

ABC Newsletter will be abbreviated next week due to the holidays.

Issue #1
January 13, 2017

Pathogen Reduction Technology Treated Platelets for Pediatric Patients

Zika, for good and bad, helped to spur a number of changes in the blood industry. One such quick conversion may be an increased adoption of pathogen reduction technology (PRT).

“Zika really woke lay people and physicians up to the real possibility of transfusion transmitted diseases potentially impacting a fetus’ and infant’s brain development,” said Cassandra Josephson, MD, medical director of the Blood, Tissue and Apheresis Service at Children’s Healthcare of Atlanta and professor of Pathology and Pediatrics at Emory University School of Medicine.

Within three months of the first local-transmission of Zika in Puerto Rico (late March, 2016), the U.S. Food and Drug Administration (FDA) had temporarily halted blood collections on the island; the Department and Health and Human Services (HHS) had started shipping blood from mainland centers (including a number of ABC member centers); and universal testing and PRT had been implemented for platelet and plasma units. Shortly thereafter, a flood of public concern for Zika in the nation’s blood supply started—especially for pediatric and neonatal patients.

“I want to protect infants and children first as they have potentially the longest quality-adjusted life years of any transfused population,” said Dr. Josephson. “You might get Zika from a transfusion, but infants and children are more

likely to contract it from a trans-placental transmission in utero or by a mosquito bite. Further and more dubious is what we don’t know about other potential transfusion-transmitted diseases (TTD) that may be coming down the pike, and could harm pediatric patients, one of the most vulnerable transfused populations.”



A number of studies performed over the last 13 years have demonstrated the activity of PRT against important transfusion-transmitted pathogens. (Lin L, *et al*; Irsch, *et al*). Several [U.S. blood centers have implemented the only FDA-approved PRT system](#), INTERCEPT, for at least part of their platelet and plasma supply. But what we don’t have is a large well of evidence-based trials of pediatric and neonatal patients and how PRT-treated platelets affect them in the short and long-term. And that is understandable considering most trials first enroll

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OUR SPACE

ABC CEO Christine S. Zambricki, DNAP, CRNA, FAAN An Investment that Pays the Best Interest

A new year begins with new challenges, a new administration in the White House, new legislators, and a plethora of issues for blood bankers—some new and some ongoing. Against the backdrop of so much change, what is the value of ABC to its members and why must we continue to speak as a single trade organization with one strong voice?

ABC is dedicated to protecting and advancing the needs of our blood centers. Last year was marked by non-stop advocacy: responding to Zika and all of its permutations; representing and vocalizing ABC members' positions at the numerous Food and Drug Administration, Centers for Disease Control and Prevention, and Centers for Medicare & Medicaid Services committee and task force meetings; responding to draft and final guidances; and behind-the-scenes negotiations that, despite less than perfect outcomes at times, mitigated situations from being much worse.

Amidst the backdrop of strong advocacy work in 2016, ABC established the ABC Professional Institute (API) Learning Portal with over 60 courses. To date, there are 300+ member center employees using the portal, with over 1,300 member logins. The ABC cGMP (Current Good Manufacturing Practices) video and facilitator guide, funded by an FABC grant, was completed and released to every member blood center. As concern for the size of our donor population grew, ABC acquired ADRP as an international division of our organization to consolidate and focus donor recruitment efforts and education. Continuing with this worldwide effort to attract blood donors, ABC members led the way with creative approaches to the Missing Type Campaign as well. We also provided critical benchmarking reports on financial ratios, industry service fees, and C-Suite compensation.

Our awesome ABC staff can attest these complicated projects and initiatives require long hours, attention-to-detail, and most of all, teamwork. Louis Katz, MD, and the SMT staff members are constantly monitoring, reviewing, and collaborating with organizations and agencies on scientific and medical matters that shape the blood industry. Kate Fry and the Membership Services group continue to produce the meetings, workshops, fundraising campaigns and events, ABC Professional Institute offerings, publications, and public relations efforts that educate the public and our members. Sameer Ughade and the IT/Data Warehouse team sit at the intersection of business, science, and technology as they continue to onboard ABC members into the data warehouse and produce business intelligence reports to advance the industry. Finance guru John Murphy and Trudy Thompson have been steadfast in achieving a clean audit and keeping the finances of ABC transparent and sound.

Thank you to ALL of the ABC and FABC Board Members, committee members, and ABC blood centers who support ABC as we continue to advance the interests of independent blood centers. From networking to advocacy to targeted survey data/research and education, ABC membership is an investment that pays the best interest.

Christine S. Zambricki

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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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PRT PLATELETS FOR PEDS (continued from page 1)

adults simply because there are more of them receiving transfusions and funding is scarce.

“It’s a numbers game,” said Jennifer Andrews, MD, MSc, clinical assistant professor of Pathology and Pediatrics and associate director of Transfusion Medicine Fellowship Program at Lucile Packard Children’s Hospital Stanford, a part of Stanford University medical system. “There are more regulatory hoops to jump through in general, so most children and their diseases are not as well studied as adults.”

