

2014 #24

June 27, 2014

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ABC Blood Bankers Volunteer Abroad to Improve Blood Regulation, Safety

With a population of about 4.5 million and blood centers collecting about 50,000 units of blood per year, the country of Georgia faces chronic blood shortages, and Georgian blood services face a number of challenges regarding blood regulation and quality standards. Earlier this month, an America's Blood Centers' staff member and an ABC member blood center employee volunteered through the non-profit organization Global Healing to help advance blood safety and availability in Georgia.

Over the last 20 years, Global Healing, a US registered 501(c)(3) that promotes healthcare reform in resource-scarce nations, has helped introduce numerous improvements to the Georgian blood supply, particularly through the establishment of the Jo Ann Medical Center (JAMC) Blood Bank, one of the most modern blood centers in the country. As have other ABC member volunteers before them, ABC's Director of Regulatory Services Ruth Sylvester and Pete Lux, director of Blood Collection at Indiana Blood Center, joined Global Healing in its efforts to help strengthen quality control regulations and provide training on more advanced blood collection techniques to Georgian blood bankers.



During a recent mission trip to Georgia, Ruth Sylvester, ABC's director of Regulatory Services, takes a tour of a Georgian blood bank. (Photo Credit: Tai Power Seeff)

Many technological advances that American blood bankers take for granted are still lacking in Georgia, such as apheresis blood collection, which blood bankers are not trained to perform. Several months ago, Mr. Lux received an e-mail from Global Healing via the ABC International Blood Safety Alliance Listserv requesting a blood banking volunteer with apheresis training experience and a nursing background to teach Georgian medical professionals how to use apheresis collection instruments. He decided to take the opportunity to volunteer.

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OUR SPACE

Matt Granato, ABC's Chief Operating Officer

Meet Us In Seattle

What's not to love about the emerald city? The modern skyline, the futuristic space needle, the coffee culture, the lush green surroundings, and the Cascades – add to that the ABC Summer Meeting – and you've got a perfect summer getaway! We are heading to Seattle and we couldn't be happier with the program. Puget Sound Blood Center will be hosting the 52nd Summer Meeting and we hope that you will meet us there.

The Blood Center Leadership Forum on Aug. 7 will focus on *governance*, a key element of ABC's strategic plan, and *innovation*, one of ABC's core values. Why these two? It became apparent to ABC's Meetings Committee and leadership that the current blood banking environment has led members into exploring new ventures, different organizational structures, and unique partnerships to remain viable. Some have explored traditional mergers or acquisitions, but in many cases the end result is a business partnership that can be defined as nothing less than innovative. But what does innovation in the biomedical field look like? And, how do innovative ideas even get started? What type of corporate environment nurtures it? Dawn Barry and her team from Illumina will answer those questions and give members a starting point to apply innovation to their businesses, whether to survive, thrive or diversify, or simply to reorganize to keep up with the times.

However, these decisions do not happen in a vacuum and certainly not without the blessing of the blood centers' boards. Yet many members – we are told – are not managing their boards to their maximum potential. ABC's board and leadership were very pleased with the governance retreat that took place last February, conducted by Les Wallace. He was also instrumental in helping ABC craft a sound and robust strategic plan reflecting the association's core values. Managing a board and steering it toward strategic issues and away from operational micromanagement is an art, and Mr. Wallace is the artist that can inspire us all – by imparting expertise – with the right ideas to make that move.

Two large pieces of the puzzle – governance and innovation – are coming together in Seattle. In addition, we hope you join us for the Medical Directors Workshop on Aug. 5, the SMT Forum on Aug. 6, and the Members Meeting on Aug. 7, which will feature a discussion on ABC Bylaws amendments. Reserve a hotel room by July 11, and register online via <http://bit.ly/1mhJcvI>. Non-members and vendors interested in attending may contact Lori Beaston at lbeaston@americasblood.org.

mgranato@americasblood.org ♦

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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Georgian Blood Banking Project (continued from page 1)

When Mr. Lux, who has 23 years of blood banking experience, arrived in Georgia in May, he was confronted with a very different blood collection environment from what he is used to in the US. “The professionals I trained didn’t have any previous apheresis experience. In fact, no one in Georgia knew how to do apheresis,” he said. Mr. Lux also had to deliver the training through an interpreter and faced some language barriers in explaining the prompts on the machines, which are in English.



Pete Lux, director of Blood Collection at Indiana Blood Center, provides training to Georgian medical professionals on the use of an apheresis instrument. (Photo Credit: Tai Power Seeff)

Despite these challenges, the interpreter was easy to work with and the trainees were eager to learn, said Mr. Lux. He trained two professionals at the Georgian Central Blood Bank on the operation of the Haemonetics PCS2 instrument, which was donated by Canadian Blood Services, and trained another clinician at the JAMC on conducting platelet collections with the Haemonetics MCS+LN9000 system, donated by Haemonetics (North America).

“The one thing that was very obvious [at the Georgian blood banks] is that they do not have an agency like the Food and Drug Administration or the European Union overseeing their operation or providing regulatory control,” said Mr. Lux. For example, he noticed a lack of control over blood center processes, as well as variation in the way certain processes are performed.

During his trip, Mr. Lux also saw that Georgian blood services face limited access to supplies and often have insufficient resources to purchase new supplies. “I think what I learned was that we have come a long way in this country from where blood banking was 30 years ago. I think Georgia is stepping into that same path, and people in the blood banking community support that view of having more stringent regulations and following them,” said Mr. Lux.

