Donor Apheresis in South America

DATE: 4/3/2014 / TIME: 11:15AM to 11:45AM

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Disclosures for:
José Francisco C. Marques Jr, MD, PhD:

• Employee: No relevant conflicts of interest to declare
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Program

• South America - Countries and Population;

• Methodology:
  – Literature review;
  – Survey sent to the Associations of Hematologists (email);
  – Contact with Companies and Professionals in the field;
  – Research on the internet (official websites, educational, Pubmed).

• Data by country:
  – Apheresis, Blood Centers, Funding, Equipment and others.

• Considerations, Conclusions and Suggestions;

• Thanks and acknowledgments.
South America

- Area: 17,800,000,00 km²;
- 12% of Earth's surface;
- 6% of world population.

http://www.indexmundi.com/map/?v=21&r=sa&l=pt
### South America: Countries and Population

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>199,321,413</td>
</tr>
<tr>
<td>Colombia</td>
<td>45,239,079</td>
</tr>
<tr>
<td>Argentina</td>
<td>42,192,494</td>
</tr>
<tr>
<td>Peru</td>
<td>29,549,517</td>
</tr>
<tr>
<td>Venezuela</td>
<td>28,047,938</td>
</tr>
<tr>
<td>Chile</td>
<td>17,067,369</td>
</tr>
<tr>
<td>Ecuador</td>
<td>15,223,680</td>
</tr>
<tr>
<td>Bolivia</td>
<td>10,290,003</td>
</tr>
<tr>
<td>Paraguay</td>
<td>6,541,591</td>
</tr>
<tr>
<td>Uruguay</td>
<td>3,316,328</td>
</tr>
<tr>
<td>Guyana</td>
<td>741,908</td>
</tr>
<tr>
<td>Suriname</td>
<td>560,157</td>
</tr>
<tr>
<td>Falkland Id</td>
<td>3,140</td>
</tr>
</tbody>
</table>

**South America - Population 2012**

[http://www.indexmundi.com/map/?v=21&r=sa&l=pt](http://www.indexmundi.com/map/?v=21&r=sa&l=pt)
South America

- 12 countries:
  - Argentina;
  - Bolivia;
  - Brazil;
  - Chile;
  - Colombia;
  - Ecuador;
  - Guyana;
  - Paraguay;
  - Peru;
  - Suriname;
  - Uruguay;
  - Venezuela.

- 8 have Hematologists Association:
  - Argentina;
  - Brazil;
  - Chile;
  - Colombia;
  - Paraguay;
  - Peru;
  - Uruguay;
  - Venezuela.
Program

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• Thanks and acknowledgments.
In other sections of the Americas, there is not a central data resource center that gathers collections and transfusion statistics. For the purpose of this article, the author relied on sales data provided by the following apheresis machine and kit manufacturers: Gambro BCT, Baxter, Fresenius HemoCare and Haemonetics. Understandably, assumptions made from this type of data are not as precise as those from the NBDRC, but it does give the reader an understanding of collection trends as centers evolve from whole blood collection to automated multicomponent apheresis collections.

The information collected from the previously noted companies separated Brazil as a unique entity from the rest of the Latin America data. There are approximately 3.5 million WB donations in Brazil each year. Random donor platelets comprise the majority of products produced at a rate of about 50% of WB collections. The APLT account for around 40,000 collections a year, with about a 10% split rate producing around 50,000 doses.

LATIN AMERICA (EXCLUDING BRAZIL)

The other countries in Latin America collect approximately 5,000,000 WB donations annually. The majority, if not all, of these collections are by WB procedures. Random donor platelets production ranges from 50 to 70% of the WB collection. Over 70,000 APLT are collected which accounts for only a small percentage of total platelet doses.
Survey sent to the Associations of Hematologists (email)

- Sent on the 12.11.2013 and 01.10.2014 (9 questions):

1. Number of blood donations per year (conventional and apheresis) and percentage of the population;
2. Number of transfusions per year by components’ type both conventional and apheresis;
3. Other destinations of the blood components (export, industry, etc);
4. Number of transfusion centers and those that do apheresis;
5. Annual number and type of therapeutic apheresis procedures;
6. Diseases most often treated with therapeutic apheresis;
7. Annual number of PBPC collection (autologous and allogeneic);
8. Geographical distribution of centers that do apheresis (capital, interior, large and small cities);
9. Payment (percentage of public and private) and economic viability.
Survey sent to the Associations of Hematologists (email)

