table 18 and Table 19 give the type of equipment used by the number of treatments and number of patients. A diversity of equipment types were reported; in particular from the European region.

Table 20 shows the type of membrane plasma separator used by the number of treatments and number of patients. Noteworthy is the absence of use of membrane plasma separators in the North American and

TABLE 18. *Type of equipment used*

Equipment	Asia	Europe	North America	Central/South America	Total
Aminco	0 (0,1)	0 (0)	0 (0)	0 (0)	0 (0,1)
Asahi Plasauto	536 (53,69)	0 (0)	18 (3,3)	0 (0)	554 (56,72)
Cobe Spectra	126 (27,28)	1053 (41,108)	1460 (147,148)	145 (18,18)	2784 (233,302)
Dideco BT	45 (6,6)	107 (2,3)	0 (0)	0 (0)	152 (8,9)
Haemonetics M10	0 (0)	0 (0)	0 (0)	11 (1,1)	11 (1,1)
Kuraray	540 (102,103)	0 (0)	0 (0)	0 (0)	540 (102,103)
Self-assembled	160 (22,22)	0 (0)	0 (0)	0 (0)	160 (22,22)
Toray	2 (1,4)	0 (0)	0 (0)	0 (0)	2 (1,4)
Other	309 (51,159)	4404 (176,232)	0 (0)	13 (1,1)	4726 (228,392)

Number of treatments (number of patients if # treatments noted, number of patients treated).

TABLE 19. *'Other' type of equipment used*

Equipment	Asia	Europe	North America	Central/South America	Total
Total 'other'	309 (51)	4404 (176)	0 (0)	13 (1)	4726 (228)
Kaneka MA 01	18 (1)	707 (9)	0 (0)	0 (0)	725 (10)
Fenwal Autopheresis C; Medicap ADA	0 (0)	536 (24)	0 (0)	0 (0)	536 (24)
Medicap ADA	0 (0)	493 (19)	0 (0)	0 (0)	493 (19)
Fresenius 4008 ADS	0 (0)	412 (7)	0 (0)	0 (0)	412 (7)
HELP Plasmat Secura; Kanaka MA 01 Sulflux-FS5	0 (0)	370 (2)	0 (0)	0 (0)	370 (2)
Kaneka MA 01, DALI	0 (0)	327 (2)	0 (0)	0 (0)	327 (2)
Diapact, Braun	0 (0)	195 (33)	0 (0)	0 (0)	195 (33)
Diapact	186 (43)	5 (1)	0 (0)	0 (0)	191 (44)
HELP (Plasmat Futura); Kaneka MA 01	0 (0)	176 (2)	0 (0)	0 (0)	176 (2)
Kaneka MA 01; DALI ADS; HELP Plasmat Futura	0 (0)	154 (3)	0 (0)	0 (0)	154 (3)
BM 25 - Baxter	0 (0)	121 (14)	0 (0)	0 (0)	121 (14)
Fenwal Autopheresis C; Excorim; Medicap ADA	0 (0)	116 (3)	0 (0)	0 (0)	116 (3)
DALI	0 (0)	105 (4)	0 (0)	0 (0)	105 (4)
HELP Plasmat Futura	0 (0)	104 (2)	0 (0)	0 (0)	104 (2)
Fenwal Autopheresis C; Excorim	0 (0)	64 (4)	0 (0)	0 (0)	64 (4)
Selecta 1006 Sifra	0 (0)	62 (5)	0 (0)	0 (0)	62 (5)
Bellco double head pump	0 (0)	60 (3)	0 (0)	0 (0)	60 (3)
Medicap ADA; Excorim	0 (0)	55 (4)	0 (0)	0 (0)	55 (4)
Kaneka	53 (1)	0 (0)	0 (0)	0 (0)	53 (1)
Excorim	0 (0)	42 (3)	0 (0)	0 (0)	42 (3)
Citem; Medicap ADA	0 (0)	39 (2)	0 (0)	0 (0)	39 (2)
Hemaplex BT 900	0 (0)	34 (1)	0 (0)	0 (0)	34 (1)
Fenwal Autopheresis C, Citem	0 (0)	28 (2)	0 (0)	0 (0)	28 (2)
Fresenius AS 104 / Prosorba	0 (0)	24 (2)	0 (0)	0 (0)	24 (2)
TRIO	0 (0)	19 (2)	0 (0)	0 (0)	19 (2)
Bellco BT 900	0 (0)	18 (2)	0 (0)	0 (0)	18 (2)
B Braun Diapact	0 (0)	17 (3)	0 (0)	0 (0)	17 (3)
HELP (Plasmat Futura) LDL-Aphersis	0 (0)	16 (1)	0 (0)	0 (0)	16 (1)
Medicap ADA, Fenwal Autopheresis C	0 (0)	14 (2)	0 (0)	0 (0)	14 (2)
Haemonetics MCS+	0 (0)	0 (0)	0 (0)	13 (1)	13 (1)
Kaneka MA 01 Selesorb	0 (0)	13 (1)	0 (0)	0 (0)	13 (1)
BM 11 Edwards, Adasorb Medicab	0 (0)	12 (1)	0 (0)	0 (0)	12 (1)
BM 11/Adasorb/Globafin	0 (0)	12 (1)	0 (0)	0 (0)	12 (1)
Fresenius AS 104/Imunabsorba	0 (0)	12 (1)	0 (0)	0 (0)	12 (1)
Diapact Bellco MPS05	0 (0)	11 (1)	0 (0)	0 (0)	11 (1)
Hospal BSM 22-SC	10 (2)	0 (0)	0 (0)	0 (0)	10 (2)
BM 11/Adasorb	0 (0)	8 (1)	0 (0)	0 (0)	8 (1)
AS 104 Fresenius, Citem 10 Fresenius	0 (0)	5 (1)	0 (0)	0 (0)	5 (1)
Blood pump	0 (0)	4 (1)	0 (0)	0 (0)	4 (1)
Fresenius AS 104 / Citem 10	0 (0)	4 (1)	0 (0)	0 (0)	4 (1)
Fenwal Autopheresis; Life18; ADA Medicap	0 (0)	3 (2)	0 (0)	0 (0)	3 (2)
Fresenius AS 204	3 (1)	0 (0)	0 (0)	0 (0)	3 (1)
Prosorba associated to Cobe Spectra	0 (0)	3 (1)	0 (0)	0 (0)	3 (1)
Diapact Bellco M05	0 (0)	2 (1)	0 (0)	0 (0)	2 (1)
Diapact Bellco	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
Fresenius AS 104	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)
Fresenius AS 204 / Fresenius Comtec	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
Not specified	38 (2)	0 (0)	0 (0)	0 (0)	38 (2)