In 2011, Global Healing was invited to work with the National Center for Disease Control and Public Health of Georgia (NCDC) to help the nation advance down that very path toward more stringent blood safety regulations and quality control measures, as well as to ramp up volunteer blood donor recruitment.



Ruth Sylvester gives a presentation about Good Manufacturing Practices to Georgian regulatory officials. (Photo Credit: Tai Power Seeff)

“The healthcare system in Georgia is 99 percent privatized and blood centers – all except the JAMC Blood Bank – are for-profit. The absence of an active regulatory agency has allowed blood centers to operate within their own defined set of quality and safety guidelines,” said Vincent Lok, program manager at Global Healing. “There hasn’t been any strict enforcement on how blood

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Georgian Blood Banking Project (continued from page 3)

centers should operate. Many of the standards are outdated, and while they are still good standards, there are no inspections or audits to ensure compliance by blood centers.”

Global Healing has been working with the Georgian NCDC and the Ministry of Labour, Health, and Social Affairs (MOLHSA) on developing a more robust set of blood regulation standards, updating the existing materials, and training health inspectors on how to conduct blood center audits and provide meaningful reports that will encourage corrective action, said Mr. Lok. During her visit to Georgia, Ms. Sylvester helped to further this initiative by teaching officials at the NCDC and the MOLHSA about Good Manufacturing Practices (GMPs). These regulations, enforced in the US by FDA, help ensure that blood centers maintain public safety by adhering to proper processing procedures.

“It was really a privilege for me to be able to help them in their quest to an improved blood supply. I was an active part of the adoption of GMPs in the US blood supply, and if my experiences can help them, then that is a great thing,” said Ms. Sylvester. “The attendees engaged in excellent discussions regarding the current status of the blood operations in Georgia and possible next steps they could take,” she added.

Following the lectures, Ms. Sylvester and the other volunteers helped the Georgian health officials develop a six-month plan outlining the next steps. The plan provides a timeline for the NCDC and the MOLHSA to examine current standards, develop quality control measures, and establish an auditing tool.

“In any country, one of the biggest challenges is working with the local government on healthcare reform – there are a lot of government officials and stakeholders who need to be involved in the decision-making process,” said Mr. Lok. “I think most of the blood centers are fairly welcoming of training and development, whether that be in the lab or quality management. While Global Healing is helping to lead roundtable discussions with local blood banking stakeholders, it will be up to the Georgian government to adopt and approve any changes in national blood policy and regulation.”

Ms. Sylvester and the Global Healing group also met with Deputy Minister Mariam Jashi, MD, MPH, MPA, at the MOLHSA of Georgia to discuss the blood safety regulation plans. “It was a very positive meeting, and Dr. Jashi fully supports the adoption of GMPs within the Georgian blood system,” said Ms. Sylvester. “The Georgian people are extremely friendly and gracious hosts. It was a very rewarding trip for me personally,” she added.

“Our volunteers are really invaluable,” said Nina Renata Aron, program associate at Global Healing. “We have expertise in managing these types of projects and understand how national blood systems work, but bringing in somebody like Ruth who has tremendous experience in blood banking and a real familiarity with GMPs and quality management, as well as practical ‘on the ground experience’ is just incredibly valuable.”



Pictured above (from left to right) Ruth Sylvester, ABC; Deputy Minister Mariam Jashi, MD, MPH, MPA, at the Ministry of Labor, Health, and Social Affairs of Georgia; Vincent Lok, Global Healing; and Nina Renata Aron, Global Healing. (Photo Credit: Tai Power Seeff)

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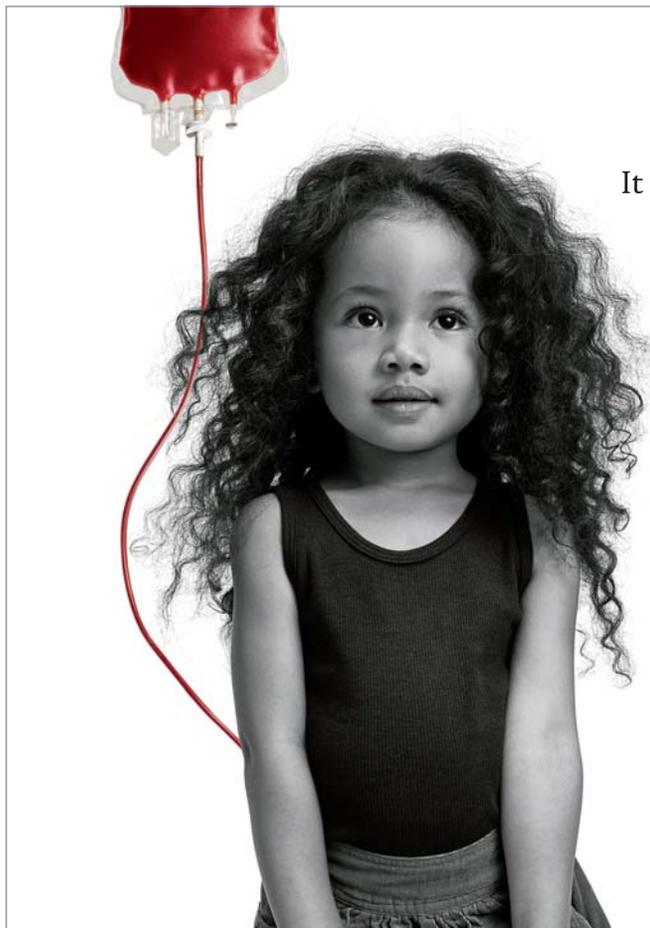
Georgian Blood Banking Project (continued from page 4)

In addition to its work in Georgia, Global Healing facilitates a number of other sustainable health programs in cardiac surgery, blood banking, and pediatrics in Haiti, Honduras, Ukraine, and Vietnam. The success of these programs relies on blood banking and other healthcare professionals who volunteer their time and knowledge, as well as organizations that donate their resources.