Cooperatives, said Dr. Andrews, are helping to change that. A number of pediatric research groups, like the Children’s Oncology Group, have formed with hundreds of expert members who share data and help enroll children across the globe in clinical trials to better understand pediatric diseases and treatments, including transfusion medicine and hematology/oncology trials. But pathogen reduction for pediatrics is understudied as a whole, said Dr. Andrews.

Funding is always a primary consideration, noted Traci Heath Mondoro, PhD, chief of the Translational Blood Science and Resources Branch at the National Heart, Lung, and Blood Institute (NHLBI). NHLBI is funding studies focused on fundamental questions in pediatric and neonatal transfusion medicine, such as the most appropriate target hematocrit to maintain preterm infants or the effect of the age of standard red blood cells in critically ill children. “Studies with PRT blood products represent the next level of investigation in these fields, so we have not yet seen any proposals focused on clinical trials with PRT products in the pediatric or neonatal populations,” added Dr. Mondoro. “NHLBI staff members do have open dialogues with Terumo and Cerus scientists and are happy to work with them on potential grant applications.”

But large-scale clinical trials on pediatric patients receiving PRT platelets have not yet been completed. A research piece we include later in this *Newsletter* shows an INTERCEPT trial of nearly 3,500 people, 8.7 percent of whom are pediatric patients, including 23 neonates. The original SPRINT study in 2001 also contained a similar percentage of pediatric patients. Probably the most studied pediatric patients in a PRT trial were 242 children in 2015 (Knutson, *et al*). The study concluded with no unexpected serious adverse events related to the use of PRT-treated platelets.

Many European countries have been giving PRT-treated platelets to pediatric and adult patients alike for years and post-implementation hemovigilance studies could provide some important pediatric data over time.

Adult studies over the last decade have shown us that while platelet proteins sustain some damage during PRT and post-transfusion platelet counts are lowered, hemostatic efficacy is maintained (Kaiser-Guignard, *et al*; Murphy, *et al*; Cazenave, *et al*). More large adult-based studies are in the works as well, Terumo’s “Efficacy of Mirasol-treated Apheresis Platelets in Patients with Hypoproliferative Thrombocytopenia (MiPlate)” was recently awarded government funding to evaluate Mirasol-treated apheresis platelets in subjects with hypoproliferative thrombocytopenia. The “Evaluate the Efficacy and Safety of RBCs Derived from Mirasol treated Whole Blood Compared with Conventional RBCs in Patients Requiring Chronic Transfusion Support” trial (PRAISE) will also evaluate red blood cells derived from Mirasol-treated whole blood.

“With the PRT process, you are going to damage some of the platelets—some of them will be blown to bits, primarily due to the UV light,” said Dr. Mondoro. “There are so many platelets in any given unit that it’s okay to sacrifice some for the benefit gained through pathogen reduction. We also don’t know how to predict which platelets will perform well and which ones won’t stop bleeding.”

The focus, for now, seems to be moving toward a whole-blood product. “Planned trials are focused on programs that will support U.S. licensure of INTERCEPT for red cells; protocols, including specifics on

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PRT PLATELETS FOR PEDS (continued from page 3)

patient population, are currently being discussed with FDA,” a Cerus spokesman noted. Terumo conducted whole blood trials in Ghana, Africa, in 2014, during which no unexpected adverse events were recorded (Allain *et al*) and malaria transmission was interrupted. “A whole-blood system would be a game-changer,” agreed Dr. Andrews.

“Mirasol-treated platelets have been studied with general patient groups, including small numbers of pediatric patients. However, we have not sponsored any clinical trials focused on pediatric patients at this time. Our focus remains on executing clinical trials that are designed to provide safety and efficacy evidence of the product to support FDA approval in the U.S.,” noted a Terumo BCT spokesperson.

While doctors and professionals await more large-scale PRT clinical trials for the most in-need patients, Dr. Andrews said the risks of TTDs in the blood supply far outweigh the perceived cons of PRT.

“The proof is in the pudding,” she said. “The studies have shown it to be efficacious. We’re dealing with a very vulnerable population and parents are very fixated on why there are still infections from blood transfusions—Zika most recently and bacterial sepsis. They’re surprised there are still transfusion transmitted-infections possible. So even though the frequency of TTD won’t ever be zero, PRT is really important for children.”

Citations: Lin L., Dikeman R., Molini B., *et al*. Photochemical treatment of platelet concentrates with amotosalen and long-wavelength ultraviolet light inactivates a broad spectrum of pathogenic bacteria. *Transfusion*. October 2004. DOI: 10.1111/j.1537-2995.2004.04125.x.

Murphy S., Synder E., Cable R., *et al*. Platelet dose consistency and its effect on the number of platelet transfusions for support of thrombocytopenia: an analysis of the SPRINT trial of platelets photochemically treated with amotosalen HCl and ultraviolet A light. *Transfusion*. November 11, 2005. DOI: 10.1111/j.1537-2995.2005.00671.x.