Number of treatments (number of patients).

TABLE 20. *Type of membrane separator used*

Membrane separator	Asia	Europe	North America	Central/South America	Total
Asahi	459 (76,93)	120 (14,14)	0 (0)	0 (0)	579 (90,107)
Bellco	49 (4,4)	0 (0)	0 (0)	0 (0)	49 (4,4)
Gambro	0 (0)	83 (5,5)	0 (0)	0 (0)	83 (5,5)
Kuraray	623 (119,120)	0 (0)	0 (0)	0 (0)	623 (119,120)
Toray	2 (1,1)	0 (0)	0 (0)	0 (0)	2 (1,1)
Other	77 (7,7)	4 (1,2)	0 (0)	0 (0)	81 (8,9)
Dideco	45 (6)	0 (0)	0 (0)	0 (0)	45 (6)
AS 104	0 (0)	4 (1)	0 (0)	0 (0)	4 (1)
Not specified	32 (1)	0 (0)	0 (0)	0 (0)	32 (1)

Number of treatments (number of patients if # treatments noted, number of patients treated).

TABLE 21. *Type of filter used for membrane plasma treatment*

Filter	Asia	Europe	North America	Central/South America	Total
Asahi	168 (60,75)	18 (3,3)	0 (0)	0 (0)	186 (63,78)
Kuraray	643 (113,114)	0 (0)	0 (0)	0 (0)	643 (113,114)
Other	45 (6,6)	25 (1,1)	0 (0)	0 (0)	70 (7,7)
Dideco	45 (6)	0 (0)	0 (0)	0 (0)	45 (6)
Bellco double head pump+Filancing pump	0 (0)	25 (1)	0 (0)	0 (0)	25 (1)

Number of treatments (number of patients if # treatments noted, number of patients treated).

Central/South American regions where plasma separation is by centrifugal methods only. Table 21 show the type of filter used for membrane plasma treatment by the number of treatments and the number of patients. Membrane plasma treatment is carried out predominantly in the Asian region. Table 22 gives the methods of sorptive plasma treatment used by the number of treatments and the number of patients. Sorptive plasma treatment procedures reported and patients treated by such is dominated by the use of sorptive plasma treatment in the European region followed far behind by the Asian region.

Table 23 shows the number of occurrences of each side-effect or complication during the treatment and up to 2 h after its cessation. Blood access difficulties were the most commonly reported side-effect in par-

TABLE 22. *Method of sorptive plasma treatment used*

Method	Asia	Europe	North America	Central/South America	Total
Asahi	28 (6,11)	18 (3,3)	0 (0)	0 (0)	46 (9,14)
Cypress	0 (0)	0 (0)	0 (0)	6 (1,1)	6 (1,1)
Kaneka	96 (4,4)	1529 (26,27)	0 (0)	0 (0)	1625 (30,31)
Other	0 (0)	2122 (78,83)	0 (0)	0 (0)	2122 (78,83)
IgG Therasorb		559 (23)			
LDL Therasorb		266 (7)			
DALI		240 (8)			
ADA system + double head pump		230 (3)			
Fresenius DALI		228 (6)			
Fresenius (DALI) 4008 ADS		184 (1)			
Immunosorba; IgG Therasorb		113 (6)			
Bellco double head pump		58 (4)			
Immunosorba		46 (3)			
Globafine		44 (4)			
IgG Therasorb; Immunosorba		34 (2)			
Immunosorba Fresenius		31 (2)			
Bellco pump		30 (1)			
Protein A		21 (3)			
Protein A / Fresenius		12 (1)			
Prosorba		3 (1)			
Fresenius Prosorba (Protein A)		1 (1)			
Not specified		22 (2)			

Number of treatments (number of patients if # treatments noted, number of patients treated).