“From a personal standpoint, this was really my first volunteer mission of any sort and it was an amazing trip, and it is something that I will always be quite proud of – having trained three people in a country of 4 million to do something that nobody else knew how to do,” said Mr. Lux. “Anyone who is presented with an opportunity to experience another culture outside the US and really embrace it, needs to do it.”

More information about Global Healing and its projects can be found at www.globalhealing.org. Those interested in volunteer opportunities may contact Mr. Lok at vince@globalhealing.org. ♦

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INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified. ♦

ABC Hosts Fund Development, Communications, and Donor Management Workshop in Sacramento

About 75 blood center marketing, communications, fundraising, donor recruitment professionals, and vendors met at the Citizen Hotel in Sacramento, Calif. from June 17 to 20 for America's Blood Centers Fund Development, Communications, and Donor Management (FDCDM) Workshop, co-hosted by BloodSource. Attendees were able to hear presentations from experts, share best practices, and network with colleagues.

Attendees arrived on Tuesday, June 17 and heard a variety of presentations about fund development, including discussions on building philanthropy across generations, cause marketing and corporate partnerships, and getting the board of directors to support fundraising activities. On Wednesday, speakers focused on fund development and communications topics, including a talk by Alex Sheen, founder of Because I Said I Would, a social movement and non-profit dedicated to the betterment of humanity through the importance of a promise. Mr. Sheen shared his experiences and thoughts about the importance of staying true to your word.

On Thursday, attendees heard presentations on communications and donor recruitment topics including the future of plasma, media partnerships, and using data to improve donor management and recruitment. Later that evening, attendees were treated to an exclusive culinary experience and networking event on the beautiful Sacramento River, hosted by BloodSource. Guests enjoyed delicious food and beverages from Sacramento, often called the farm-to-fork capital of the US.



Attendees at the recent FDCDM Workshop enjoy an evening networking reception hosted by BloodSource on the scenic Sacramento River.

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INSIDE ABC (continued from page 6)

The workshop wrapped up on Friday with an engaging presentation on “Changing Behavior in a Changing Industry” by Christine Sopa. Her industry-specific presentation focused on how to implement lasting behavior change strategies to motivate a team to achieve results in the evolving blood banking environment. She also discussed how to navigate situations using effective communication strategies and foster strong relationships between staff.

“I want to take a moment to thank the FDCDM Workshop team and the wonderful folks at BloodSource for an absolutely fantastic workshop,” said one workshop attendee, Avery W. Krouse, donor communications supervisor at Blood Assurance. “This was my first time attending an ABC function and I truly felt like I got a lot of great insight, not only from the great speakers but also from conversing with my colleagues. I enjoyed meeting new colleagues and I look forward to seeing what we can do with the kernels of wisdom we’re all taking home.”

ABC Thanks FDCDM Workshop Sponsors

America’s Blood Centers would like to thank the workshop host, BloodSource, and the following sponsors for helping to make this workshop a success.

**New Issue of Blood Bulletin Now Available to ABC Members**

America’s Blood Centers recently published the Spring edition of the *Blood Bulletin*, a quarterly educational publication authored by transfusion medicine experts and provided to ABC members to share with their local hospital customers. This publication offers blood centers the opportunity to provide a value-added service to hospitals through educating clinicians about relevant transfusion medicine topics.

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INSIDE ABC (continued from page 8)

The June 2014 *Blood Bulletin*, titled “Overview of Factor Xa Inhibitors: Evaluation, Bleeding Management, and What’s Coming Next,” was authored by Kyle Annen, DO, of Heartland Blood Center and BloodCenter of Wisconsin, and was reviewed by ABC’s SMT Publications Committee.

The document is designed so that ABC member blood centers can insert their logo in the blank space upper right corner of the first page before distributing it to hospitals. ABC members can access the *Blood Bulletin* at <http://bit.ly/UMyNTe>. Questions or comments can be sent to Chris Gresens, MD, *Blood Bulletin* editor, at Chris.Gresens@bloodsource.org or to ABC Publications Editor Betty Klinck at bklinck@americasblood.org.

ABC Issues Joint Statement with AABB, ARC on National Gay Blood Drive

America’s Blood Centers, AABB, and the American Red Cross (ARC) issued a joint statement today regarding the National Gay Blood Drive, scheduled for July 11. The organizers of the National Gay Blood Drive seek to increase attention on the US lifetime blood donation deferral for men who have sex with other men (MSM) since 1977. This policy has been in place since the early 1980s to reduce the risk of transfusion-transmissible infections.

This nationwide blood drive will take place at participating local blood centers and blood drives across the country on July 11. Individuals who are ineligible to donate blood are expected to attend these blood drives and bring with them other individuals who are eligible to donate. Additional staff may be necessary to accommodate an increase in presenting donors. ABC members can access talking points at <http://bit.ly/1pXbcuw>, and the joint statement is available at <http://bit.ly/TpWHm7>.