Cazenave J.P., Folley G., Bardiaux L., *et al*. A randomized controlled clinical trial evaluating the performance and safety of platelets treated with MIRASOL pathogen reduction technology. *Transfusion*. October 29, 2010. DOI: 10.1111/j.1537-2995.2010.02694.x.

Irsch J. and Lin L. Pathogen Inactivation of Platelet and Plasma Blood Components for Transfusion Using the INTERCEPT Blood System. *Transfusion Medicine and Hemotherapy*. February 2011. DOI: 10.1159/000323937.

Kaiser-Guignard J., Canellini G., Lion N., *et al*. The clinical and biological impact of new pathogen inactivation technologies on platelet concentrates. *Blood Reviews*. November 2014. DOI: <http://dx.doi.org/10.1016/j.blre.2014.07.005>.

Knutson F., Osselaer J., Pierelli L., *et al*. A prospective, active haemovigilance study with combined cohort analysis of 19,175 transfusions of platelet components prepared with amotosalen–UVA photochemical treatment. *Vox Sanguinis*. May 15, 2015. DOI: 10.1111/vox.12287.

Allain J.P., Owusu-Ofori A.K., Assennato S.M., *et al*. Effect of *Plasmodium* inactivation in whole blood on the incidence of blood transfusion-transmitted malaria in endemic regions: the African Investigation of the Mirasol System (AIMS) randomised controlled trial. *The Lancet*. April 23, 2016. DOI: [http://dx.doi.org/10.1016/S0140-6736\(16\)00581-X](http://dx.doi.org/10.1016/S0140-6736(16)00581-X).

Amato M., Schennach H., Astl M., *et al*. Impact of platelet pathogen inactivation on blood component utilization and patient safety in a large Austrian Regional Medical Centre. *Vox Sanguinis*. December 21, 2016. DOI: 10.1111/vox.12456. 



America's Blood Centers®
It's About *Life.*

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

CME Credits Available at the Annual Meeting

ABC is pleased to announce the Business and Leadership forums during the ABC Annual Meeting in Washington, D.C., will now offer continuing medical education (CME) credits. Previously, only the Scientific Forum of the Annual Meeting and the MD Workshop at the Summer Meeting were offered for CME credit. We are excited to expand this benefit to our members and attendees.

All presentations during the Leadership Forum, except for the API & ADRP Update presentation, will be available for a combined total of 3.0 CME credits. Two and a half combined CME credits will be given for attending the Business Forum sessions: "Improving Business with Blood Center Metrics," as presented by Martin Grable, CEO and president of the Community Blood Center of the Carolinas; "Panel: Sharing Key Metrics and How These Metrics Are Used to Drive Success," which includes presentations from Gregg Boothe, associate director and COO of Hoxworth Blood Center; Scott Bush, CEO of SunCoast Blood Bank; and David Green, president of Blood Centers Divisions at Blood Systems, Inc.; and the "Blood Center Metrics Breakouts," moderated by Rachelle Fondaw, director of Education & Grants at ABC.

For information on how to register for the ABC Annual Meeting, contact [Lori Beaston](#). We look forward to seeing you in March!

Join us for our webinar "9 Ways to Energize, Empower and Engage Your Employees." As part of the America's Blood Centers' Professional Institute (API) educational and professional development offerings, we are pleased to announce this webinar, which will highlight a coaching system used to energize, empower, and engage employees and their individual strengths to maximize both the individual's and an organization's success. The webinar is February 7, 2017, at 2 p.m. EST and will be presented by Gary Markle, executive coach and founder of consulting firm Energage. Register for the webinar [here](#).

January is National Blood Donor Month. Member centers across the country are paying tribute to their blood donors and encouraging new ones. Rock River Valley Blood Center is giving donors a coupon for free McDonald's ice cream cones or pie. Virginia Blood Services is giving away T-Shirts and many more blood centers are running social media campaigns and other freebies for donors. During this month, ABC is asking member centers to include the hashtag #AmericasGotBlood and have donors post selfies during this time on the social media outlet of their choosing (Facebook, Twitter, Instagram, etc.) with the hashtag. We will retweet them as a way to thank donors and encourage others to give. 💧

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!



RESEARCH IN BRIEF

In a recent Scandinavian study there was no association found between the storage duration of red blood cells and mortality in transfusion recipients. Using the Scandinavian Donations and Transfusions (SCANDAT2) database, researchers followed all adult transfusion recipients in Denmark and Sweden from 2003 to 2012 and found no increase in mortality among those transfused with blood units stored for longer periods compared to patients transfused with fresher blood. Using three independent analytical approaches in this study of 854,862 adult patients, there was no difference in 30-day mortality for those receiving blood stored for 30 to 42 days and patients receiving blood stored for 10 to 19 days.

Citation: Halmin M., Rostgaard K., Lee B.K., *et al.* Length of Storage of Red Blood Cells and Patient Survival after Blood Transfusion. *Annals of Internal Medicine*, December 20, 2016. DOI: 10.7326/M16-1415.

