



INFUSION

Mid-Atlantic Association of Blood Banks

President's Message



Dear MAABB Members,

Greetings! About this time of year my mind fills with thoughts of spring, spring break and of course the MAABB Annual Meeting. This year our meeting is March 11 – 12, earlier than last year. We are also returning to the Anne Arundel Medical Center in Annapolis, Maryland and partnering with Microbiology.

The Board has developed a fantastic slate of speakers. You can read more about their topics in this issue of Infusion. The topics are current and cutting edge. Supervisors and technologist at all levels will be informed and challenged. Personally, I look forward to hearing about the current Blood Bank topics through the meeting.

Our Annual Meeting also provides opportunities for us to gather, compare notes and catch up. It's wonderful to see faces I have not seen since last year. I encourage you to attend the business meeting held on Saturday morning. We are always looking for individuals to add to our collective hands. If you are not already a member, consider joining. If you are a member, consider going to the next level and becoming a state delegate. You can be the voice of the membership during key decision making.

Exhibitors love our meeting. They get to spend quality time with you and you with them. We have 17 confirmed exhibitors attending, so make sure you visit each during the meeting.

Finally, the AABB Assessor Training will be taking place on Thursday March 10, prior to the annual meeting, Contact the AABB directly for additional information.

I look forward to seeing all of you at the meeting. Come up and say hi!!

Michele Carter Hunt
Manager of Instruction, Fundamentals and Continuing Education
Biomedical Services

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What Are Cellular Therapy Laboratories Doing in 2011

Jo Procter, MEd, BS, MT & SBB(ASCP), CQA(ASQ)

Many have seen the beating heart on a scaffold that scientists in regenerative medicine have produced. See The New York Times article "Team Creates Rat Heart Using Cells of Baby Rats by Lawrence K. Altman published January 14, 2008 at <http://www.nytimes.com/2008/01/14/health/14heart.html>. The pictures can be viewed at <http://singularityhub.com/2009/06/23/stem-cells-used-to-grow-hearts-cool-new-pics-and-vid/#>. Regenerative medicine is an emerging and exciting field that has started to offer new solutions for repairing damaged or diseased tissues or organs in humans. According to Regenerative Medicine.net at <http://regenerativemedicine.net>, regenerative medicine is an acceleration of the healing process to fully restore the health of damaged tissues and organs. There are four concentrations in the field: 1) Medical devices and artificial organs 2) Tissue engineering and biomaterials 3) Cellular therapies 4) Clinical translation that uses the therapies in active trials. So, what are we doing in cellular therapy laboratories today?

In the area of hematopoietic progenitor cell (HPC) transplant, we are looking to minimize the preparative or conditioning regimen for the patient to just the right mix of chemotherapeutic agents with or without radiation to allow for a pre-determined dose of CD34+ hematopoietic progenitor cells to fully engraft without too many CD3+ lymphocytes to cause severe graft versus host disease, but allow for graft versus leukemia effect if needed. HPC transplants are being used to treat many diseases and in the case of acute myeloid leukemia in children with HLA-matched siblings have become the treatment of choice. See <http://emedicine.medscape.com/article/208954-overview> for an excellent review article by Venkata Samavedi and coauthor, Ronald A. Sacher updated on 12/29/10. In other diseases such as sickle cell anemia, HPC transplant is a potential cure but we are still looking for the sure cure that may be found with gene transduction (transfer of genetic material via a vector) or gene replacement. Since the molecular basis for the disease is known and gene transduction of HPCs using lentiviral vector containing anti-sickling globin genes work in mouse models there is much promise that scientists will learn how to specifically replace the sickle cell gene with a normal copy of the gene. See Gene Replacement Therapy for Sickle Cell Disease and Other Blood Disorders by Tim M. Townes in *Hematology 2008* at <http://asheducationbook.hematologylibrary.org/cgi/content/full/2008/1/193> for more specifics on the technology.

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April 29- 30, 2011

The Mirage Resort & Casino, Las Vegas, NV

For more details and to register visit www.jointmeeting.net

Cellular Therapy : A Little History

Alyce M. McKelvy MA, MT(ASCP), CQA(ASQ)
Quality Assurance Specialist
Charles S. Carter Cellular Therapy Laboratory

Cellular Therapy as a field of study is relatively new. For many years it was loosely regulated under the auspices of the Blood Bank world starting in 1970 with the Public Health Service Act. It wasn't until 1993 and the Interim Rule for Human Tissue Intended for Transplantation: tissue donor testing to prevent HIV and hepatitis that the separation began. Somatic cell therapy and gene therapy products gained regulatory attention in 1993. In 1995 cord blood started its journey toward a FDA licensed product. The definitive break came with the introduction of "The Tissue Rule" in 1997, aka 21 CFR 1270, followed closely by the proposed 21 CFR 1271 in 1998. CFR 1271 was finalized in bits and pieces through 2004. It includes the rulings on Donor Eligibility and the subparts D,E, and F comprise what is known as cGTP, Current Good Tissue Practice for Manufacturers of HCT/Ps (Human Cells, Tissues and Cellular and Tissue Based Products).