ABC, AABB, and ARC believe the MSM deferral criteria should be made comparable with criteria for other behaviors that pose an increased risk for transmission of transfusion-transmitted infections. These organizations strongly support the use of rational, science-based deferral periods that are applied fairly and consistently among blood donors who engage in similar risk activities. Furthermore, ABC, AABB, and ARC support ongoing research to evaluate deferral policies and prevent potential risks to the blood supply. ♦

RESEARCH IN BRIEF

The risks and benefits of red blood cell (RBC) transfusions for patients with trauma and major bleeding may vary considerably based on a patient’s predicted risk of death upon arrival at a trauma center, according to a study in *PLOS Medicine*. The study, conducted by Pablo Perel, MD, MSc, PhD, and colleagues of the London School of Hygiene & Tropical Medicine in the UK, suggests that trauma patients who have the highest predicted death on arrival at a trauma center receive the greatest benefit from RBC transfusions but for those with the lowest predicted risk of death at baseline, RBC transfusion is associated with a higher chance of death (study available at <http://bit.ly/1v9rlfT>). The authors used data from the CRASH-2 trial, which evaluated the effect of tranexamic acid in patients with trauma; it included 20,127 trauma patients with significant bleeding from 274 hospitals in 40 countries were assessed. The authors evaluated the association between RBC transfusion and all cause mortality at 28 days post-trauma. The analysis was stratified by predicted risk of death based on clinical observations upon arrival at the trauma center. In patients with ≤ 20 percent predicted mortality, transfusion was associated with an increase in all-cause mortality, while in those >50 percent predicted mortality, transfusion

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RESEARCH IN BRIEF (continued from page 8)

was associated with reduced mortality. The authors caution, “Our study suggests that blood transfusion could be harmful for those patients whose predicted risk of death is low. However, as our study was observational, important biases cannot be ruled out, and we cannot claim a causal link. Therefore, this hypothesis should be prospectively evaluated in a randomized trial.” These kinds of data should inform the interpretation of the growing literature weighing the benefits of transfusion in a variety of clinical situations.

Citation: Perel P, *et al.* Red blood cell transfusion and mortality in trauma patients: risk-stratified analysis of an observational study. *PLoS Med.* 2014 June 17;11(6):e1001664.

A recent study in *PLOS Pathogens* describes the performance of the protein misfolding cyclic amplification (PMCA) assay to detect prions in blood samples from animals during the asymptomatic incubation period and from humans with variant Creutzfeldt-Jakob Disease (vCJD). vCJD is a transmissible spongiform encephalopathy that was recognized in the mid-1990s. It is believed to be transmitted by consumption of contaminated products from bovines with “Mad Cow” disease. Four infections in the UK have been attributed to transfusions from donors who subsequently developed vCJD, leading to consideration of the need for a donor screening assay. Olivier Andréoletti and colleagues, from the Ecole Nationale Vétérinaire de Toulouse in France, have optimized the PMCA method, which mimics the process by which misfolded (toxic) vCJD prions propagate, and determined experimental conditions that enable efficient PMCA amplification of the vCJD agent in blood. In both sheep and macaque models, the assay can accurately identify infected animals and will detect the presence of vCJD prions in blood from macaques shortly after the initial infection. Samples from vCJD patients and non-infected controls were tested in a blinded analysis in two different labs. The assay correctly and consistently identified three of the four vCJD affected patients, and yielded no false-positive results in any of the 141 healthy controls. The negative result in one of the vCJD samples raises the question of the sensitivity of the assay and/or of the potential absence of vCJD agent in the blood of some patients. The authors conclude that their “results represent substantial progress towards an applicable vCJD blood detection assay. Such assays could be used to identify vCJD infected but asymptomatic individuals and/or for screening donated blood for the presence of vCJD agent.”

Citation: Andréoletti O, *et al.* Preclinical detection of variant CJD and BSE prions in blood. *PLOS Pathog.* 2014 June 12;10(6):e1004202. 

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer’s name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Publications Editor Betty Klinck at newsletter@americasblood.org. You will be sent a writer’s guide that provides information on style conventions, story structure, deadlines, etc.



SAVE THE DATE

America's Blood Centers Information Technology Workshop

Indianapolis, IN – September 16-17, 2014

Hosted by



Negotiated hotel room rate: \$159 + tax

http://bit.ly/omni_indianapolis

2014 Workshop Fees (early bird/regular)

2-day registration: \$390/\$445

Scholarship opportunities available to ABC members to cover the cost of registration fees and help with travel expenses. Application form and details will be made available once registration opens.

“The Indiana Blood Center is looking forward to welcoming ABC members to Indianapolis for the Information Technology Workshop. We anticipate a vibrant dialogue, exchange of ideas and discussions on the time tested best practices used by our member centers. This will be an excellent opportunity to mingle with your peers, meet new people and prepare for the rigors of the changes bound to hit the information technology world. We look forward to seeing you in Indianapolis this Fall.”

– Byron Buhner
President and CEO, Indiana Blood Center

Sponsorship opportunities available. Contact Abbey Nunes at anunes@americasblood.org for details.



Indianapolis International Airport (IND) is served by most major US airlines and offers non-stop service to 34 destinations; check www.indianapolisairport.com for more information.