Patients with fever after transfusion are more likely to be suffering from transfusion-associated circulatory overload (TACO) than an allergic reaction. Researchers performed a three-year retrospective analysis of 972 reactions in which 267 reactions were classified definite or probable TACO and of those 8.2 percent exhibited a fever. When comparing rate of TACO with fever to the rate of allergic reactions with fever, the odds ratio was 5.2 (2.9 to 9.4 [95 percent confidence interval]). Authors confirm prior work demonstrating that fever is fairly common with TACO.

Citation: Parmar N., Pendergrast J., Lieberman L., *et al.* The association of fever with transfusion-associated circulatory overload, *Vox Sanguinis*, December 21, 2016 online. DOI: 10.1111/vox.12473.

REDS-III researchers used an electronic screening algorithm to determine TACO incidence at four U.S. hospitals. Of the 14,300 transfusion episodes studied at these four hospitals during a three-month window in 2014, 3,412 TACO algorithm alerts were received and classified based on two sets of hemovigilance criteria—those of the Centers for Disease Control and Prevention, National Healthcare Safety Network and revised criteria proposed by the International Society for Blood Transfusion. The suspected TACO cases were also analyzed by a separate expert clinical panel. Patients with TACO were flagged using this algorithm and hemovigilance criteria had improved oxygenation levels within 24 hours; however, the expert panel's determination only matched 57 percent and 54 percent of the hemovigilance diagnoses, respectively. New diagnostic criteria for TACO are needed, the researchers concluded.

Citation: Roubinian N.H., Hendrickson J.E., Triulzi D.J., *et al.* Incidence and clinical characteristics of transfusion-associated circulatory overload using an active surveillance algorithm. *Vox Sanguinis*. December 21, 2016 online. DOI: 10.1111/vox.12466.

INTERCEPT treatment of platelet concentrates does not impact patient safety and is not associated with increased bleeding. Austrian researchers studied Cerus' INTERCEPT pathogen reduction technology treatments on platelet concentrates in adults and pediatric patients, including neonates. There was no significant difference between the adverse events (AEs) experienced by those patients in the test groups (1,694 patients receiving 7,705 transfusions) and those in the control groups (1,797 patients and 8,611 transfusions). The number of red blood cell units in the test versus control patients used was not significantly different (control = 10.8 vs. test = 10.2), which suggests that using PRT platelets was not associated with increased bleeding.

Citation: Amato M., Schennach H., Astl M., *et al.* Impact of platelet pathogen inactivation on blood component utilization and patient safety in a large Austrian Regional Medical Centre. *Vox Sanguinis*. December 21, 2016 online. DOI: 10.1111/vox.12456. ♦



BRIEFLY NOTED

The National Heart, Lung, and Blood Institute (NHLBI) announced they will be moving ahead with the Recipient Epidemiology and Donor Evaluation Study-IV-Pediatric (REDS-IVP) initiative. Funding would be awarded, if any, in fiscal year 2019. REDS-IV-P will involve both translational and clinical research in the safety and effectiveness of transfusion therapies, focusing on neonates and children as well as adult patients.

A modified activin receptor type IIB fusion protein that promotes late-stage erythroid differentiation, luspaterecept, could help beta-thalassemia patients increase hemoglobin levels and lower their need for transfusions. In a report of a phase two trial to the American Society of Hematology, 30 transfusion-dependent and 34 non-transfusion-dependent patients were treated with the drug every three weeks for up to 12 weeks. Of the non-transfusion patients, 78 percent had increased their hemoglobin levels by at least 1 g/dL and of the patients receiving transfusions, 67 percent had at least a 50 percent reduction in need for transfusions for 12 to 48-plus weeks after treatment. Most toxicity was mild to moderate and liver-iron decreased with treatment. A phase three, placebo-controlled trial has started.

Citation: Piga A.C., *et al.* Abstract 851. Presented at: ASH Annual Meeting and Exposition; December 3 to 6, 2016; San Diego. ♦

RECENT REVIEWS

Commentary in *Transfusion* advocates to change the syndrome “possible TRALI” to “transfused acute respiratory distress syndrome (ARDS).” The authors noted that TRALI and ARDS have different risk factors and clinical courses. They suggest that antibody mediated and non-antibody mediated TRALI have consensus support, but “possible TRALI” includes many patients with alternative causes of ARDS and should not be called TRALI.

Citation: Toy P., Kleinman S.H., Looney M.R., *et al.* Proposed revised nomenclature for transfusion-related acute lung injury. *Transfusion*. December 26, 2016 online. DOI: 10.1111/trf.13944.

In a commentary on the use of whole blood for acutely hemorrhaging civilian trauma patients, the authors call for more studies on cold-stored whole blood (WB). Echoing an article from Spinella *et al* that we summarized in [Newsletter #35](#), the authors of this commentary recapped decades’ worth of military use of whole blood, including cold-stored whole blood, as a treatment strategy for trauma patients. While component therapy continues to be the standard of care for civilians, there continues to be a call for trials comparing cold-stored WB to the standard in both pre-hospital and in-hospital trauma resuscitation settings.