AABB published the first separate Standard for Hematopoietic Progenitor Cells in 1996 and further defined Cord Blood requirements with Standards for Cord Blood Services in 2001. That same year FACT also published separate standards for Cellular Therapy products and Cord Blood standards in 2000.

Other Organizations that are instrumental in defining the cellular therapy world are AATB (American Association of Tissue Banks), NMDP (National Marrow Donor Program), CAP (College of American Pathologists) The Joint Commission, ISBT (International Society of Blood Transfusion) and CLIA (Clinical Laboratory Improvement Amendments). Blood bankers will recognize many of these organizations. There are many similarities between cellular therapy and the blood world; the most important, of course, is the focus on Quality. Four areas are paramount: Donors and Donor Safety, Transfusion Transmitted Disease Testing, Requirement for an established Quality Program, and adherence to the Quality System Essentials. Like blood bank facilities, CT facilities come in all shapes and sizes. There are also three distinct functions: collection, processing, and storage/distribution.

But, there are also significant differences. Cellular Therapy (CT), for the most part, is white cell-based rather than red cell-based. Our donors are eligible or ineligible rather than approved or deferred. Noncompliant products can be accepted (providing mandatory documentation is in place). CT products are considered "infused or transplanted" rather than transfused. A big difference is that CT products can be expanded, gene-transduced, or otherwise manipulated. CT products more often focus on HLA typing rather than ABO, although ABO plays a major role in chimerism and engraftment. Only recently have true allogeneic CT products been developed and headed for licensure. Allogeneic in the CT world has been synonymous with directed, mostly from family-related. NMDP has spearheaded the MUD (Matched Unrelated Donor) program, but products are still directed to a specific, identified recipient. Another difference is the preferred storage method. Although blood products can be glycerolized and stored frozen, refrigerated storage is the norm. For CT products, liquid nitrogen storage is the rule rather than the exception for products that are not infused as a fresh product.

But the bottom line for both disciplines is the creation of a final product that is SAFE, PURE, and POTENT!

Notice to MAABB Membership:

The 2011 Membership Business Meeting will take place, Saturday, March 12th at 8:00 am at the Anne Arundel Health Sciences Institute 7th Floor. Please plan to attend.

Does your company need
to target blood banking
and transfusion medicine
professionals?

**Put your
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For advertising information
please contact
info@eventstrategy.net
or 859-264-7822

Hemovigilance – What’s IT All About?

Janice Sigmon, MA, MT(ASCP)SBB, CQA (ASQ)

If you check out “Hemovigilance” on the internet, you will find that it is a term coined in the mid-1990’s for “surveillance of blood safety”. While blood establishments in the United States (U.S.) were challenged by the Food and Drug Administration to change the perspective of blood banks from an extended arm of healthcare to a business enterprise with the “Establishment of Current Good Manufacturing Practices (cGMPs)”, European blood banks were challenged to initiate “hemovigilance” programs, country by country. Motivated by the spread of Human Immunodeficiency Virus (HIV) and variant Creutzfeldt-Jakob Disease (vCJD), European quality assurance programs looked closely at the clinical aspects of transfusion safety. They developed uniform descriptions and definitions for monitoring adverse transfusion events, and they shared statistics and lessons learned to benchmark and to improve transfusion safety. Both U.S. cGMPs and European hemovigilance programs were mandated by their respective governments.

Today, U. S. blood bankers are voluntarily turning their attention to surveillance of patient and donor safety through hemovigilance programs sponsored by the Public Health Service, the Centers of Disease Control, and the AABB. These organizations recommend and encourage blood banks and transfusion services to register their institutions with the National Healthcare Safety Network (NHSN) and the AABB and to make *secure* monthly reports of adverse transfusion and donor events, incidents, and near-misses using uniform descriptions and definitions. They will then be analyzed and published for nation-wide reference benchmarking and safety improvement.

While Hemovigilance is not a nation-wide mandated program in the U.S. in 2011, per the AABB, its relevance has been recognized in a number of states and mandatory reporting is being legislated. The benefits of consistent reporting and measuring of one’s donor and transfusion outcomes against those of like institutions cannot be over-emphasized. Comparable statistics can provide a tangible measure of quality as a recognized standard of care and improvement.