TABLE 23. *Side effects or complications following treatment*

Side effect / complication	Asia	Europe	North America	Central/South America	Total
Hypotension	36 (31)	88 (43)	51 (27)	9 (6)	184 (107)
Blood access difficulties	64 (37)	264 (72)	20 (8)	13 (6)	361 (123)
Bleeding - access site	20 (14)	27 (12)	6 (3)	0 (0)	53 (29)
Bleeding - other site	1 (1)	0 (0)	2 (1)	0 (0)	3 (2)
Shock	12 (12)	1 (1)	0 (0)	0 (0)	13 (13)
Fever/chills	42 (23)	11 (10)	6 (4)	3 (2)	62 (39)
Circuit clotting	24 (19)	48 (23)	0 (0)	1 (1)	73 (43)
Allergic reaction	33 (5)	3 (3)	20 (11)	5 (3)	61 (22)
Hemolysis	34 (19)	12 (10)	0 (0)	0 (0)	46 (29)
Pain other than at access site	8 (8)	32 (13)	2 (2)	0 (0)	42 (23)
Respiratory distress	4 (4)	7 (4)	5 (4)	1 (1)	17 (13)
Hepatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Death	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
Other	14 (7)	15 (11)	11 (6)	10 (6)	50 (30)
Paresthesia	5	0	3	2	10
Hypocalcemia	0	3	0	0	3
Leakage of extracorporal system	0	2	0	0	2
Nausea	0	1	1	0	2
Nausea, chills	0	0	1	0	1
ACE-INH related symptoms	0	1	0	0	1
Acute myocardial infarction	0	0	0	1	1
Arterial hypertension, tachycardia	0	0	0	1	1
Blood leakage COBE spectra system	0	1	0	0	1
Cardiac arrhythmia	0	0	0	1	1
Citrate-induced mild, non-systemic reactions	0	1	0	0	1
Citrate-induced reaction on DALI (AC 1:20)	0	1	0	0	1
Device problem	1	0	0	0	1
Headache	0	0	1	0	1
Hypertension	0	0	0	1	1
Technical problems-plasma separator leak	0	1	0	0	1
Tingling sensation and lower extremity spasticity	1	0	0	0	1

Number of episodes (number of patients).

ticular due to the blood access difficulties in the European region. Hypotension was the second most commonly reported side-effect.

The reported response to apheresis and payment provider, noted in Table 24, show that 78.8% of the patients showed improvement, whereas 14.6% indicated that their condition remained the same. These results showed a higher positive response to apheresis compared with the last most recent survey (3). Government support for their treatment was received by 71.2% of the patients. The Asian region reported the highest percent of patients receiving support from the government at 86.6%, the European region reported 65.8%, the North American region reported 40.5%, and the Central/South American region reported only 5.6%. The European

TABLE 24. *Patients' response to apheresis and the type of payment provider used. Figures show number of patients (percentage of patients)*

Type	Asia	Europe	North America	Central/South America	Total
Response to apheresis					
Improvement	284 (80.2)	220 (76.7)	118 (79.2)	15 (83.3)	637 (78.7)
Same	49 (13.8)	52 (18.1)	16 (10.7)	1 (5.6)	118 (14.6)
Worsening	16 (4.5)	1 (0.4)	2 (1.3)	0 (0.0)	19 (2.4)
Treatment discontinued	5 (1.4)	11 (3.8)	8 (5.4)	2 (11.1)	26 (3.2)
Not assessable	0 (0.0)	3 (1.0)	5 (3.4)	0 (0.0)	8 (1.0)
No. patients	354	287	149	18	808
Payment provider					
Self/family	25 (7.3)	2 (0.7)	3 (3.6)	2 (11.1)	32 (4.4)
Private insurance	10 (2.9)	6 (2.2)	47 (56.0)	15 (83.3)	78 (10.8)
Government	297 (86.6)	183 (65.8)	34 (40.5)	1 (5.6)	515 (71.2)
Hospital/institution	5 (1.5)	85 (30.6)	0 (0.0)	0 (0.0)	90 (12.4)
Other	6 (1.8)	2 (0.7)	0 (0.0)	0 (0.0)	8 (1.1)
No. patients	343	278	84	18	723

region reported that 30.6% of the patients received payment form the Hospital/Institution. In the North American region the highest percent for the payment provider was 56.0% from private insurance and the Central/South American region reported 83.3% of the payments provided also by private insurance.

DISCUSSION

The format of the questionnaire used for this survey was similar to that used for the 1983 (1) and 2000 (3) surveys. However, unlike in previous surveys where the survey forms were mailed out and returned for data processing this survey was based through a secure dedicated website.

Of the over 500 centers solicited, data was received from only 33 centers or less than 6% reporting from four continents. We encountered several issues with the methodology of data collection. The internet data collection was new to many who had participated in previous surveys and there was some reluctance to use an online system. Some centers requested to submit paper forms. The time needed to enter patient data continues to be a major issue for busy physicians and their assistants so the deadline was extended by 2 months to allow for additional data collection. The Health Insurance Portability and Accountability Act (HIPAA) compliance was a question that arose for several centers in the US. The study was approved prior to opening the Registry for data collection by the Institutional Review Board of the Cleveland Clinic Foundation which ensured that all patient data was collected without individual identifiers and no persons without prior training in the handling of patient data had access to raw data. In future announcements, notification of the IRB approval was made to the Centers. Acknowledgment of participation of collaborative Centers and persons was not done in previous surveys to protect the privacy of the Centers. For this survey, we have the shared results prior to publication and published the names of participating Centers and persons to acknowledge their efforts publicly.

Considering the difficulties encountered with the change in format for submitting data and that no compensation was provided to the centers for their efforts, we consider this response rate acceptable as it was similar to the 2000 survey (3).

