Conflict of Interest Disclosure

My primary conflict of interest comes from the work of the Center for Transfusion Medicine Research and include Grants and Research Support from:

- TerumoBCT, Inc., Lakewood, CO
- New Health Sciences, Inc., Bethesda, MD
- Pall Corp, Port Washington, NY
- Fresenius-Kabi, Bad Hamburg, Germany
- Cerus, Concord, CA
- Fenwal, Inc., Lake Zurich, IL
- Terumo, Inc., Elkton, MD
- Hemerus Medical, LLC, Saint Paul, MN
- BASF Corp, Houston, TX
- BCSI, Seattle, WA
- Therakos, Exton, PA
- As well as the Department of Defense

No products and/or services of any of these companies will be discussed today.
Challenge..

- How many of you believe that apheresis medicine will exist in 20 years?

- I strongly encourage you to work on the recommendations we will discuss today if you do not want that to be the case...
APHERESIS AS TECHNOLOGY
System evolution (S-curve)

Treatment (Apheresis) is one drug away from disappearance
Patterns of technological innovation in biotechnology

RPV - resources, processes, and values from Clayton Christensen’s Theory

Somatic Gene Therapy (SGT)

Monoclonal Antibodies Technology (MAT)

Publications in Apheresis

Published articles with “apheresis” present using http://www.ncbi.nlm.nih.gov/pubmed
Gartner Hype Cycle

- Peak of Inflated Expectations
- Plateau of Productivity
- Slope of Enlightenment
- Trough of Disillusionment
- Technology Trigger
Apheresis Devices Manufacturers’ Possible Dilemma…

**Diagram:**
- **Orange Line:** Increasing marginal patent value
- **Red Line:** Risk
- **Dotted Lines:** Flat value fluctuations
- **Arrows:**
  - Discovery
  - Trial run
  - Phase 1
  - Phase 2
  - Phase 3
  - Expiration of patent protection

**Legend:**
- **1–2 years**
- **2–4 years**
- **4–8 years**
- **1–2 years**

**Note:**
www.nature.com
APHERESIS RESEARCH...
Apheresis Medicine – the challenge

- The literature in apheresis medicine is often limited to case reports and case series (observational studies).

- Out of 51 indications in JCA Special Issue 2007 (category I-III):
  - 19 has RCT* of mixed quality
  - 32 has NO RCTs*

- Out of 59 indications in JCA Special Issue 2010 (category I-III):
  - 28 has RCT* of mixed quality
  - 31 has NO RCTs*

- At the ASFA Annual Meetings it has been very apparent that apheresis medicine lacks the high quality of RCTs.

* RCT – Randomized Controlled Trial

Szczepiorkowski ZM et al, J Clin Apheresis, 2010;25(3):83-177
Who can we blame…but ourselves.

State of the Science in Transfusion Medicine 2009

ORGANIZING COMMITTEE
CHAIR: Dr. M. Blajchman

SUBCOMMITTEES ARE ESTABLISHED BY ORGANIZING COMMITTEE

SUBCOMMITTEE IDENTIFIES TOPICS FOR RCT AND GENERATES THE PROPOSAL

DRAFT I

COMMENTS FROM THE SUBCOMMITTEE

DRAFT II

REVIEW BY THE EXTERNAL PANEL AND ORGANIZING COMMITTEE: CHANGES MADE BY THE SUBCOMMITTEE

FINAL

REVIEW BY THE EXTERNAL PANEL

PRESENTATION OF THE PROPOSALS AT THE SOS SYMPOSIUM (9/14-15/09)

EXTERNAL PANEL
Dr. H. Klein (Chair)
Dr. P. Ness
Dr. C. Hillyer
Dr. N. Luban
Dr. P. Toy

MANUSCRIPT COMPILED TO BE PUBLISHED IN 2010

REVIEW BY THE EXTERNAL PANEL, DISCUSSION AND FINAL RECOMMENDATIONS TO THE NHLBI AND SUBCOMMITTEES

NHLBI TO DEVELOP FUNDING PRIORITIES FOR 5 TO 10 YEAR PERIOD
## The SOS Subcommittees