You can learn more about the details of Hemovigilance at the MAABB in Annapolis in March.

What Are Cellular Therapy Laboratories Doing in 2011 - CONTD

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There is also much work being done with adoptive immunotherapy for cancer patients using therapeutic T cells, natural killer cells, dendritic cell vaccines and other cellular vaccines. The challenge for those working in the field of cellular therapy is to continue to advance the technology so that the laboratory can deliver the cell(s) of choice which may be minimally or extensively manipulated at the required dose to cure a specific disease in a specific patient. The efficacy and safety of the cellular therapy needs to be established.

In addition to the science, cellular therapy laboratories are working on preparing a collective body of knowledge for the field of cellular therapy, developing hands on training programs in cell processing laboratories, using standardized nomenclature world wide, developing more closed system processing techniques and standardizing practices used to collect, manufacture, cryopreserve, thaw and evaluate purity, potency and sterility of products. There never seems to be a dull moment in the cellular therapy laboratory!

**2011 MAABB Annual Meeting & MD Microbiology Conference
March 11 - 12, 2011**



**Anne Arundel Health Sciences Pavilion
2001 Medical Parkway Annapolis, Maryland, 21401**

Full Meeting Registration
(Includes all lunches & social events)

Member... \$255.00
Non Member... \$285.00
Student... \$80.00

Single Day Registration
(Includes that day's lunch & social events)

Member... \$125.00
Non Member... \$160.00
Student... \$80.00

Half Day Registration

Member... \$90.00
Non Member... \$125.00
Student... \$80.00

Additional Banquet Tickets \$40.00

Use our secure online Meeting registration. Advance registration is encouraged for the 2011 MAABB Annual Meeting & MD Microbiology Conference! Registration forms and payment **MUST BE RECEIVED** by March 7, 2011. After this date, registrations will only be accepted on-site in Annapolis. To register at the member rate, 2011 MAABB membership must be current or included with your Meeting registration. Printable membership applications can be found at www.maabb.org. Register Online at www.maabb.org >Annual Meeting > Registration Link.

Exhibitors



American Red Cross • BD Diagnostics •
Bio-Rad Laboratories • CaridianBCT •
Cellestis CSL Behring • Creative Testing
Solutions • Kol Bio-Medical Instruments, Inc
• GenesisBPS • MacoPharma USA • Merid-
ian Bioscience, Inc. • Miller-Keystone Blood Cen-
ter • Ortho Clinical Diagnostics • Quotient Biodi-
agnostics, INC • Remel, part of Thermo Fisher
Scientific • Siemens Healthcare Diagnostics

2011 MAABB Annual Meeting & MD Microbiology Conference Program

Day	Time	Track	Event
Thursday, March 10	Full Day		AABB Assessors Training
Friday, March 11	8:00 am - 11:00 am		Exhibit Hall Set-up
	1:00 pm - 2:00 pm	BB	Performing Internal Audits, Judy Sullivan, MS, MT(ASCP)SBB, CQA (ASQ)
	2:00 pm - 3:00 pm	BB	International Blood Safety, CDR Roland Fahie, MSC, USN
	3:00 pm - 3:30 pm		Break
	3:30 pm - 4:30 pm		New Advances in Pediatric Blood Management, Wendy Paul, MD
	4:30 pm - 5:30 pm		Break
	5:30 pm - 6:15 pm	BB & Micro	TBA
	6:15 pm - 7:00 pm	BB & Micro	The Latest Technology for Detecting HIV Infections, Niel Constantine, PhD
	7:00 pm - 7:15 pm		Break
	7:15 pm - 8:00 pm	Micro	Current Technologies for the Diagnosis of Chlamydia trachomatis and Neisseria gonorrhoeae Infections, Charlotte Gaydos, PhD
Saturday, March 12	7:00 am - 8:00 am		Continental Breakfast
	8:00 am - 8:30 am		MAABB Annual Business Meeting & Awards
	8:30 am - 9:30 am	BB	Overview of Blood Group Genetics, Trina Horn, MLT(ASCP),MS
		Micro	Digital Imagery in Microbiology, Joseph Campos, PhD, D(ABMM)
	9:30 am - 9:40 am		Break
	9:40 am - 10:40 am	BB	Nuts & Bolts of Biovigilance, Janice Sigmon, MA, MT(ASCP)SBB, CQA(ASQ)
		Micro	Hey Bugs, Leave Those Kids Alone (Case Presentations), Joseph Campos, PhD, D(ABMM)
	10:40 pm - 11:40 pm	BB	NAT Testing, Kip Kuttner, DO
		Micro	The Microbiology Product and Device Review Process, Ribhi Shavar, PhD, D(ABM)
	11:40 am - 12:30 pm		Lunch - Exhibit Hall Open
	12:30 pm - 1:15 pm	BB	H1N1 Convalescent Plasma, Thomas Luke, MD
		Micro	Topics in Mycology, Sean Zhang, PhD, D(ABMM)
	1:15 pm - 2:00 pm	BB	Top Ten AABB Non-conformances: Avoid the Pitfalls, Judy Sullivan, MS, MT(ASCP)SBB, CQA (ASQ)
		Micro	What We Can Learn from Influenza Surveillance and Anti-Viral Drug Testing, Robert Myers, PhD
	2:00 pm - 2:15 pm		Break
	2:15 pm - 3:00 pm	BB	Blood Support in Afghanistan, COL Francisco J. Rentas, PhD, SBB, MS, USA
		Micro	Current State of the Art and Best Practices for Blood Cultures, Stefan Riedel, MD, PhD, D(ABMM)