In the review of this survey and its results, one should be considerate of these issues. The geographic distribution of the individual survey responders can have a very important influence on the results reported. For the North American region, data was reported only from the United States. Based on the estimated populations in the various regions, the centers reporting from the various countries are not necessarily proportional to patient numbers reported.

For all regions except the Central/South American region, the number of female patients reported was higher than the number of male patients. The largest reported race of patients was Caucasian; Asian was second. As in prior surveys (1,3) diseases of the nervous system were the most prevalent treatment diagnoses (31.2%). The top treatment diseases were myasthenia gravis, thrombotic thrombocytopenic purpura and systemic lupus erythematosus. Regional differences were noted in treatment diagnosis as reported in the previous surveys. Patient selection is most probably a major influence as the regional differences noted in treatment type, number of treatments per patient, equipment choice, and drug usage. Patient selection is most likely highly related to payment provider. The treatment diagnosis has a major impact on the number of treatment and equipment type. For example, significantly higher numbers of treatments per patient were given to the diagnosis of hypercholesterolemia (3853 treatments per 45 patients; 85.6 treatments per patient) as compared with myasthenia gravis (1021 treatments per 148 patients; 6.9 treatments per patient).

As in prior surveys, only a small percentage of the treatments reported were for cytapheresis (about 4% of the total). This survey showed electrolyte solutions as the most frequently used replacement solution in contrast to the previous surveys where albumin solution was more frequently reported. Plasma treatment procedures accounted for over 29% of all the procedures. This is down from the 43.8% reported in the last survey (3). Plasma sorption treatments represented 18.2% of all treatments, which is up slightly from 16.7% in the last survey (3). Blood access continues to be of clinical procedural concern and was ranked as the highest side-effect or complication in the treatments. Nearly two times more reports were given compared with the second highest side-effect or complication in treatment of hypotension. Regional differences continue to exist on the types of blood access methods used with significant diversity within the regions on the type of blood access method used. Regional differences continue to be seen for the type of anticoagulants used with heparin as the anticoagulant of choice in the Asian and European regions whereas citrate is the dominant anticoagulant of choice in the North American and Central/South American regions.

Compared with previous surveys, a higher percentage of patients are noted as showing improvement (78.8% *vs* 73.1% in 2000 *vs* 64.2%in 1983, respec-

tively). A trend also noted is the increased higher percentage of the patients reported to have the government as the payment provider (71.2% *vs* 69.4% in 2000 *vs* 30.8% in 1983, respectively).

As noted by these results and compared with those in the 2000 (3) and 1983 (1) surveys, regional differences continue to exist. As noted previously, we believe that through a thorough understanding of these differences, whether related to the regional economics as reimbursement requirements, technology availability, or disease demographics, better treatment schemes and clinical protocols can be made available.

In future apheresis surveys, consideration will be given to methods to increase the response rate by increasing the data collection from Centers, perhaps by providing additional incentives (e.g. subsidized data collection through government, industry, third party payors, or collaborations with other interested surveyors). We will also consider ways to improve the user-friendliness of survey and update the format to include new therapies and technologies.