<table>
<thead>
<tr>
<th>Transfusion Medicine</th>
<th>Hemostasis/Thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet Products</td>
<td>Platelet Disorders: Bleeding</td>
</tr>
<tr>
<td>ICU/Trauma</td>
<td>Platelet Disorders: Thrombosis</td>
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<tr>
<td>Pediatric and Neonatal</td>
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<tr>
<td>Medical</td>
<td>Thrombosis: Therapy</td>
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<tr>
<td>Therapeutic Apheresis, Plasma, Cryoprecipitate</td>
<td>Thrombosis: Prevention</td>
</tr>
<tr>
<td>RBC: Conservation and Management</td>
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<tr>
<td>CONSIDERED APHERESIS STUDIES</td>
<td>F/U</td>
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<tr>
<td>---------------------------------------------------------------------------------------------</td>
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<tr>
<td>Impact of leukocytapheresis on short term and long term outcome of patients with <strong>hyperleukocytosis</strong>.</td>
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<tr>
<td>Simple phlebotomy vs two RBC apheresis in management of patients with <strong>hemochromatosis</strong>.</td>
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<tr>
<td>Simple plasma infusion vs plasma exchange in patients with <strong>acute liver failure</strong>.</td>
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<tr>
<td>Erythrocytapheresis vs simple transfusion in patients with severe <strong>babesiosis/malaria</strong></td>
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<tr>
<td>Extracorporeal photopheresis vs. other modalities in patients with <strong>chronic GvHD</strong>.</td>
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<tr>
<td>Plasma exchange vs. symptomatic treatment in the elderly patients with <strong>hemolytic uremic syndrome</strong> (ADAMTS-13 WNL).</td>
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<tr>
<td>CONSIDERED APHERESIS STUDIES</td>
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<tr>
<td>Plasma exchange vs. other treatment in patients with <strong>Devic’s syndrome</strong> (<strong>neuromyelitis optica</strong>).</td>
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<tr>
<td>Plasma exchange vs. other treatment in patients with <strong>paraproteinemic polyneuropathies</strong>.</td>
<td></td>
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<tr>
<td>Plasma exchange in <strong>MOF 2/2 sepsis</strong> (other groups are looking at this in pediatric population).</td>
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<tr>
<td>Plasma exchange vs. no plasma exchange in treatment of patients with <strong>Goodpasture’s syndrome</strong> (+/- alveolar hemorrhage) (one small RCT performed).</td>
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<tr>
<td><strong>Management of TTP</strong> (recombinant products; replacement fluids…).</td>
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</table>
# Final Proposals from the Subcommittee:

<table>
<thead>
<tr>
<th>Study #</th>
<th>Title</th>
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<tr>
<td>TM 113</td>
<td>Plasma in Critical Care: a sequentially stratified, non-inferiority trial of Plasma versus No-treatment for critical care patients undergoing invasive bedside procedures</td>
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<tr>
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</tbody>
</table>
Winners and (sore) Losers…
Conclusions from 2009

- The State of the Science Symposium has addressed many topics of interest to transfusion medicine and hemostasis/thrombosis community.

- Though, the apheresis proposals were not considered in the top tier; there is increased awareness of importance of this area in future clinical trials and some funding mechanisms do exist (e.g. R43).

- The indications for therapeutic apheresis for many (rare) diseases are difficult to study in the context of RCT.
No failure is big enough to become a pessimist…

"NEVER, NEVER, NEVER, NEVER GIVE UP."
SIR WINSTON CHURCHILL

www.zazzle.com
nedhardy.com
Here comes 2011/2012…and somewhere NE from NYC.