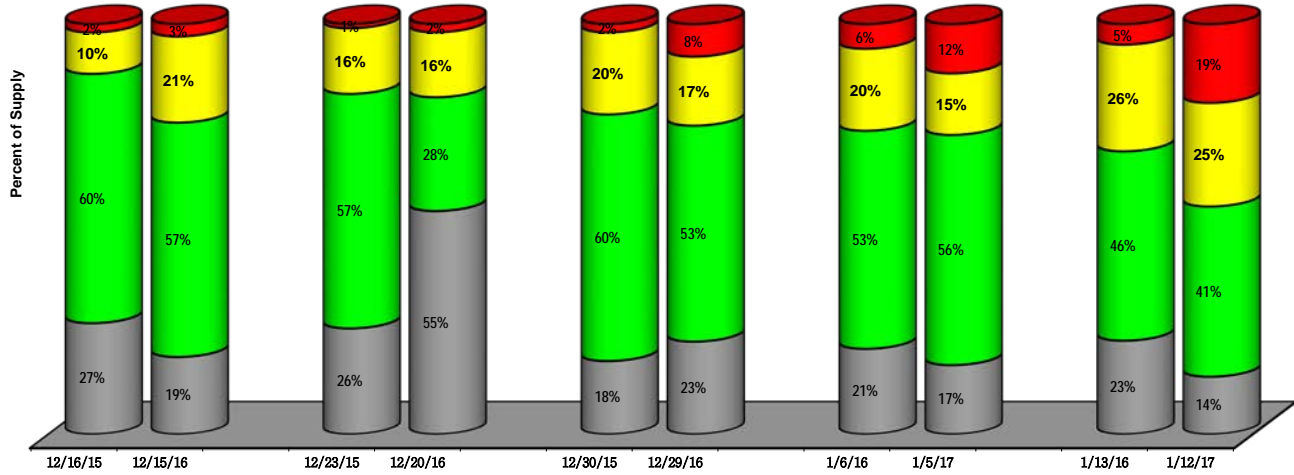
Citation: Bahr M.P., Yazer M.H., Triulzi, D.J., *et al.* Whole blood for the acutely haemorrhaging civilian trauma patient: a novel idea or rediscovery? *Transfusion Medicine*. December 2016. DOI: 10.1111/tme.12329. ♦

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 Lisa Spinelli 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 the ABC Blood Supply, 2016 vs. 2017



No Response
 Green: 3 or More Days
 Yellow: 2 Days
 Red: 1 Day or Less

The order of the bars is (from top to bottom), red, yellow, green, and no response



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Join over 250 recruitment, collections and marketing leaders from over 20 countries for the ADRP Annual Conference.

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"The 2016 ADRP Conference was a perfect blend of Recruitment & Collections content. To hear leaders in our industry from around the world share best practices was priceless.

—Pamela B. Rascon, Director, Community Resources, Sheppard Community Blood Center, GA

**May 1-3, 2017
Chicago, Illinois**

Subscribers Registration: \$550

(Includes Breakfast and Lunch on Tuesday and Wednesday)

Hotel Rate for ADRP: \$199/night

Chicago Hilton International

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adrp.org/annual-conference



INFECTIOUS DISEASE UPDATES



A study with a recombinant vesicular stomatitis virus-based Ebola vaccine had nominal 100 percent efficacy rate. An open-label, cluster randomized vaccination trial in Guinea and

Sierra Leone used the Ebola virus glycoprotein vaccine (rVSV-ZEBOV) on people with confirmed contact with Ebola or who had contact with someone who contracted Ebola. The study used a ring vaccination approach somewhat reminiscent of the smallpox eradication strategy. Participants were vaccinated immediately or 21 days after randomization and the vaccine was 100 percent effective (95 percent confidence interval, 68.9-100 percent) in the cohort randomized to immediate vaccination. Researchers of the study concluded, and an accompanying commentator agreed, the vaccine's efficacy may have reduced Ebola spread during the 2013 to 2016 outbreak in Guinea. It is still unclear how long-lasting the vaccine's protective nature is, however, the high protective rate, notes the commentator and study authors, is a solid foundation on which to build.

Citations: Henao-Restrepo A.M., Camacho A., Longini I.M., *et al.* Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomised trial (Ebola Ça Suffit!). *The Lancet*. December 22, 2016 online. DOI: [http://dx.doi.org/10.1016/S0140-6736\(16\)32621-6](http://dx.doi.org/10.1016/S0140-6736(16)32621-6).

Geisbert T. First Ebola virus vaccine to protect human beings? *The Lancet*. December 22, 2016 online. DOI: [http://dx.doi.org/10.1016/S0140-6736\(16\)32618-6](http://dx.doi.org/10.1016/S0140-6736(16)32618-6). ♦

REGULATORY NEWS

The **Food and Drug Administration (FDA) released an Ebola final guidance earlier this week.** The guidance will require a number of interventions when widespread Ebola infection is recognized by the U.S. Centers for Disease Control and Prevention (CDC) in one or more countries. The guidance recommends updates to donor educational materials. Other recommendations are to be implemented when the CDC has classified one or more countries as having widespread transmission of Ebola virus. Guidance is provided for donor deferral intervals and for product retrieval, quarantine and notification of consignees.