REGULATORY NEWS

The Food and Drug Administration issued on June 20 a draft guidance for industry and FDA staff titled “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices” (available at <http://1.usa.gov/VoIfwI>). Since FDA imposed regulatory oversight over certain software applications referred to as medical device data systems (MDDS), many blood centers and healthcare providers have found themselves for the first time designated as manufacturers subject to applicable medical device regulations. This draft guidance, from the Center for Devices and Radiological Health (CDRH) however, eases the regulatory burden regarding devices that collect and store information generated by other medical devices. FDA proposes in the draft guidance that it “does not intend to enforce compliance with the regulatory controls that apply to MDDS, medical image storage devices, and medical image communications devices, due to the low risk they pose to patients and the importance they plan in advancing digital health.” In February 2011, FDA down-classified MDDS from the highest-risk Class-III medical device to a low-risk Class I device. “Since down-classifying MDDS, the FDA has gained additional experience with these types of technologies, and has determined that these devices pose a low risk to the public,” stated the FDA draft guidance. It is not clear whether FDA’s Center for Biologics Evaluation and Research (CBER) will apply this enforcement discretion to blood establishment computer systems (BECS) accessories. America’s Blood Centers is developing comments on the draft guidance with the ABC IT and Scientific, Medical, and Technical Steering Committees. Comments on the guidance must be received by Aug. 25 and may be submitted electronically to <http://www.regulations.gov> (reference docket no. FDA-2014-D-0798). Comments can be submitted in

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REGULATORY NEWS (continued from page 10)

writing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. (Source: FDA draft guidance, 6/20/14)

AABB released for comment a proposed interim standard regarding mitigation of transfusion related acute lung injury (TRALI) for inclusion in the 29th edition of Standards for Blood Banks and Transfusion Services. The proposed revision to Standard 5.4.1.2 would require using TRALI risk mitigation strategies for apheresis platelets. If approved for publication, this requirement would not take effect until two years after the interim is considered final. The interim standard revisions read as follows, “Plasma, whole blood, and apheresis platelets for allogeneic transfusion shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.” It specifies that for apheresis components, the standard shall be implemented in 2016 (two years from the final approval). The interval before implementation is to allow collection facilities sufficient time to alleviate any effect on apheresis platelet availability that could otherwise arise with implementation of the Standard. Comments on the standards may be submitted through July 20 to standards@aabb.org. (Source: AABB Weekly Report, 6/20/14) ♦

THE WORD IN WASHINGTON

America’s Blood Centers CEO Christine Zambricki, DNAP, CRNA, FAAN, met this week with Sen. Chris Murphy (D-CT) (pictured right) to discuss the legislative and regulatory issues that are important to ABC and its member blood centers. Sen. Murphy serves on the Senate Health, Education, Labor, and Pensions Committee, which is influential in promoting ABC’s legislative agenda. ABC promotes the interests of its members through meeting with members of Congress on Capitol Hill, as well as regulatory officials. One-page informational documents on current issues being championed by ABC to further the interests of member blood centers are available to ABC members at <http://bit.ly/1hrWyDp>.



The Advanced Medical Technology Association (AdvaMed) held a congressional briefing in Washington, D.C., on June 18 on innovation in veteran’s care medical technology and diagnostics for the battlefield. The speakers highlighted how medical advancements are helping to improve care for veterans and active duty military, as well as the importance of investing in ongoing research in this area. There are currently more than 22 million US veterans of the armed services living in the US, and another nearly 2.3 million currently serving in the military on active duty. Veterans can experience unique healthcare challenges, both in terms of battlefield injuries and the after-effects of their time spent in service. Through earlier diagnosis and intervention, less invasive procedures, and more effective treatments, medical technology is revolutionizing healthcare across the continuum of service and enhancing the lives of America’s troops. Attendees heard information about more than a dozen companies and their innovative medical technologies, including spinal cord stimulation, joint/limb replacements, wound care products, neurological devices, and other products. US Rep. Adam Kinzinger (R-IL), a US Air Force veteran, attended the briefing to support innovation of medical technology and diagnostics to support the military. Other speakers included Scott Brooks, CEO of Regenesys Biomedical, Inc.; Jackie Maffucci, PhD, research director at Iraq and Afghanistan Veterans of America; Adrienne P. S. Smith, MD, medical director of BioD, LLC, and former medical director of the Emergency Department for the US Air Force; and US Army Sgt. Justin Minyard (Ret.), a decorated 13-year veteran who was a first responder after the Sept. 11

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THE WORD IN WASHINGTON (continued from page 11)

attack on the Pentagon. He has served in both Afghanistan and Iraq and at the briefing shared his personal story about how medical technology changed his life by helping him to recover from a spinal injury incurred during his service. He has now embarked on a new mission to educate injured veterans and others about how medical technology can significantly improve their quality of life. His story is available on the AdvaMed website at <http://bit.ly/1ITjMbY>. Sgt. Minyard and other speakers emphasized the importance of continuing support from Congress and national health agencies to advance medical technology for veterans and patients everywhere. AdvaMed also discussed several advocacy initiatives, many of which align with those of America's Blood Centers, such as improving the timeliness and transparency of the Food and Drug Administration, repealing the medical device tax, and working on reimbursement issues with the Centers for Medicare & Medicaid Services. (Source: AdvaMed press release, 6/11/14) ♦

GLOBAL NEWS

NHS Blood and Transplant (NHSBT), the blood and tissue supplier of England and North Wales, announced recently that it has successfully certified its customer service against the International Standard for Service Excellence (TISSE). TISSE assesses the level of customer service of a given organization against the 5 P's Service Quality Model (people, policies, processes, premises, and product), as well as the organization's current performance. The assessment took place earlier this year, and NHSBT was awarded the Four Star International Benchmark level of compliance against the Standard, making it the first organization in the UK to achieve this level of certification. "This is a wonderful achievement that reflects the hard work that has been put in by all staff across NHSBT to listen to our customers and improve the service we offer," said Teresa Allen, assistant director of Customer Service at NHSBT. "We do not intend to rest on our laurels and will now develop an annual program of audit to ensure compliance is maintained in the first instance and ultimately built upon as we strive toward a level of excellence through increased compliance against the Standard." TISSE is a relatively new benchmark for organizations worldwide to differentiate from competitors and achieve customer service efficiency and effectiveness. Developed and governed by the International Customer Service Institute, the standard provides a framework to focus on delivering customer service excellence. There are three levels of certification from the highest, five stars, to three stars. NHSBT will take on post-certification audits every year to ensure they still meet the standard required to be an accredited organization. (Source: NHSBT media release, 6/20/14) ♦