Yan Yun Wu, MD, PhD
And
A Few Helpers…
National Institutes of Health
State of Science Symposium
in Therapeutic Apheresis

National Heart Lung and Blood Institute
People Science Health

Fenwal

HAEMONETICS®
The Blood Management Company

TERUMO BCT
Unlocking the Potential of Blood

ASEA
American Society for Apheresis
PROCESS
NHLBI Staff

Steering Committee

Organizing Committee

Writing Committees

Suggestions / Overall Directions

Process design / Project supervision

Proposals
Summary
Presentations

Spring 2012
Summer 2012
Fall 2012
STEERING COMMITTEE
Paul Ness
Edward Snyder
Harvey Klein
Jerry Gottschall
Steven Spitalnik
Zbigniew M. Szczepiorkowski
YanYun Wu
Phyllis Mitchell (NHLBI)
Simone Glynn (NHLBI)
ORGANIZING COMMITTEE
Laura Cooling
Jerome Gottschall
Joseph Kiss
Harvey G. Klein
Michael Linenberger
Paul Ness
Anand Padmanabhan
Bruce Sachais
Joseph Schwartz
Edward Snyder
Zbigniew M. Szczepiorkowski, Yanyun Wu

Winter / Overall Directions
Spring / Project supervision
**Suggestions / Overall Directions**

**Process design / Project supervision**

**CARDIOVASCULAR**
Nora Ratcliffe,
Patrick Moriarty,
Jeffrey L. Winters,
Leslie Cooper,
Yanyun Wu

**NEPHROLOGY**
Edward Wong,
Rasheed Balogun,
Ray Patricio,
Mark E Williams,
Chisa Yamada,
Bruce Sachais

**PARASITOLOGY**
Peter Krause,
Edouard Vannier,
Yanyun Wu,
Edward Snyder

**MOF, INFECTION and OTHER**
Steven Sloan,
Nicole A. Aqui,
Nancy Dunbar,
Chester Andrzejewski,
Joseph E. Kiss,
Joseph Carcillo,
Yara A Park,
Yanyun Wu

**NEUROLOGY**
Shanna M Morgan,
Beth Shaz,
Meghan Delaney,
Erin Meyer,
Katerina Pavenski,
Zbigniew M Szczepiorkowski

**Fall 2012**
PHOTOPHERESIS
Nora Ratcliffe,
Nancy Dunbar,
Brenda J. Grossman,
Jill Adamski,
Jennifer Schneiderman,
Steven Sloan,
John E. Levine,
Jill Adamski,
Michael Linenberger,
Joseph Schwartz,
Beth Shaz,
Nicole A. Aqui,
Yanyun Wu,
Zbigniew M. Szczepiorkowski,
Barbara Jean Bryant,
Anna Koo,
Shanna M. Morgan,
Laura Cooling

HEMATOLOGY/ONCOLOGY
Anand Padmanabhan,
Laura Connely-Smith,
Brenda J. Grossman,
John E. Levine,
Jennifer Schneiderman,
Joseph Schwartz,
Bruce Sachais,
Michael Linenberger

SUGGESTIONS / OVERALL DIRECTIONS

Summer 2012
Fall 2012
State of the Science in Apheresis (NHLBI Sponsored)

Organ System
1. Cardiovascular
2. Heme-Onc
3. Rheumatologic
4. Renal
5. Neurological
6. Others

Pathomechanism
- Antibody Immune Mechanism
- Cellular Immune Mechanism
- Inherited diseases (removal of the substance from the bloodstream; e.g. hypercholesterolemia)
- Removal of cells from the circulation (e.g. exchange transfusion; removal abnormal cells)
- Others

Technology
- Plasma exchange; Immunoabsorption; Photopheresis
- LDL-Cholesterol apheresis; Pediatric consideration
- Others
Discussion questions:

- What are the scientific opportunities in therapeutic apheresis?

- What are the challenges/barriers to increase therapeutic Apheresis research?
Discussion questions:

- How to encourage more researchers in this area?