The **Director of the Center for Biologics Evaluation and Research released a Fiscal Year 2016 report.** In the report, a number of new products were listed for the treatment and control of numerous bleeding disorders and diseases. Also noted were final guidances on Zika; published reports and articles on blood disorders as well as infectious diseases and risks for transfusion transmissible infections; their public hearings and workshops; and the launch of the Transfusion Transmissible Infections Monitoring System. ♦

WORD IN WASHINGTON

A bill to repeal the medical device tax was introduced. As the Republican-led Congress begins to lay the foundation upon which they could repeal the Affordable Care Act (ACA), one section of ACA is already under attack from both sides of the aisle. A bipartisan bill with over 230 co-sponsors (HR 184) was introduced into the House of Representatives last week and on Wednesday into the Senate, named the Protect Medical Innovation Act of 2017. The bill would make permanent a suspension of the medical device tax that's been in place since December 2015. The 2.3 percent tax was placed upon the sale price of medical devices when ACA passed in 2010 and received criticism from both Republicans and Democrats that the tax placed undue burden on the device industry and stifled innovation and growth. (Source: Regulatory Affairs Professional Society.com, [Bipartisan House Bill Seeks to Repeal Medical Device Tax](#). January 4, 2017) ♦



AMERICA'S BLOOD CENTERS 55th ANNUAL MEETING



"The 2017 ABC Annual Meeting in Washington, DC is the premier place for industry leaders to experience peer-to-peer collaboration and networking, exclusive educational events and the opportunity to be an advocate for your blood center on Capitol Hill."

– Christine Zambricki, Chief Executive Officer, America's Blood Centers

March 24-28, 2017 – Washington, DC

Future Leader Scholarship Program (Funded by FABC)

Details available upon registration.

Registration Fees (Member/Non-member)

Annual Meeting: \$975 / \$1,605

International Blood Safety Forum (Friday only): \$275 / \$275

International Blood Safety Forum & Business Forum (Fri & Sat only): \$410 / \$410

Business Forum through Advocacy Forum (Sat through Tue): \$760 / \$1,330

Registration opens early December. For questions, contact [Lori Beaston](#).

Sponsorship Opportunities

For questions or to learn more about sponsorship opportunities, contact [Jodi Zand](#).

Meeting Schedule

Friday, March 24

International Blood Safety Forum

Saturday, March 25

Business Forum

ABC Board Meeting

Sunday, March 26

ABC Members Meeting

SMT Forum & Celso Bianco Lectureship

FABC Reception

Monday, March 27

Blood Center Leadership Forum

20th Annual Awards of Excellence

ABC's Got Talent Season II

Tuesday, March 28

Advocacy Forum

Capitol Hill Visits

Hotel Information

Ritz-Carlton (Pentagon City)

Hotel room rate: \$249 + tax

Reserve hotel by March 3



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**ABC's
Got Talent**

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MARCH 27, 2017

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IN MEMORIAM



Corey Dubin. Mr. Dubin, a fierce critic but great friend of the blood community for many years, passed away on January 4, 2017. Mr. Dubin, a vocal former member on the Food and Drug Administration's Blood Products Advisory Committee and co-founder and Emeritus President of the Committee of Ten Thousand, had severe hemophilia and contracted the infections that so reliably accompanied the disease before virally inactivated plasma-derived factor concentrates were regularly available. Corey was a tireless advocate for many years for those affected in "his" epidemic specifically, but also fought for general reform of the public health system—a system he saw as dangerously reactive; missing opportunities to anticipate and prevent outcomes like those that so affected him and his companions. Moreover, he was a bridge from his community to ours through hard times when rancor often made communication tough. His intelligence, advice, good humor and friendship will be sorely missed. 📌

MEMBER NEWS



National Center for Blood Group Genomics (NCBGG) opens. New York Blood Center and their partner organization Community Blood Center of Greater Kansas City have established a state-of-the-art genomics testing center now open, exclusively, in Kansas City. The NCBGG is the first laboratory and research center of its kind in the nation to specialize in precision medicine applied entirely to blood transfusion. The NCBGG mission is to provide the highest quality testing services for extended blood typing at lower cost for donor centers and the patients they serve to

improve the practice of transfusion medicine, to develop the next generation of testing, and to train the next generation of leaders. (Source: NYBC press office).

Mississippi Valley Regional Blood Center (MVRBC) has joined the National Blood Collaborative (NBC). NBC is a national organization of blood centers that supports collecting, processing, and distributing blood to local communities and NBC's hospital customers. Mike Parejko, CEO of MVRBC, said, "This collaboration allows us to maintain our independence as a community-based blood center even as we find new opportunities through NBC. We are now positioned to increase the diversity of our services, add new revenue streams, and to enhance the service we provide for patients and hospitals in both the local and national healthcare continuum. We can already see a number of 'wins' as we get underway and even more advantages on the horizon." (Source: [MVRBC press release](#), January 3, 2017)

San Bernardino, Calif.-based blood center LifeStream honored their thirteenth donor to reach the 100-gallon mark.