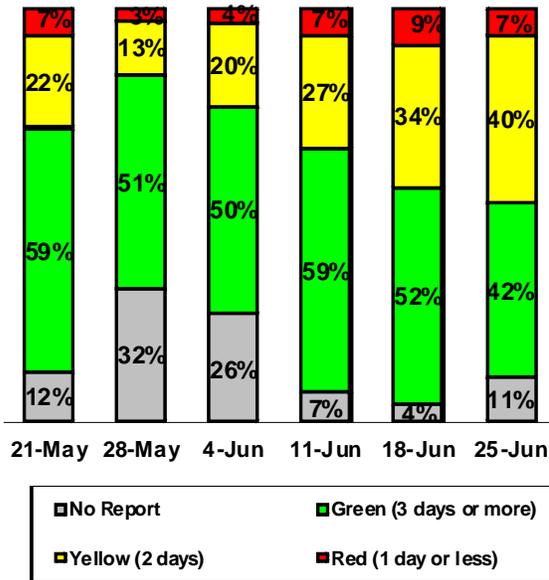
At the formal presentation of the TISSE certificate to NHSBT, made to Chief Executive Lynda Hamlyn (left) and Assistant Director of Customer Service Teresa Allen (center) in June at the organization's donor center in West End of London, presented by Darren Young, director of Business Development at Customer Service Network.

We Welcome Your Letters

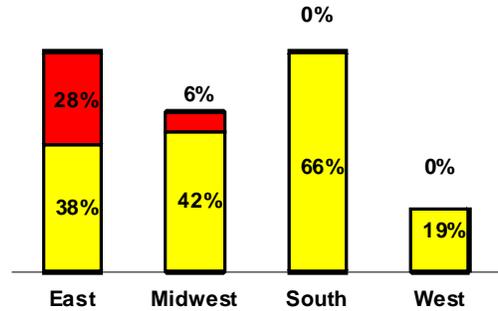
The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, June 25, 2014



Percent of Total ABC Blood Supply Contributed by Each Region
 East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily Updates are available at:
www.AmericasBlood.org

PEOPLE

Paul D. Mintz, MD, has been appointed director of the newly created Division of Hematology Clinical Review in the Office of Blood Research and Review at the Food and Drug Administration’s Center for Biologics Evaluation and Research. This division is responsible for the clinical review of blood-derived medical products and their recombinant or transgenic analogues. The division will also review certain devices related to these products and will conduct relevant toxicology and clinical pharmacology reviews. Dr. Mintz is a former president of AABB and served on AABB’s board of directors for nine years. He has also served as a member of the board of trustees of the National Blood Foundation. Dr. Mintz was a member of the faculty of the University of Virginia School of Medicine from 1979 until 2011 where he was a tenured professor of Pathology and Internal Medicine. He also served as chief of the Division of Clinical Pathology and Medical Director of the Clinical Laboratories and Transfusion Medicine Services at the University of Virginia Health System. At the University of Virginia, Dr. Mintz was an elected member of the Clinical Staff Executive Committee. His role as an educator was recognized with a Dean’s Award for



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Teaching Excellence by the university. Dr. Mintz was co-medical director of Virginia Blood Services from 2008 until 2011. A recipient of a Transfusion Medicine Academic Award from the National Heart, Lung, and Blood Institute, Dr. Mintz also was awarded a research grant from the National Blood Foundation (NBF) and is an NBF Scholar. He was a member of the Medicare Coverage Advisory Committee of the Centers for Medicare and Medicaid Services. He also served as president of the Mid-Atlantic Association of Blood Banks (MAABB) and was a recipient of the MAABB's Charles E. Walter Memorial Award. Dr. Mintz is widely published and is a member of the editorial board of *Transfusion*. He also served as the Transfusion Medicine Section Editor for the American Journal of Clinical Pathology and is on the editorial board of the Annals of Clinical and Laboratory Science. In addition, he has designed and served as principal investigator for numerous clinical and device trials. He is the sole editor of all three editions of Transfusion Therapy: Clinical Principles and Practice, published by AABB Press.

Rick Axelrod, MD, MBA, president/CEO and medical director of LifeStream, San Bernardino, Calif. and Desert Blood Services, La Quinta, Calif., and ABC vice president, was appointed June 18 as chairman of the Coachella Valley Economic Partnership (CVEP). CVEP is a non-profit economic vitality organization devoted to attracting, retaining, and expanding business and developing a high-skilled workforce to advance the economy and quality of life of the region. "This is an exciting time for me, as CVEP recently created a health and medical innovation center," said Dr. Axelrod. "As a member of the healthcare community it is clear that future opportunities in healthcare economic development are plentiful. The new center creates strong alignment with CVEP's workforce excellence initiatives, its Health Industry Council, and youth scholarship program to create desirable healthcare jobs, while motivating students in the region to choose healthcare careers." Dr. Axelrod's term as chairman is one year. (Source: LifeStream announcement, 6/20/14) ♦

**MEETINGS****July 31 FDA Blood Products Advisory Committee Meeting, Silver Spring, Md.**

The Food and Drug Administration will hold a meeting of its Blood Products Advisory Committee (BPAC) on July 31 from 8 a.m. to 5:30 p.m. at the FDA White Oak Campus, at 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503). During the morning, the committee will discuss Baxter Healthcare Corp.'s biologics license application for HvQia, Immune Globulin Infusion 10 percent (human) combined with Recombinant Human Hyaluronidase for the treatment of patients with primary immune deficiency disorders. In the afternoon, the committee will discuss reentry of blood donors deferred on the basis of Chagas disease test results. Both sessions are open to the public. More information can be found in the Federal Register announcement at <http://1.usa.gov/1lw3cPZ>.