• Hematologists associations to which the survey were sent:
  1. Argentina:
     – La Sociedad Argentina de Hematologia y Oncologia;
     – Asociación Argentina de Hemoterapia e Inmunohematologia (feb.2014);
  2. Chile:
     – La Sociedad Chilena de Hematología;
  3. Colombia
     – La Asociación Colombiana de Hematologia y Oncologia;
  4. Paraguay:
     – La Sociedad Paraguaya de Hematologia y Hemoterapia;
  5. Peru:
     – La Sociedad Peruana de Hemoterapia y Banco de Sangre;
  6. Uruguay:
     – La Sociedad de Hematología del Uruguay;
  7. Venezuela:
     – Sociedad Venezolana de Hematología.

Result: No data!!!
Contact with Companies and Professionals in the field

- Doctors, Technicians, Distributors, etc:
  - Relevant information from 7 countries:
    - Argentina;
    - Chile;
    - Colombia;
    - Ecuador;
    - Peru;
    - Uruguay;
    - Venezuela.
Research on the Internet

• Official websites:
  – PAHO, WHO, Government, etc;

• Educational:
  • Google, etc;

• Pubmed.

• It was noticed:
  – A lot of data about Donation and Blood transfusion, Fractionation, Serology, Quality, Safety, etc;
  – Almost **NOTHING** about apheresis!
Research on the Internet

- Main:

## Blood donation in South America: Number of Blood Units – PAHO - 2011

<table>
<thead>
<tr>
<th>Country</th>
<th>Blood Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>1,101,438</td>
</tr>
<tr>
<td>Bolívia</td>
<td>79,960</td>
</tr>
<tr>
<td>Brazil</td>
<td>3,356,382</td>
</tr>
<tr>
<td>Chile</td>
<td>230,308</td>
</tr>
<tr>
<td>Colombia</td>
<td>710,825</td>
</tr>
<tr>
<td>Ecuador</td>
<td>211,818</td>
</tr>
<tr>
<td>Guyana</td>
<td>6,361</td>
</tr>
<tr>
<td>Paraguay</td>
<td>74,079</td>
</tr>
<tr>
<td>Peru</td>
<td>141,202</td>
</tr>
<tr>
<td>Suriname</td>
<td>10,917</td>
</tr>
<tr>
<td>Uruguay</td>
<td>95,812</td>
</tr>
<tr>
<td>Venezuela</td>
<td>416,346</td>
</tr>
</tbody>
</table>

Blood donation in South America

<table>
<thead>
<tr>
<th>Country</th>
<th>% donation/pop/year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>1,0</td>
</tr>
<tr>
<td>Bolívia</td>
<td>0,6</td>
</tr>
<tr>
<td>Brazil</td>
<td>1,9</td>
</tr>
<tr>
<td>Chile</td>
<td>1,4</td>
</tr>
<tr>
<td>Colombia</td>
<td>1,2</td>
</tr>
<tr>
<td>Ecuador</td>
<td>1,1</td>
</tr>
<tr>
<td>Paraguay</td>
<td>0,8</td>
</tr>
<tr>
<td>Peru</td>
<td>0,6</td>
</tr>
<tr>
<td>Uruguay</td>
<td>2,8</td>
</tr>
<tr>
<td>Venezuela</td>
<td>1,5</td>
</tr>
</tbody>
</table>

Research on the Internet
Pubmed – Publications by Country

• Argentina:
  – 20 publications: Donors: 2; Therapeutic: 9; Others: 9.
Research on the Internet
Pubmed – Publications by Country

- Brazil:
  - 59 publications: Donors: 14; Therapeutic: 22; Others: 23.
Bolivia:
- 1 publication: Donors: 0; Therapeutic: 1; Others: 0.

Chronic Chagas' heart disease: a disease on its way to becoming a worldwide health problem: epidemiology, etiopathology, treatment, pathogenesis and laboratory medicine.