While Michael Testi was donating at the Riverside Donor Center, he also enjoyed a ceremony in his honor, performed by the center's President and CEO Rick Axelrod, MD. Mr. Testi has continued donating via apheresis since being diagnosed with Type 2 diabetes about 10 years ago. Center staff cheered on for Mr. Testi as Dr. Axelrod presented the long-time donor with a framed certificate in recognition of the achievement and limited edition 100-gallon donor polo shirts. (Source: LifeStream press office) 📌





GLOBAL NEWS



Biotest, a German-based plasma and biological drug maker, will soon be offering a new hemophilia A drug. The fourth-generation recombinant human factor VIII is intended to prevent and stop bleeding episodes in children and adults with hemophilia A. The factor VIII preparation is produced from a human cell line, but not from human plasma. The new product will be offered in early 2017 to patients in Germany, Austria, and Switzerland. (Source: [Biotest press release](#), November 3, 2016) ♦

COMPANY NEWS



Cambridge, Mass.-based Shire announced they are growing to focus on rare diseases. The biopharmaceutical company will expand their facilities by adding a building to their office location as well creating a new 550,000 square-foot campus by 2019. The list of rare diseases Shire plans on targeting with investigational new therapies for such diseases as hemophilia, von Willebrand disease, primary immunodeficiency disease, and hereditary angioedema. (Source: International Blood/Plasma News, November 2016) ♦

CALENDAR

2017

Jan. 24: **ABC Board of Directors Retreat, Nashville, Tenn.** E-mail [Lori Beaston](#) for more information.

Feb. 8-9: **FDA, Identification and Characterization of the Infectious Disease Risks of Human Cells, Tissues, and Cellular and Tissue-Based Products; Public Workshop.** College Park, Md. For more information, click [here](#).

Feb. 13-14: **AABB U.S. Hemovigilance Symposium, Atlanta, Ga.** To register and more information, click [here](#).

February 13-15: **PharmaConference's 13th Annual FDA and the Changing Paradigm for HCT/P Regulation conference, Alexandria, Va.** For more information, click [here](#).

Mar. 2-3: **IPFA 2nd Asia Workshop on Plasma Quality and Supply, Yogyakarta, Indonesia.** To register for the workshop, click [here](#).

Mar. 24-28: **Annual Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Department. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Mar. 25: **Board Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Department. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

April 6: **National Institutes of Health's Public Workshop: Emerging Tick-Borne Diseases and Blood Safety** Bethesda, Md. For more information, click [here](#).

Apr. 18-19: **Heart of America Association of Blood Banks (HAABB) 50th Annual Spring Meeting, Kansas City, Mo.** For more information and to register, go to <http://www.haabb.org>.

May 1-3: **2017 ADRP Annual Conference, Chicago, Ill.** More information is available on the [website](#).

CALENDAR (continued from page 12)

May 16-17: **IPFA/PEI 24th International Workshop on “Surveillance and Screening of Blood-borne Pathogens”**, Zagreb, Croatia. To register, click [here](#).

June 6-8: **Technical & Quality Workshops, America’s Blood Centers, Omaha, Neb.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

June 17-21: **27th Regional Congress of the ISBT, Copenhagen, Denmark.** [Click to register for the event.](#)

Aug. 1-4: **Summer Meeting, MD Workshop & Golf Tournament, America’s Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 4: **Board Meeting, America’s Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 11-12: **IPFA/BCA 3rd Global Symposium on The Future for Blood and Plasma Donations, Atlanta, Ga.** [Registration will open in mid-September.](#) ♦

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 Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: lmaundy@americasblood.org.

POSITIONS

Scientist, Hematology. (Company: Cerus Corporation; Location: Concord, CA) Initiates, directs and executes scientific studies for multiple projects for the INTERCEPT Blood System. Focus on registration studies with external collaborators. Acts independently as Study Director: Experimental design, preparation of protocol, study execution, data analysis, and preparation of final report. Assists in planning and conduct of external registration studies. Notes trends and aberrations in data; identify problems and suggesting/conducting experiments to determine root cause and develop solutions. Participates on project teams providing contribution of ideas, developing of plans, execution of plans, and timely reporting of results. Ph.D. in a biology-related discipline preferred with a minimum of two years relevant experience or MS/MA in a biology-related discipline with a minimum of eight years relevant experience; BA/BS required with a minimum of 11 years relevant experience. Experience with platelet and RBC function and or plasma coagulation desirable. For full job description and to apply visit: <http://www.cerus.com/Careers>.