- What are the investigators’ perspectives on applying for grants, review process, collaboration?
Outcome Questions:

- Recommendations on key scientific priorities in Therapeutic Apheresis research

- Recommendations from the scientific community to Develop NHLBI Therapeutic Apheresis program
Outcome Questions:
- Recommendations on how to enhance collaboration among different scientific communities about Therapeutic Apheresis.
- Recommendations on strategies to successfully implement Therapeutic Apheresis research.
Outcome Questions:

- Recommendations on benchmarks to measure progress.
Preparation…and the day of reckoning…

- Participants were invited individually, and additional participants were invited based on the available space.
- Each participant at the SOS meeting received a PDF file with all proposals and presentations (605 pages…)
- Each writing committee had an allotted time for presentations and discussion…
DAY 1
<table>
<thead>
<tr>
<th>TIME</th>
<th>PROGRAM INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30-9:00</td>
<td>Opening Remarks [5 min]:</td>
</tr>
<tr>
<td></td>
<td>Phyllis Mitchell, MSc, Program Director TMCTB</td>
</tr>
<tr>
<td></td>
<td>Workgroup formation:</td>
</tr>
<tr>
<td></td>
<td>Yanyun Wu, MD, PhD, Co-Chair</td>
</tr>
<tr>
<td></td>
<td>Zbigniew &quot;Ziggy&quot; M. Szczepiorkowski, MD, PhD, Co-Chair</td>
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<tr>
<td></td>
<td>Acknowledgement:</td>
</tr>
<tr>
<td></td>
<td>Edward Snyder, MD</td>
</tr>
<tr>
<td></td>
<td>Welcome and Introduction of Keynote Speaker:</td>
</tr>
<tr>
<td></td>
<td>W. Keith Hoots, MD, Director Division of Blood Diseases and Resources</td>
</tr>
<tr>
<td></td>
<td>Keynote [20 min]:</td>
</tr>
<tr>
<td></td>
<td>Harvey Klein, MD</td>
</tr>
</tbody>
</table>
Cardiovascular Diseases

Moderator: Harvey Klein, MD

1. Immunologic predictors of left ventricular function following Protein A immunoadsorption for the treatment of acute myocarditis
   Speaker: Jeffrey L. Winters, MD

2. Lipid-apheresis for the Treatment of Peripheral Arterial Disease
   Speaker: Patrick M. Moriarty, MD, subgroup co-chair
1. Use of TPE in Patients with anti-PF4/heparin antibodies
   Speaker: Bruce Sachais, MD, PhD

2. Erythrocytapheresis (RBCX) in the management of pain in Sickle Cell Disease (SCD)
   Speaker: Anand Padmanabhan, MD, PhD, subgroup chair

3. A Prospective Study of Leukocytapheresis vs. Cytoreductive Chemotherapy in the Urgent Management of Adult Hyperleukocytic Acute Myeloid Leukemia
   Speaker: Laura Connelly-Smith MBBCh, DM
Photopheresis

Moderator: Edward Snyder, MD

1. Summary of ECP.
   Speaker: Steven Sloan, MD

2. State of the Science: Clinical trials using Extracorporeal Photopheresis for Treatment and Prevention of Graft-Versus-Host Disease following allogeneic hematopoietic cell transplant
   Speaker: Carrie Kitko, MD

3. Extracorporeal Photopheresis: Opportunities for Therapy
   Speaker: Nora Ratcliffe, MD, subgroup chair
Multi-organ failure, infections and other conditions

Moderator: Jerome Gottschall, MD

1. Introduction to apheresis to treat other disease states
   Speaker: Steven Sloan, MD, PhD, subgroup chair

2. Randomized trial of plasma exchange in severe sepsis with Thrombocytopenia-associated multisystem organ failure (TAMOF).
   Speaker: Joseph Carillo, MD

3. Apheresis Therapy for Malignant Pertussis.
   Speaker: Yara Park, MD

4. Assessment of Therapeutic Plasma Exchange (TPE) in the Management of Patients with Chronic Idiopathic Urticaria (CIU)
   Speaker: Chester Andrzejewski, PhD, MD

5. Babesiosis
   Speaker: Peter Krause, MD
Renal Diseases

Moderator: Jerome Gottschall, MD

1. Introduction
   Speaker: Edward Wong MD, subgroup chair

2. Randomized Clinical Trial of Plasma Exchange In Patients Undergoing Desensitization with High Dose IV-Ig for High Immunologic Risk Renal Transplantation
   Speaker: Rasheed Balogun, MD