Abstract
Chagas' disease, caused by Trypanosoma cruzi infection, is ranked as the most serious parasitic disease in Latin America. Nearly 30% of infected patients develop life-threatening complications, and with a latency of 10-30 years, mostly Chagas' heart disease which is currently the major cause of morbidity and mortality in Latin America, enormously burdening economic resources and dramatically affecting patients' social and labor situations. Because of increasing migration, international tourism and parasites transfer by blood contact, intraterine transfer and organ transplantation, Chagas' heart disease could potentially become a worldwide problem. To raise awareness of this problem, we reflect on the epidemiology and etiopathology of Chagas' disease, particularly Chagas' heart disease. To counteract Chagas' heart disease, in addition to the general interruption of the infection cycle and chemotherapeutic elimination of the infection agent, early and effective causal or symptomatic therapies would be indispensable. Prerequisites for this are improved knowledge of the pathogenesis and optimized patient management. From economic and logistics viewpoints, this last prerequisite should be performed using laboratory medicine tools. Consequently, we first summarize the mechanisms that have been suggested as driving Chagas' heart disease, mainly those associated with the presence of autoantibodies against G-protein-coupled receptors; secondly, we indicate new treatment strategies involving autoantibody apheresis and in vivo autoantibody neutralization; thirdly, we present laboratory medicine tools such as autoantibody estimation and heart marker measurement, proposed for diagnosis, risk assessment and patient guidance and lastly, we critically reflect upon the increase in inflammation and oxidative stress markers in Chagas' heart disease.

PMID: 21165506 [PubMed - indexed for MEDLINE]
Research on the Internet
Pubmed – Publications by Country

• Colombia:
  – 3 publications: Donors: 0; Therapeutic: 1; Others: 2.


Research on the Internet
Pubmed – Publications by Country

• Peru:
  – 1 publication: Donors: 0; Therapeutic: 1; Others: 0.

**Abstract**

Cryoglobulinemia may be found in up to 30% of patients that had received liver transplants after hepatitis C virus (HCV) cirrhosis. Three types of cryoglobulinemia are recognized: type I, composed of monoclonal immunoglobulins associated with lymphoproliferative diseases and myeloma; type II cryoglobulinemia is comprised of a monoclonal component which has rheumatoid factor activity and hence binds to polyclonal immunoglobulins (in certain parts of the world have been found to be associated with hepatitis C infection); and type III cryoglobulinemia consists exclusively of polyclonal immunoglobulins with rheumatoid factor activity (associated with connective tissue diseases and chronic infections including hepatitis C). Immunocompetence, autoimmunity and clonal expansion of B cell lymphocytes have not been analyzed simultaneously in previous reports of patients with cryoglobulinemia after liver transplantation. We have describe immunological abnormalities associated with cryoglobulinemia in a patient who had received liver transplant for HCV cirrhosis. In addition, in the present work HCV RNA determination was performed directly in the cryoprecipitate and not only in peripheral blood. We have observed enrichment of HCV RNA in the cryoprecipitates which might be a better demonstration of the possible role of HCV in the pathogenesis of the cryoglobulinemia.

**PMID:** 15438389 [PubMed - indexed for MEDLINE]
Research on the Internet

Pubmed – Publications by Country

- Chile:
  - 10 publications: Donors: 0; Therapeutic: 8; Others: 2.

[PubMed search results for apheresis in Chile]
Research on the Internet
Pubmed – Publications by Country

- Uruguay:
  - 3 publications: Donors: 0; Therapeutic: 0; Others: 3.
Research on the Internet

Pubmed – Publications by Country

- **Venezuela:**
  - 3 publications: Donors: 0; Therapeutic: 1; Others: 2.
Research on the Internet
Pubmed – Publications by Country

• Total South America:
  – Publications: 100;
  – Donors: 16;
  – Therapeutic: 43;
  – Others: 41 (including PBPC collections).
Program

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  – Contact with Companies and Professionals in the field;
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• Data by country:
  – Apheresis, Blood Centers, Funding, Equipment and others.

• Considerations, Conclusions and Suggestions;

• Thanks and acknowledgments.
Brazil

- Apheresis donation per year:
  - Official data not available. Only for platelets transfusion: 24,454 (0.68% of transfusions) and granulocytes concentrates: 5,014 (0.14%) (2009).