Associate Director & Sr. Scientist, Platelet and Plasma Biology. (Company: Cerus Corporation; Location: Concord, CA) Lead research and/or development studies to support the INTERCEPT Platelet and Plasma platforms. Be a technical expert and key member of the Development team in the areas of plasma coagulation and/or platelet physiology. Direct studies to support both product development and commercial supply for the

INTERCEPT System for platelets and plasma. Manage laboratory team to support product line extensions studies to meet corporate timelines. Interface with cross functional team leaders. Function as study director in designing, conducting and analyzing own experiments and, potentially, those performed at other sites. Ph.D., with a minimum of seven years relevant experience or master’s degree in a scientific discipline with a minimum of 10 years’ experience. For full job description and to apply visit: <http://www.cerus.com/Careers>.

Reference Technologist III (Job 08030 Seattle (First Hill); Immunohematology Reference Laboratory). Bloodworks Northwest is currently seeking an experienced Medical Laboratory Technologist/Blood Bank Technologist to work in the Immunohematology Reference Laboratory (IRL) at our First Hill Seattle location. This position is eligible for sign on bonus and also offers great benefits and competitive pay. Requirements include: Bachelor of Science degree in clinical laboratory science or other biological science or equivalent; education must meet CMS/CLIA qualification requirements to perform high complexity testing. Also required are two years of immunohematology reference laboratory experience and current certification as MLS (ASCP), BB (ASCP) or MLT(ASCP) or equivalent certification. SBB(ASCP) certification is preferred. The

(continued on page 14)

POSITIONS (continued from page 13)

requirement for two years of Immunohematology reference lab experience may be waived with SBB(ASCP) certification. Demonstrated familiarity with computers and keyboarding skills for performing order entry, and the ability to see red, green, blue and yellow are required. We are also looking for excellent customer service skills and the ability to prioritize and reprioritize, and handle tight deadlines, stressful situations and emergency requests. **IMPORTANT NOTICE REGARDING APPLYING:** Please visit our [website](#) and apply to either jobs 08029 or 08030. EEO Employer

Clinical Laboratory Scientist. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a nonprofit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Clinical Laboratory Scientist. The Clinical Laboratory Scientist is responsible for activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Clinical Laboratory Scientist performs reference immunohematological testing and participates in training, validation, implementation of new procedures, and compliance with regulatory and standard-setting agencies. Experience, Education and Licensure: Four-year degree from an accredited college or university in science, medical technology or a related field. Valid current California license as a Clinical Laboratory Scientist. Preferred experience as a technologist in a clinical laboratory and familiarity with standard laboratory methods and techniques, ability to perform standardized routine testing, specialized testing in blood donor processing, and immunohematology. Will train the right candidate. To Apply: Contact Adam Summers (asummers@nccbb.org); Northern California Community Blood Bank; 2524 Harrison Avenue, Eureka, CA 95501; (707) 443-8004.

Associate Medical Director. Michigan Blood seeks Physician, board certified in Clinical Pathology or Hematology and board certified in Transfusion Medicine (or eligible to achieve certification in the first year of employment), to assist in all medical/clinical aspects of donor eligibility, therapeutic apheresis, transfusion medicine consultation and patient reporting from our clinical laboratories. Candidate will also assist with the medical and technical review of SOP's, validations and variances as assigned. Requirements include being a team player with excellent verbal and written communication skills. Experience in donor qualification, therapeutic apheresis and transfusion medicine consultation for transfusion service is preferred. Michigan Blood provides blood products and services for more than 70 hospitals throughout Michigan, and is an established leader in quality and service. In addition, Michigan Blood provides therapeutic apheresis, cellular therapies for the treatment of cancer and transfusion medicine consultations. We offer a competitive salary and benefit plan. If you like to work with

people, have good communication and customer service skills, and the desire to make a lifesaving difference, please send your resume and cover letter to: www.miblood.org.

Assistant Manager Donor Testing (Laboratory Supervisor). (Department: Donor Testing; Reports To: Manager Donor Testing Lab; Status: Full-time, 1.0FTE, and Exempt; Schedule: Monday – Friday, 3rd Shift 9 p.m. - 5:30 a.m.; Benefits: Medical, Dental, Vision, 401K, PTO / EST, to name a few!) Take the next step in your career in our high profile donor testing laboratory with our non-profit mission based organization. Primary Purpose: Manages testing laboratory 3rd shift staff and coordinates operations associated with testing blood donors for infectious disease and immune-hematology during these shifts. Provides adequate training and performance appraisals. To apply please go directly to our website with an updated resume: <https://home2.eease.adp.com/recruit2/?id=19192882&t=1>.

Medical Technologist. The Rhode Island Blood Center (RIBC) is seeking a Medical Technologist (MLT, MT, SBB, or BB). This position is based in Providence, RI. The primary responsibilities of the Technologist position include: routine testing of donor blood samples with proper technique and documentation, labeling of blood components, performing and documenting quality control procedures, and generating client reports for donor testing. MLT, MT, BB or SBB (ASCP) certification is required. Please apply online at www.rIBC.org. **JOIN THE TEAM THAT GIVES THE GIFT OF LIFE!!!** RIBC is an equal opportunity employer. 📌