2011 Call for Awards



The Charles E. Walter Memorial Award

Presented to a Mid-Atlantic Association of Blood Banks member who has contributed in an exceptional manner to the field as a blood banker, donor recruiter, immunohematologist or teacher. Candidates for this award must be members in good standing and must reside or be employed (currently or at some previous time) within the MAABB region.

The Mary C. Doerr Meritorious Service Award

Presented to a Mid-Atlantic Association of Blood Banks member who has demonstrated outstanding service to the Association. Outstanding service may be shown by longstanding participation on the board of directors or a recognized committee, or by sustained support of the association at the regional level. Candidates must have been members for at least three years and reside or be employed within the MAABB region.

The Cindy Oliver Award

Presented to an individual who has contributed in an extraordinary way to the success of the Mid-Atlantic Association of Blood Banks. Recipients of this award are recognized for a contribution, landmark event, or new endeavor that helps sustain the association or promotes its growth and prosperity. Candidates not required to be members or reside within MAABB region.

I nominate:

Name _____

Address _____

Phone/Email _____

for the following award (check one)

- Charles E. Walter Memorial Award
- Mary C. Doerr Meritorious Service Award
- Cindy Oliver Award

Description of individual's accomplishments and/or service that qualify him/her for the award:

Your Name _____

Address _____

Phone/Email _____

Signature _____

Return completed form by March 4, 2011
Fax to: 280-978-6516

MAABB Officers and Delegates

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DELEGATES

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District of Columbia

Al Langeberg, langebea@gunet.georgetown.edu
Wendy Paul, wmpaul@cnmc.org

Maryland

Janet Cass-Baxter, jcassbaxter@aaahs.org
Judith Sullivan, jsullivan@aabb.org

Virginia

Patrick Francis, pfrancis@its.jnj.com
Joyce A. Westerman, joyce.westerman@langley.af.mil

INFUSION

Editor

Walter Cancel, walter.cancel@medstar.net

Publisher

Strategy Association & Event Management, darnall@eventstrategy.net

Our Mission

It is the goal of the MAABB to become the most effective state/regional association of blood banks. This Association serves the Mid-Atlantic region for continuing professional education in the medical, scientific, technical and administrative aspects of blood banking and transfusion medicine.



Membership Application

(Please type or print clearly)

Name: _____ Degree/Certification: _____
(Last) (First) (MI)

Home Address: _____

City: _____ State: _____ Zip Code: _____

Work Institution: _____

Work Address: _____

City: _____ State: _____ Zip Code: _____

Home Phone: _____ Work Phone: _____

Mobile Phone: _____ Fax: _____

Email: _____

Please provide at least one email address (no more than two) as news of upcoming MAABB events and our Infusion newsletter is now sent via email.

Preferred Mailing Address: Home Work

MAABB Committees:

Committee descriptions are found on the MAABB website: www.maabb.org

Please check the committee(s)/subcommittee(s) on which you are currently serving or are interested in joining:

Member Relations

Education

Annual Meeting

Webpage

Donor Operations

Workshops

Infusion

Technical Workshops (TWC) Seminar Program

Public Relations

Training, Regulatory

Administrative, Quality (TRAQ)

Would you be willing to participate in our workshops as a speaker or instructor? Yes No

Would you be willing to serve as a district/state delegate? Yes No

Membership Category: Individual (\$35.00 per annum) Sustaining (\$65.00 per annum)

Make check payable to **MAABB**.

Please return this form with your payment to:

MAABB
P.O. Box 9374
Silver Spring, MD 20916-9374

MAABB use only:
Member ID: _____

MAABB membership application version 3 (12.09)

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