Sept. 10-12 EBA Workshop Transportation and Logistics Management Systems, Copenhagen, Denmark

The European Blood Alliance (EBA) will hold a workshop on Transportation and Logistics Management Systems from Sept. 10-12 at the Danske Regioner in Copenhagen,

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Denmark. Discussions will cover topics such as logistics questionnaire and mobile donor decisions, transportation from collection sites to blood centers, and transportation from blood centers to hospitals. Those interested must register by Aug. 1. Please contact georgsen@dadlnet.dk to obtain a registration form.

Sept. 11 **European Medicines Agency Workshop: Advanced Therapy Medicinal Products: How to Bring Cell-based Medicinal Products Successfully to the Market, Dresden, Germany.**

The European Medicines Agency (EMA) will host a workshop on “Advanced Therapy Medicinal Products: How to Bring Cell-based Medicinal Products Successfully to the Market,” on Sept. 11 at the Maritim Internationales Congress Centrum in Dresden, Germany. The workshop is co-organized by the EMA’s Committee for Advanced Therapies and the German Society for Transfusion Medicines and Immunohematology (DGTI) in collaboration with the German Stem Cell Network. It aims to bring together industry, academia, hospitals, and regulators to discuss how to progress the development and authorization of advanced therapy medicinal products. More information and registration details can be found on the DGTI Annual Meeting website at <http://bit.ly/1vdH9OI>.

Sept. 25 **8th Annual Center for Human Immunology Symposium, Milwaukee, Wis.**

The Center for Human Immunology Symposium will be held on Sept. 25 at the BloodCenter of Wisconsin’s Blood Research Institute in Milwaukee, Wis. This one-day symposium will feature discussions led by experts on “Immune Cell: Genome, Transcriptome & Signalosome.” More information and registration details can be found at <http://bit.ly/VtEWEn>.

Nov. 11-12 **IPFA Workshop on Plasma for Fractionation Asia Pacific, Taipei, Taiwan.**

The International Plasma Fractionation Association (IPFA) will hold the inaugural IPFA Asia Pacific Workshop on plasma fractionation. This workshop will identify and discuss key issues, strategies, and opportunities to meet the increasing requirements for plasma for fractionation and essential plasma derived medicinal products in the Asia Pacific region. In collaboration with and hosted by Taipei Medical University (TMU), a comprehensive range of topics will be addressed, such as donor recruitment, screening and diagnostics for blood borne pathogens, regulatory issues, and much more. More information and registration details can be found at <http://bit.ly/1jV4RKa> ♠

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: lnorwood@americasblood.org.

POSITIONS AVAILABLE

Regional Sales Manager. Michigan Blood is looking for a Manager of Donor Relations to lead regional donation efforts throughout the greater Saginaw and Traverse City communities. We are a growing blood center that relies upon voluntary blood donations to supply many Michigan hospitals. This Saginaw based position will develop relationships and growth strategies and lead a team that achieves donation goals through community blood drives. This includes projecting forecasts to meet hospital demands, planning community special events and analyzing department programs to achieve goals. This position requires a minimum of three to five years of experience managing a sales team. Bachelor's degree plus five or more years of related experience preferred. Familiarity with Michigan communities and nonprofit work is desirable. The ideal candidate will demonstrate a proven track record of sales leadership, community engagement and professional communication. We offer a competitive salary and benefit plan. If you want to be part of a lifesaving organization, please apply via our website: www.miblood.org. EOE

Chief Information Officer (Puget Sound Blood Center). We are currently seeking a Chief Information Officer (CIO) to innovatively lead the strategic development and management of information resources in support of our goals, mission and vision. This role is responsible for multiple systems throughout the organization including patient, donor and administrative systems. Emphasis will be ensuring systems meet objectives efficiently, comply with regulations and meet customer needs. Fifteen-plus years' experience in IT strategic planning and execution in a senior management role is required. Bachelor's degree in related field preferred. Master's degree is desirable. Must have proven experience in IT architecture design and data warehousing/data marts, demonstrated strength in project management and strong vendor management experience. Experienced with the demands of IT within health delivery and research settings is also required. Interested Applicants: send application materials to HumanResources@psbc.org or fax to (866) 286-8495. Should you have a disability that requires assistance and/or reasonable accommodation with the job application process, please contact HR: humanresources@psbc.org, (206) 292-6500, 921 Terry Avenue, Seattle, WA 98104. EEO Employer/Vet/Disability.

Donor Recruiter. Community Blood Center of the Carolinas (CBCC) is opening a new collection and distribution facility in Greensboro, N.C. We are seeking an energetic sales professional to develop donations, sponsors, and business relationships within the community. A minimum of two years of outside sales experience is required. Candidates must be able to work well under pressure with a demonstrated ability to build new territories and meet goals. Own transportation and computer skills are required. Our ideal candidate is highly motivated and works well with executives, employees, and groups with the ability to express our service philosophy of empowering individuals to make a difference in their lives and the lives of others by educating, providing a superior experience, and building loyal relationships. Email resume and salary requirements to cbccteam@cbcc.us; resumes without salary requirements will not be considered. EOE/Drug Free Work Zone.