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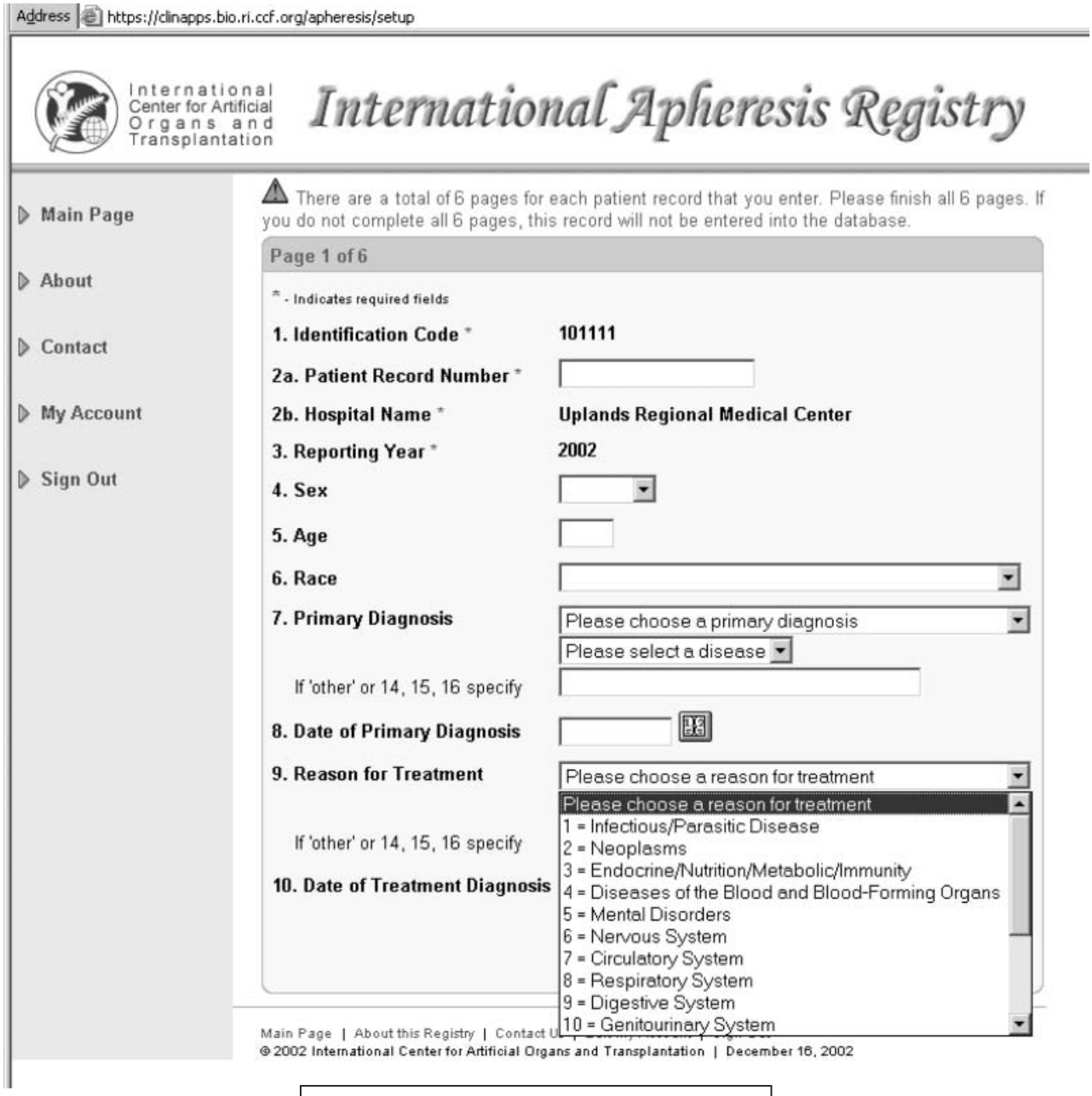
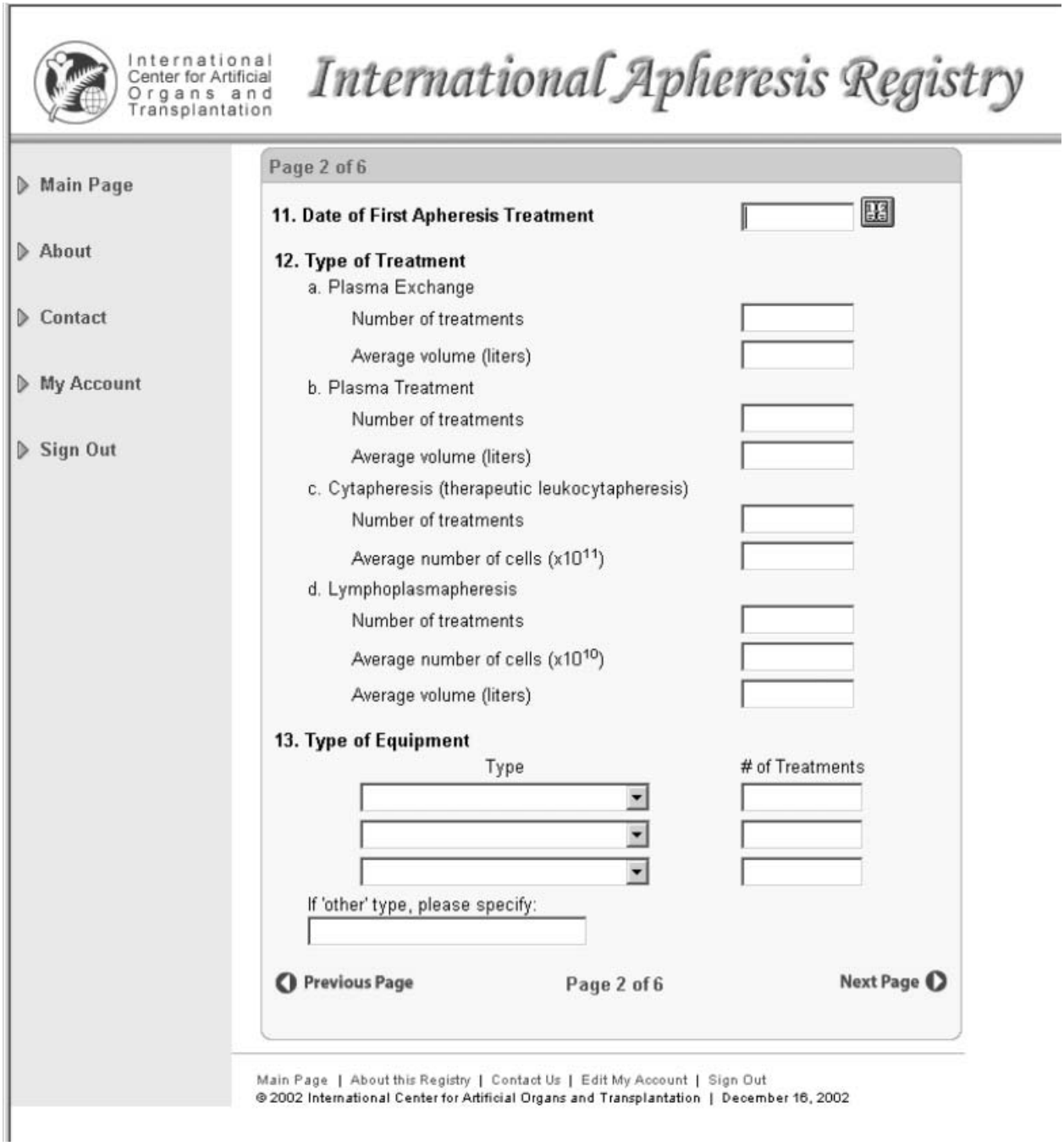
APPENDIX I