- Blood Centers:
  - 2359 (Which make apheresis: 106).

http://www1.anvisa.gov.br/anvisa/hemocad/RelatoriosHemocad.jsp
## Frequências e Percentuais dos Procedimentos de Transfusão Ambulatorial e Hospitalar, por Tipo de Hemocomponente, Brasil, 2009

<table>
<thead>
<tr>
<th>Procedimento</th>
<th>SUS Público</th>
<th>Private Contratado</th>
<th>Private não Contratado</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
<td>%</td>
</tr>
<tr>
<td>Concentrado de Granulócitos</td>
<td>1.598</td>
<td>0,10%</td>
<td>3.291</td>
<td>0,22%</td>
</tr>
<tr>
<td>Concentrado de Hemácias</td>
<td>794.944</td>
<td>52,23%</td>
<td>830.914</td>
<td>55,11%</td>
</tr>
<tr>
<td>Concentrados de Plaquetas</td>
<td>315.803</td>
<td>20,75%</td>
<td>283.465</td>
<td>18,80%</td>
</tr>
<tr>
<td>Crioprecipitado</td>
<td>28.537</td>
<td>1,88%</td>
<td>52.601</td>
<td>3,49%</td>
</tr>
<tr>
<td>Plaquetas por Aférese</td>
<td>8.391</td>
<td>0,55%</td>
<td>6.813</td>
<td>0,45%</td>
</tr>
<tr>
<td>Plasma Fresco</td>
<td>261.308</td>
<td>17,17%</td>
<td>226.574</td>
<td>15,03%</td>
</tr>
<tr>
<td>Plasma Isento de Crioprecipitado</td>
<td>6.845</td>
<td>0,45%</td>
<td>6.976</td>
<td>0,46%</td>
</tr>
<tr>
<td>Sangue/Componentes Irradiados</td>
<td>26.515</td>
<td>1,74%</td>
<td>37.757</td>
<td>2,50%</td>
</tr>
<tr>
<td>Unidade de Sangue Total</td>
<td>78.000</td>
<td>5,13%</td>
<td>59.229</td>
<td>3,93%</td>
</tr>
<tr>
<td></td>
<td>1.521.941</td>
<td>100%</td>
<td>1.507.620</td>
<td>100%</td>
</tr>
</tbody>
</table>

Fonte: Ministério da Saúde/SAS, Sistema de Informações Ambulatoriais do SUS (SIA/SUS), Sistema de Informações Hospitalares (SIH/SUS) e Associação Brasileira de Bancos de Sangue (ABBS).

Brazil

• Funding:
  – Public (SUS):
    • Therapeutic R$ 180,00 (~USD: $ 75,82);
    • Platelets donation: R$ 508,00 (~USD $ 214,00);
    • 1 USD = R$ 2,378;

• Companies / Equipments:
  – Fresenius: AS 104/Com.Tec;
  – Haemonetics: MCSs;
  – Terumo: Spectra/Optia/Trima.
Brazil

Blood Donations: Public X Private
(2013)

No official data
Brazil

Market for Apheresis – Kits: Total: 72,662
(2013)

No official data
Brazil

Market share – Kits: Total: 72,662 (2013)

No official data
Brazil

Market share - Customer Number (Platelets)

Total: 106
(2013)

No official data
Brazil

Market share – Platelet Kits: Total: 55,426 (2013)

No official data
Brazil

Market share – Plasmapheresis Kits: Total: 8,288 (2013)

No official data
Brazil

Market share – Double PRBC Kits: Total: 5,357 (2013)

No official data
Brazil

Market share – PBPC Kits: Total: 3,591 (2013)

No official data
Brazil


No official data
Argentina

- Apheresis donation per year:
  - Platelets: 11,500;
- Blood Centers:
  - Data not obtained;
- Funding:
  - Data not obtained;
- Companies / Equipments:
  - Terumo sold in 2013, 10,000 platelets Kits and 0 PRBC Kits.
Bolivia

- Apheresis donation per year:
  - Data not obtained;
- Blood Centers:
  - Data not obtained;
- Funding:
  - Data not obtained;
- Companies / Equipments:
  - Data not obtained.
Chile

- Apheresis donation per year: Platelets: 9,000;
- Blood Centers: Data not obtained;
- Funding:
  - Reimbursement: USD: 250,00 per procedure;
- Companies / Equipments:
  - Equipments: Total – 47:
    - Fresenius Com.Tec: 2; Amicus: 2;
    - Haemonetics MCS Plus: 13;
    - Terumo: TRIMA: 7; Optia: 4; Cobe Spectra: 18;
    - Terakos: 1.
  - Terumo costumers Kits per year:
    - 1,800 Platelets / 15 PRBC / 200 PBPC;
    - Multiple components and granulocytes: data not obtained.
Colombia

- Apheresis donation per year:
  - 20,000 platelets, 1,000 double RBC and 550 PBPC.
- Blood Centers:
  - 94;
- Funding:
  - Public: Included in the tariff; The client can invoice the Kits to the healthy system.
- Companies / Equipments:
  - Terumo sold in 2013, 10,000 platelets Kits and 1,000 PRBC Kits.