3. Defining the Role of Therapeutic Plasma Exchange in Atypical Hemolytic Uremic Syndrome Treated with Eculizumab
   Speaker: Mark E. Williams, MD

4. Feasibility of Apheresis Using Adsorption Columns for Desensitization/Antibody Mediated Rejection in Renal Transplant Recipients
   Speaker: Chisa Yamada, MD

5. Randomized Clinical Trial of Early Plasma Exchange in Focal Segmental Glomerulosclerosis Patients in Renal Transplantation. Prospective Biomarker Study
   Speaker: Edward Wong, MD, subgroup chair
1. Introduction to Neurologic Principles and Challenges
   Speaker: Shanna Morgan, MD, subgroup chair

2. Neuromyelitis optica (NMO):
   a. Use of TPE and steroids day one versus steroids alone day one for acute NMO attacks.
   b. Use of TPE as maintenance therapy in NMO.
   Speaker: Shanna Morgan, MD, subgroup chair

3. Randomized controlled trial of IVIG versus TPE for acute myasthenia gravis associated with anti-MuSK
   Speaker: Beth Shaz, MD

4. Efficacy of TPE vs. intravenous gammaglobulin (IVIG) in treatment of severe acute disseminated encephalomyelitis (ADEM): A Multicenter Prospective Observational Study.
   Speakers: Meghan Delaney, DO, MPH and Katerina Pavenski, MD FRCPC.

5. Rare Neurologic Diseases Registry and Biorepository.
   Speaker: Erin Meyer, DO, MPH
Day 1 “what your thoughts…”

State of the Science Symposium in Therapeutic Apheresis; Natcher Conference Center; Nov 28-29, 2012

Please score each presentation after discussion and return to registration desk prior to leaving at the end of day 1. The results will be collated and presented on day 2. Use scale of 1 to 9 with 1 being the highest and 9 the lowest level of support.

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Author/Presenter</th>
<th>Medical Significance(^1) (1-9)</th>
<th>Feasibility(^2) (1-9)</th>
<th>Overall Enthusiasm(^3) (1-9)</th>
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</thead>
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<td>About something</td>
<td>Somebody</td>
<td>3</td>
<td>5</td>
<td>8</td>
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<tr>
<td>CARDIOVASCULAR</td>
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<tr>
<td>Myocarditis</td>
<td>Winters</td>
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<tr>
<td>PVD diabetes</td>
<td>Moriarty</td>
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</table>