Online data entry forms for the 2002 international apheresis registry



Click on arrow for drop down menus


International Center for Artificial Organs and Transplantation
International Apheresis Registry
Main Page
About
Contact
My Account
Sign Out
Page 2 of 6
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. Cytapheresis (therapeutic leukocytapheresis)
Number of treatments
Average number of cells (x10^11)
d. Lymphoplasmapheresis
Number of treatments
Average number of cells (x10^10)
Average volume (liters)
13. Type of Equipment
Type
# of Treatments
If 'other' type, please specify:
Previous Page
Page 2 of 6
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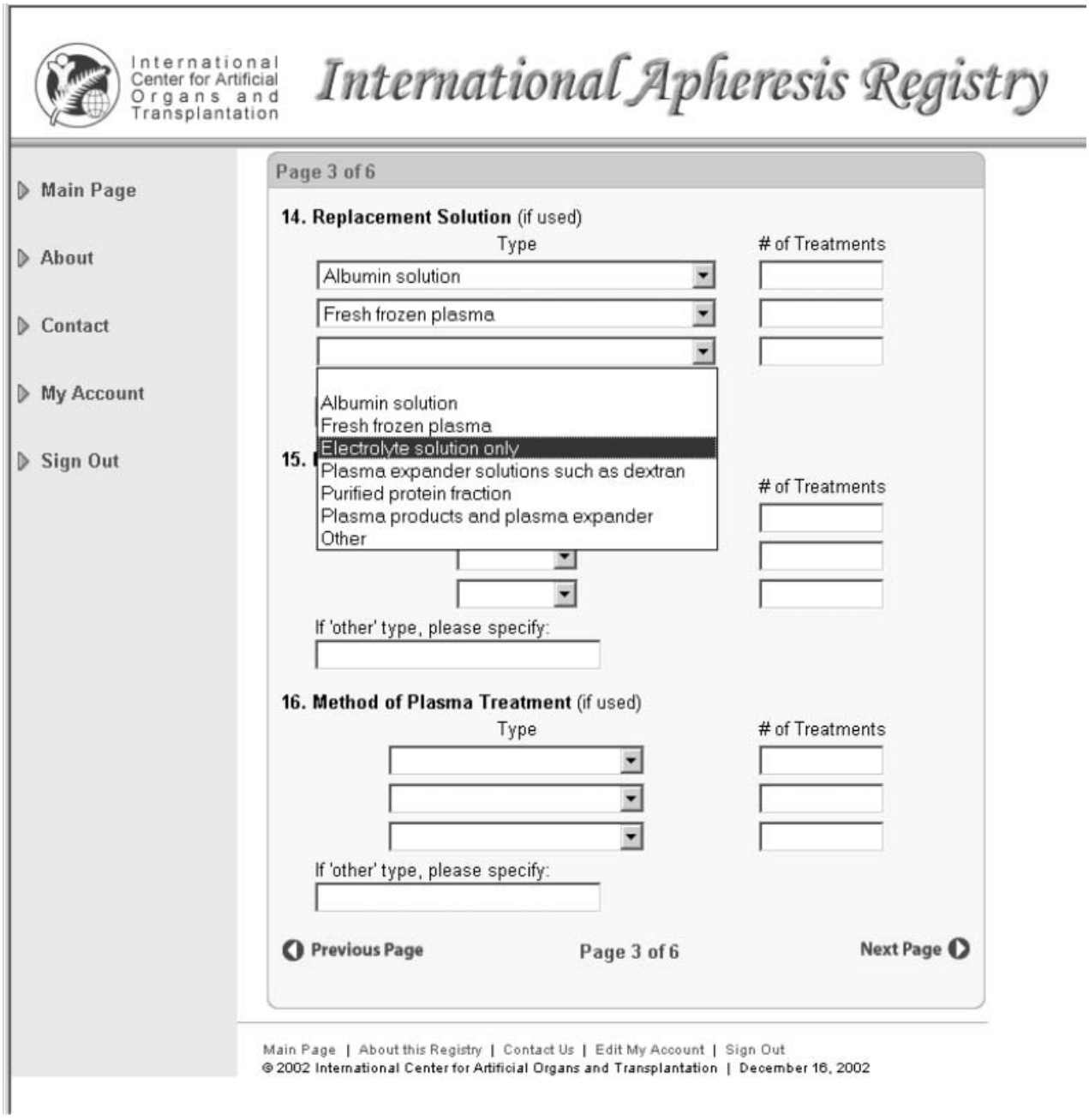
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14. Replacement Solution (if used)
Type
# of Treatments
Albumin solution
Fresh frozen plasma
Albumin solution
Fresh frozen plasma