No official data
Ecuador

• Apheresis donation per year:  
  – 3,000 platelets and 60 PBPC.
• Blood Centers:  
  – 8 public and 17 private;
• Funding:  
  – Public: Reimbursement of $315.00 per procedure;
  – Private: Each patient pays by procedure
• Companies / Equipments:  
  – Data not obtained.

No official data
Guyana

- **Apheresis donation per year:**
  - Data not obtained;
- **Blood Centers:**
  - Data not obtained;
- **Funding:**
  - Data not obtained;
- **Companies / Equipments:**
  - Data not obtained.
Paraguay

- Apheresis donation per year:
  - Data not obtained;
- Blood Centers:
  - Data not obtained;
- Funding:
  - Data not obtained;
- Companies / Equipments:
  - Data not obtained.
Peru

- **Apheresis donation per year:**
  - 12,000 platelets;
- **Blood Centers:**
  - 155 public and 51 private;
- **Funding:**
  - Data not obtained;
- **Companies / Equipments:**
  - Data not obtained.

No official data
Suriname

- Apheresis donation per year:  
  - Data not obtained;
- Blood Centers:  
  - Data not obtained;
- Funding:  
  - Data not obtained;
- Companies / Equipments:  
  - Data not obtained.
Uruguay

• Apheresis donation per year:
  – 2,000 platelets;

• Blood Centers:
  – 74: Public: 38 / Private: 36

• Funding:
  – Data not obtained;

• Companies / Equipments:
  – Terumo sold in 2013, 2,000 platelets Kits and 0 PRBC Kits.

• Others data:

No official data
Venezuela

- Apheresis donation per year:
  - 4,000 platelets;
- Blood Centers:
  - 130 public and 95 private;
- Funding:
  - Data not obtained;
- Companies / Equipments:
  - Terumo sold in 2013, 1,500 platelets Kits and 0 PRBC Kits.
Apheresis Activity in Venezuela

Christiane Saltiel*

Banco Metropolitano de Sangre (Metropolitan Blood Bank), Caracas, Venezuela

Interest for apheresis activity has been growing in Venezuela. In 1976 there were only a few devices; in 2003, 80 apheresis machines performed 27,675 donor apheresis procedures and 547 therapeutic procedures countrywide. We report the activity at the Metropolitan Blood Bank (the largest one of the country) in the period 1999–2003: 597 therapeutic procedures were performed in 171 patients, during 212 crisis episodes. The average age was 38 ± 16 years, 65% male and 35% female. Most of the therapeutic procedures were therapeutic plasma exchange for hematology diseases (mainly thrombotic thrombocytopenic purpura and hemophilia inhibitors), including 184 therapeutic procedures with the Autopheresis-C (Baxter Healthcare Corp., Deerfield, IL). Most common adverse effects (3.9%) were hypotension and allergic reactions to the plasma. J. Clin. Apheresis 20: 95–100, 2005 © 2005 Wiley-Liss, Inc.
“We have made every possible efforts to Popular Power Ministry staff for Health to obtain the statistics data of Transfusion Medicine and specifically for Apheresis procedures, but we have not received any response. Given the high political polarity, staffs do not want to give data for any Scientific Society and its are only managed for their own statistics. Unfortunately we can not provide data for the presentation. Best Regards,”
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Remember: Literature Review

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10 years later: Its still the same!!!
Considerations, Conclusions and Suggestions

• Despite the difficulties, such:
  – Lack of official information;
  – 3 different languages: Portuguese, English and Spanish;
  – Absence of official data;
  – Hard work for data collection, among others;

• The challenge was accepted, due to:
  – Curiosity;
  – Importance of organizing and encouraging the inclusion of apheresis surveys in official Institutions and Associations (WHO, PAHO, AABB, ASFA, WAA, ABHH, etc).
Thanks and acknowledgments

- Our extensive recognition is directed to:

  - Companies Fresenius, Haemonetics and Terumo, on behalf of the people who provided the data;

  - Doctors, Technicians and Friends from Spanish speaking countries of South America for their cooperation in giving opinions, shared anxieties and for helping us in every way;

  - Friends from Brazil who went to great lengths to provide data and arguments for the viability of this presentation;

  - You, listeners, for understanding data limitations and tolerance to my English mistakes;

  - The committee organizing of this event, for the confidence in inviting me to this presentation.
Thanks: marquesj@unicamp.br