1) medical significance addresses the utility of therapeutic apheresis in treatment of the discussed medical condition; 2) feasibility addresses the possibility that the study can be performed (exclude financial constraints); 3) overall enthusiasm addresses your personal view on the value of this proposal.
DAY 2
<table>
<thead>
<tr>
<th>TIME</th>
<th>PROGRAM INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30-9:50</td>
<td>Open forum discussion with a focus on research prioritization</td>
</tr>
<tr>
<td>Moderator:</td>
<td>Paul Ness, MD</td>
</tr>
<tr>
<td>9:50-10:05</td>
<td>Break</td>
</tr>
<tr>
<td>10:05-11:15</td>
<td>Open forum discussion with a focus on implementation</td>
</tr>
<tr>
<td>Moderator:</td>
<td>Paul Ness, MD</td>
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<tr>
<td>11:15-11:35</td>
<td>Break</td>
</tr>
<tr>
<td>11:35-11:58</td>
<td>Recommendation to National Heart, Lung and Blood Institute</td>
</tr>
<tr>
<td>Speaker:</td>
<td>Paul Ness, MD</td>
</tr>
<tr>
<td>11:58-12:00</td>
<td>Concluding remarks</td>
</tr>
<tr>
<td>Speaker:</td>
<td>Zbigniew &quot;Ziggy&quot; M. Szczepiorkowski, MD, PhD, Co-Chair</td>
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</tbody>
</table>
40 submitted responses; over 2,500 entries
16 (40%) respondents provided comments
Score of 1 – the highest impact
Score of 9 – the lowest impact
Summary Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Highest Score (mean)</th>
<th>Lowest Score (mean)</th>
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</tr>
<tr>
<td>Feasibility</td>
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<td>Overall Enthusiasm</td>
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<td>2.64</td>
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<tr>
<td>Name</td>
<td>Mean</td>
<td>SD</td>
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<td>--------------------------------------------------</td>
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<tr>
<td>Myocarditis</td>
<td>3.36</td>
<td>3.98</td>
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<td>PVD diabetes</td>
<td>2.38</td>
<td>4.05</td>
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<tr>
<td>Heparin Induced Thrombocytopenia</td>
<td>3.39</td>
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<td>Sickle Cell Disease (RBCX)</td>
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<td>Hyperleukocytosis</td>
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<td>Lung Transplantation</td>
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<td>Autoimmune diseases</td>
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<td>4.57</td>
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<tr>
<td>Vasculitis</td>
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<td>Heart Transplantation</td>
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<td>2.68</td>
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<td>4.11</td>
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<tr>
<td>Sickle Cell Disease (RBCX)</td>
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<tr>
<td>Hyperleukocytosis</td>
<td>4.10</td>
<td>4.28</td>
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<td>2.64</td>
<td>4.38</td>
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<td>Lung Transplantation</td>
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<td>4.45</td>
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<tr>
<td>Autoimmune diseases</td>
<td>4.30</td>
<td>4.54</td>
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<tr>
<td>Vasculitis</td>
<td>4.79</td>
<td>4.64</td>
</tr>
<tr>
<td>Heart Transplantation</td>
<td>3.91</td>
<td>4.75</td>
</tr>
</tbody>
</table>
Preliminary Conclusions

- There has been a large heterogeneity of the scores.
- The scores reflect high medical significance, complex feasibility and diversity of the presented topics.
- Multiple comments have very interesting suggestions which would be considered by the steering committee.
VERY PRODUCTIVE DISCUSSION...INFORMED THE NEXT STEPS...
Steering Committee

Organizing Committee

Writing Committees

Summary for NHLBI

Manuscript preparations

Manuscript preparation

Winter 2013  Spring 2013  Summer 2013
State of the Science in Apheresis (NHLBI Sponsored)

- **RECOMMENDATION 1**
  - Establish Apheresis Consortia

- **RECOMMENDATION 2**
  - Funding for Apheresis Medicine Research

- **RECOMMENDATION 3**
  - Opportunities for Young Investigators in Apheresis Medicine

State of the Science Symposium in Therapeutic Apheresis

Executive Summary from an NHLBI Working Group, November 28 - 29, 2012

The field of Apheresis Medicine incorporates multiple disease conditions, diverse medical specialties, multiple technology platforms, and multiple settings of care delivery. These specific circumstances have created the current situation where research in apheresis applications has been fragmented and insufficient to provide answers to basic scientific questions such as mechanism, relevance, appropriateness, efficacy and comparative value in comparison to other therapeutic modalities. The NHLBI sponsored Working Group for Therapeutic Apheresis formulated the following recommendations for consideration by NHLBI for implementation to expand our understanding of the role of apheresis in provision of the best care to patients.

Recommendation 1. There is a need to establish consortia for Apheresis Medicine to facilitate networking, information exchange and research collaboration among investigators, including junior investigators. These consortia would perform basic science and clinical research and investigate the best pathways to develop biorepositories and to establish biorepositories.

Justification: The creation of one or more Research Consortia devoted to research in Apheresis Medicine would allow for the establishment and support of a core group of investigators and institutions representing key specialty areas across the spectrum of Apheresis Medicine. An initial focus would be translational research priorities. In addition, we believe that a strong U.S. based consortium would facilitate participation of international investigators and societies, which would improve patient accrual on studies, especially these patients with rare disorders or who have rare indications for apheresis therapy. Such a group would significantly enhance the likelihood of completing high quality studies.