Electrolyte solution only
Plasma expander solutions such as dextran
Purified protein fraction
Plasma products and plasma expander
Other
15.
# of Treatments
If 'other' type, please specify:
16. Method of Plasma Treatment (if used)
Type
# of Treatments
If 'other' type, please specify:
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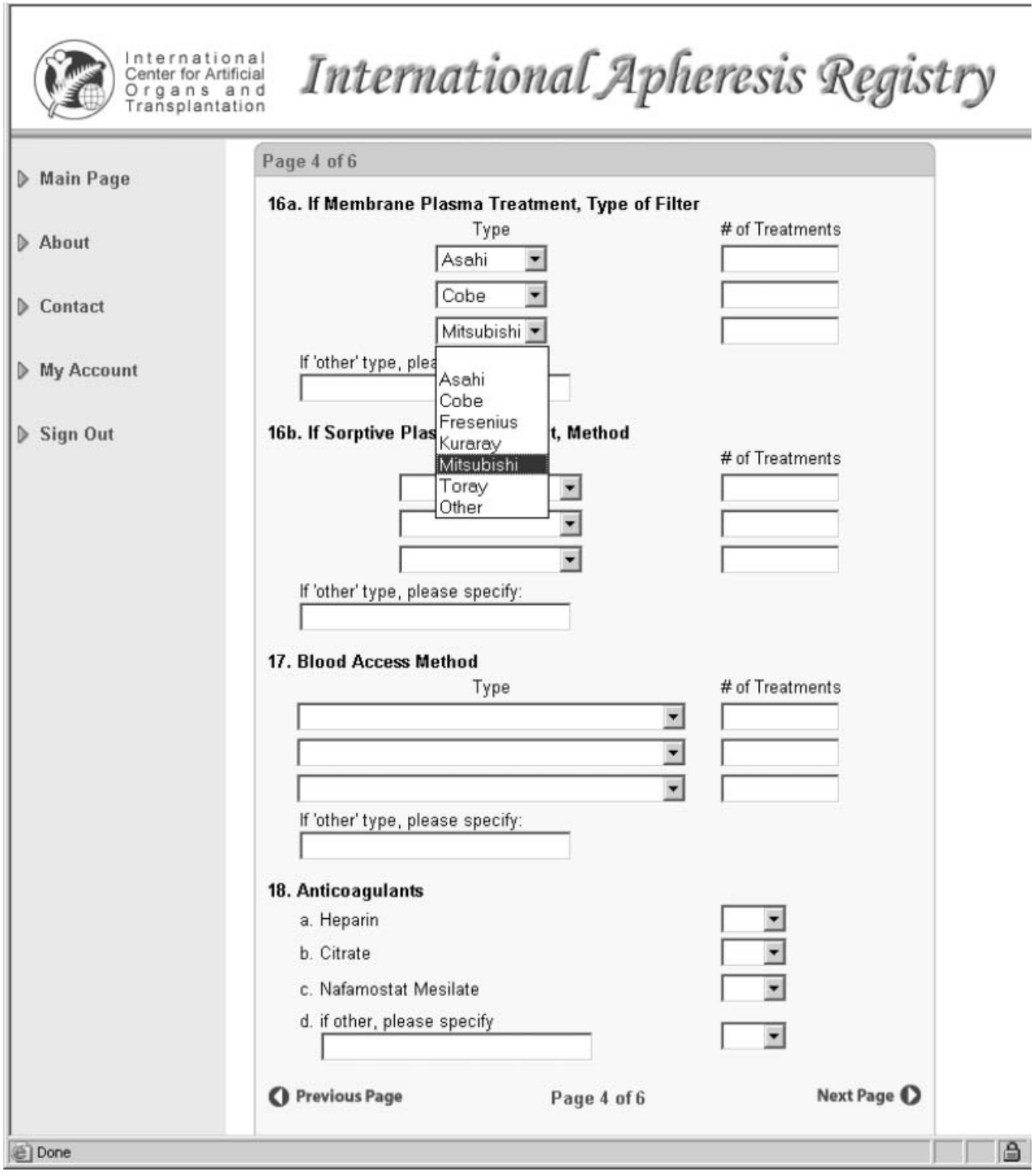
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16a. If Membrane Plasma Treatment, Type of Filter
Type
# of Treatments
Asahi
Cobe
Mitsubishi
If 'other' type, plea
Asahi
Cobe
Fresenius
Kuraray
Mitsubishi
Toray
Other
16b. If Sorptive Plas t, Method
# of Treatments
If 'other' type, please specify:
17. Blood Access Method
Type
# of Treatments
If 'other' type, please specify:
18. Anticoagulants
a. Heparin
b. Citrate
c. Nafamostat Mesilate
d. if other, please specify
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Done