Site Manager. Community Blood Center of the Carolinas (CBCC) is opening a new collection and distribution facility in Greensboro, N.C. We are seeking an experienced manager to oversee our new site. The position works in conjunction with recruitment and operations to ensure the attainment of collection and distribution goals. This position manages staff performing regulated functions/procedures as well as serves as the CBCC steward in the Greensboro community; developing and growing relationships with our new hospital partners and sponsors/donors. Our ideal candidate possesses a minimum of three to five years of supervisory and marketing/sales experience in a blood banking, plasma and/or medical environment working directly with hospitals and sponsors as well as regulated agencies such as the FDA, CLIA and/or AABB. Responsibilities include regulatory compliance, departmental budgets and fulfillment of goals. Three to five years strategic planning experience required. Prior experience engaging and speaking with the public required. Phlebotomy experience or accredited class required. Varied schedule including weekends, as well as 24/7 on-call rotation. High school diploma or GED required. MT, MLT (ASCP), RN or LPN preferred. Qualified candidates should email their resume and

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salary requirements to cbccteam@cbcc.us, resumes w/o salary requirements will not be considered. Drug Free Work Zone/EOE.

Medical Technologist. The Blood & Tissue Center of Central Texas, located in Austin, is seeking a medical technologist to perform all patient testing functions and donor processing. This includes viral marker EIA testing, ABO testing, antibody screens and work-ups, antigen testing and cross-matching, as well as RPR and CMV testing. This position will accurately label blood components that are available for distribution, diligently follow all procedures for testing, maintenance, safety, and quality control, as well as assist management to

maintain adequate supplies through careful monitoring of reagent usage and placement of new reagent stock. Qualified candidates must be able to work in an area where bio-hazardous elements can exist. BS in Medical Technology (or equivalent) and ASCP or NCA Certification as a Medical Technologist or Blood Bank Technologist is required. AS and certification as MLT or BB will also be considered. Must be at least 21 years old, have a valid driver's license, proof of vehicle insurance, and an acceptable driving record. Must be able to work a rotating weekly schedule and participate in on-call. Familiarity with cGMP, AABB, and FDA regulations is desired. Please visit www.inyourhands.org to apply. ♦

CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Norwood by e-mail (lnorwood@americasblood.org) or by fax to (202) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)

2014

July 31 Thursday. **FDA Blood Products Advisory Committee Meeting, Washington, D.C.** More information is available at <http://1.usa.gov/1lw3cPZ>.

Aug. 5 Tuesday (note: new date and day). **Medical Directors Workshop, America's Blood Centers, Seattle, Wash.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 6-7 Wednesday-Thursday (note: new dates and days). **Summer Meeting, America's Blood Centers, Seattle, Wash.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 3-5. **European Conference on Donor Health and Management, the Netherlands.** More information and registration details can be found at www.ecdhm.org.

Sept. 10-12. **EBA Workshop on Transportation and Logistics Management Systems, Copenhagen, Denmark.** For a registration form, please contact georgsen@dadlnet.dk. Registration must be received by Aug. 1.

Sept. 11. **EMA Workshop on Advanced Therapy Medicinal Products: How to Bring Cell-based Medicinal products Successfully to the Market, Dresden, Germany.** Registration details can be found on at <http://bit.ly/1vdH9OI>.

Sept. 13. **12th Annual Canadian Blood Services International Symposium - Plasma: Transfuse it, Fractionate it or Forget it?, Ontario, Canada.**

Details and registration can be found at <http://bit.ly/1mQfamU>.

Sept. 16-17. **IT Workshop, America's Blood Centers, Indianapolis, Ind.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 17. **Red Cell Genotyping 2014: Clinical Solutions, Bethesda, Md.** The agenda can be viewed at <http://bit.ly/1m3K9fQ>.

Sept. 23-24. **IPFA/BCA Global Symposium on the Future for Blood and Plasma Donations, Sacramento, Calif.** More information and registration details can be found at <http://bit.ly/1fDqJrX>.

Sept. 25. **8th Annual Center of Human Immunology Symposium, Milwaukee, Wis.** More information and registration details can be found at <http://bit.ly/VtEWEn>.

Oct. 25-28. **AABB Annual Meeting and CTTXPO, Philadelphia, Pa.** For more information: <http://bit.ly/1mmPGcW>.

Oct. 31-Nov. 3. **5th International Meeting on Emerging Diseases and Surveillance, Vienna, Austria.** More information can be found at <http://imed.isid.org>. Contact: info@isid.org.

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CALENDAR (continued on page 17)

Nov. 11-12. **IPFA Workshop on Plasma for Fractionation Asia Pacific, Taipei, Taiwan.** More information can be found at <http://bit.ly/1jV4RKA>.

Dec 9-10. **Supply Chain Optimization Workshop, America's Blood Centers, Austin, Texas.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

2015

Mar. 20-24. **Annual Meeting, America's Blood Centers, Washington, DC.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

May 5-7. **Technical/Lab & Quality Workshop, America's Blood Centers, Orlando, Fla.** Contact: ABC

Meetings Dept. Phone (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 4. **Medical Directors Workshop, America's Blood Centers, Philadelphia, Pa.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 5-6. **Summer Meeting, America's Blood Centers, Philadelphia, Pa.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 16-17. **Financial Management Workshop, America's Blood Centers, Chicago, Ill.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org. ♦