There is increasing national interest in developing rare registries, bio-registries and data-registries. Very often such efforts do not include information regarding apheresis nor do they consider apheresis information as being important data points. A centralized, well organized and sustainable registry, either established and/or new for Apheresis Medicine, would be of great value to study the outcomes of therapeutic apheresis for different disease conditions. This need is particularly relevant for rare disorders and rare indications, for which a pilot effort is already being undertaken and sponsored by ASHA- the American Society for Apheresis. It is likely that formal or informal consortia could be formed as a result of Recommendation 1. Groups of established and junior investigators can coalesce around particular disease processes or particular therapeutic approaches to develop patient registries and, ideally, biorepositories. These data could then serve as source material for pilot projects, reviews, case series evaluation of practice patterns, guideline development, case analyses and opportunities to formulate mentored, prospective research projects with high clinical impact. A centralized Therapeutic Apheresis Registry could also avoid costly unnecessary duplication of efforts in this field (e.g., with multiple registries for the same disease.

http://www.nhlbi.nih.gov/meetings/workshops/therapeutic_apheresis.htm
Recommendation 1

There is a need to establish consortia for Apheresis Medicine to facilitate networking, information exchange and research collaboration among investigators, including junior investigators. These consortia would perform basic science and clinical research and investigate the best pathways to develop biorepositories and to establish data registries.
Recommendation 2

The discipline of Apheresis Medicine is complex, dealing with a wide range of diseases and organ systems. Currently there is no “home” for grant applications in Apheresis Medicine. There is a need to specifically charge an existing Study Section, or develop specific funding opportunities to include Apheresis Medicine as it integrates within different medical specialties, e.g., renal, neurology, dermatology, oncology and infectious diseases.

Apheresis-oriented proposals should be encouraged and welcome. In the absence of being assigned to a standing Study Section, it would be important to establish ad hoc review panels for applications that address research in Apheresis Medicine or to review potential future Apheresis Medicine initiatives developed by one or more Institutes.
There is also merit in the concept of establishing collaborative programs that span several Institutes (e.g. NEI, NCI, NIAID, NIBIB, NIDDK, NINDS, NINR, etc), because they are each, homes for the different disease entities treated by apheresis. NHLBI could lead this effort considering it is home for transfusion medicine applications, apheresis medicine being one of transfusion medicine closely related medical specialty. Federal funding of Apheresis Medicine, would provide a strong stimulus for researchers and clinicians in other subspecialties, to collaborate with Apheresis Medicine specialists and in so doing, enhance the quality and depth of the translational research effort.
There is a need to promote Apheresis Medicine as a viable field of research for junior and established investigators. The influx of well-trained junior investigators committed to research in Apheresis Medicine is critical and training grants or mentorship grants that include Apheresis Medicine, should be investigated. Utilization of and integration with existing educational/training programs, such as T32 grants, K23/K24/K25 grants, institutional K12 awards and CTSA educational programs, should be explored.
APHERESIS IN THE FUTURE
THE OPPORTUNITIES...
Apheresis

Invest in Research?

Published articles with “apheresis” present using http://www.ncbi.nlm.nih.gov/pubmed
Gartner Hype Cycle

Peak of Inflated Expectations
Plateau of Productivity
Slope of Enlightenment
Trough of Disillusionment
Technology Trigger

Apheresis is one drug away from disappearance
Two roads diverged in a wood, and I
I took the one less traveled by,
And that has made all the difference.
– Robert Frost, The Road Not Taken
Acknowledgments

For all of those who worked tirelessly to find the appropriate recognition and place for apheresis medicine in the betterment of patients’ outcomes.
ABBREVIATED SWOT ANALYSIS OF THERAPEUTIC APHERESIS

**STRENGTHS**
- rapid removal of substances / cells
- (relatively) low cost
- low rate of adverse reactions

**WEAKNESSES**
- central venous access
- perception of high complication rate and cost
- limited technological progress
- low specificity of treatment

**OPPORTUNITIES**
- standardization of clinical approaches
- EBM in clinical practice
- improved understanding of disease pathophysiology

**THREATS**
- new therapies (e.g. small molecules, recombinant molecules)
- improved understanding of pathophysiology