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19. Drugs
a. Steroids
Yes
b. Immunosuppressive
Yes
No
20. Side Effects or Complications during and up to two after cessation of treatment
Type of Effects or Complications
# of Treatments
a. Hypotension
b. Blood access difficulties
c. Bleeding - access site
d. Bleeding - other site
e. Shock
f. Fever/Chills
g. Circuit clotting
h. Allergic reaction
i. Hemolysis
j. Pain other than at access site
k. Repiratory distress
l. Hepatitis
m. Death
n. Other, specify
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Address https://clinapps.bio.ri.ccf.org/apheresis/save
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21a. Response to Apheresis
Improvement
21b. Above response based upon
Objective (laboratory or measurable parameter)
22. Payment Provider
Government
If 'Other', specify
23. Person completing form
Nurse/Technician
24. General Comments (maximum 500 characters please)
Additional comments are needed to clarify special issues.
GAR 2/1/2003
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Finish This Patient Record
Finish and Save Record
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APPENDIX II

TABLE A1. *Collaborating hospitals and centers*

Participant	Department, Institution	City, Country
Mutlu Arat, MD	Department of Hematology, Ankara University Faculty of Medicine	Ankara, Turkey
Önder Arslan, MD	Department of Hematology, Ankara University Faculty of Medicine	Ankara, Turkey
Erol Ayyildiz, BSc, AT	Department of Hematology, Ankara University Faculty of Medicine	Ankara, Turkey
Rolf Bambauer, MD	Institute for Blood Purification, Arzt für Innere Medizin und Nephrologie	Homburg (Saar),Germany
Ghil Busnach, MD	Department of Nephrology, Niguarda Ca′ Granda Hospital	Milano, Italy
Kurt Derfler, MD	Apheresis Unit, Department of Internal Medicine III, General Hospital Vienna	Vienna, Austria
Giustina De Silvestro, MD	Apheresis Unit-Blood Bank, General Hospital-University of Padova	Padova, Italy
Serafina Di Giacomo, MD, PhD	Plasmapheresis Unit. Dipartimento di Clinica e Terapia Medica Applicata, Policlinico 'Umberto I', University of Rome 'La Sapienza'	Rome, Italy
Takashi Harada, MD	Renal Care Unit, Nagasaki University Hospital	Nagasaki, Japan
Hideki Hirakata, MD	Kyushu University	Fukuoka City, Japan
Osman Ilhan, MD	Department of Hematology, Ankara University Faculty of Medicine	Ankara, Turkey
Martin Jansen, MD	Apheresis Unit, Department of Internal Medicine III, General Hospital Vienna	Vienna, Austria
Stefan Kallert, MD	Franz-von-Prümmerklinik	Bad Brückenau, Germany
Andre A Kaplan, MD	Division of University of Connecticut Health Center	Farmington, CT, USA
Petar Kes, MD	Department of Dialysis, University Hospital Center Zagreb	Zagreb, Croatia
Norella C Kong, MD	Department of Medicine, Hospital UKM, National University of Malaysia	Cheras, Kuala Lumpur, Malaysia
Anna P Koo, MD	Department of Hematology and Medical Oncology, Cleveland Clinic Foundation	Cleveland, OH, USA
Jose Mauro Kutner, PhD	Hemotherapy Department, Hospital Israelita Albert Einstein	São Paulo, Brazil
Miriam Leach, MS, MT (ASCP), SBB	Department of Transfusion Medicine, Dartmouth Hitchcock Medical Center	Lebanon, NH,USA
Maura Mareri, MD	Plasmapheresis Unit, Dipartimento di Clinica e Terapia Medica Applicata, Policlinico 'Umberto I', University of Rome 'La Sapienza'	Rome, Italy
Piero Marson, MD	Apheresis Unit-Blood Bank, General Hospital-University of Padova	Padova, Italy
Hidenori Matsuo, MD	Department of Neurology and Division of Clinical Research, Kawatana National Hospital	Kawatana, Nagasaki, Japan
Luigi Moriconi, MD	Department of Nephrology, Ospedale di S. Miniato	Pisa, Italy
Kazuko Motohashi, MD	Tokatsu Clinic and Hospital	Chiba, Japan
Shigeo Negi, MD	Wakayama Medical University	Wakayama, Japan
C Michael Neuwelt, MD	East Bay Rheumatology Medical Group, University of California, Stanford University, Alameda County Medical Center, and St. Mary's Medical Center,	San Leandro, Oakland, Palo Alto and San Francisco, CA, USA
Vicki R Oberg	Meritcare Hospital	Fargo, ND,USA
Stefano Passalacqua, MD	Department of Nephrology, Columbus Hospital, Catholic University of Sacred Heart	Rome, Italy
Araci Massami Sakashita, MD	Hemotherapy Department, Hospital Israelita Albert Einstein	São Paulo, Brazil
Orhan Seyfi Sardas, MD	Hemapheresis Unit, Department of Hematology, Ankara University Faculty of Medicine	Ankara, Turkey
Koji Sawada, MD, PhD	Department of Gastroenterology, Hyogo College of Medicine	Nishinomiya, Hyogo, Japan
Sherry Shariatmadar, MD	Department of Pathology, University of Miami-Jackson Memorial Medical Center	Miami, FL, USA
Noriaki Shimada, MD	Koto Hospital	Tokyo, Japan
Kostas Sombolos, MD	Department of Nephrology, G.H. 'G. Papanikolaou'	Thessaloniki, Greece
Eun Young Song, MD	Seoul National University Hospital	Seoul, Korea
Rakesh Srivastava, MD	ISA Institute for Apheresis and Research Center	Delhi, India
Emiliano Staffolani, MD	Department of Nephrology, Columbus Hospital, Catholic University of Sacred Heart	Rome, Italy
Claudio Stefanutti, MD, PhD	Plasmapheresis Unit. Dipartimento di Clinica e Terapia Medica Applicata, Policlinico 'Umberto I', University of Rome 'La Sapienza'	Rome, Italy
Leonel N. Szterling, MD	Hospital Santa Catarina	São Paulo, Brazil
Hiromi Tasaki, MD, PhD	2nd Department of Internal Medicine, University of Occupational and Environmental Health	Kitakyushu, Fukuoka, Japan
Meltem Tol, BSc	Department of Hematology, Ankara University Faculty of Medicine	Ankara, Turkey
Silvano Wendel, MD	Sirio Libanjs	Sao Paulo, Brazil
Hin-Seng Wong, MD, MRCP	Department of Nephrology, Kuala Lumpur Hospital	Kuala Lumpur, Malaysia
Jiann-Horng Yeh, MD	Shin Kong Wu Ho-Su Memorial Hospital	Taipei, Taiwan