

A B C N E W S L E T T E R

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2016 #14

April 29, 2016

Gulf Coast Regional Blood Center First to Test Blood from Stateside Donors for Zika

ABC member Gulf Coast Regional Blood Center (GCRBC) is the first United States blood center to announce a decision to test donors for Zika virus (ZIKV) in blood donated within the continental U.S. Testing will be conducted in a Roche Molecular Systems-sponsored clinical trial under a Food and Drug Administration-approved Investigational New Drug (IND) protocol, starting in late May. Under the IND, the testing will use a real time polymerase chain reaction-based donor screening assay, a nucleic acid amplification method on the investigational cobas® 6800/8800 system.



"It was the right thing to do for patients and for the donors," said Brian Gannon, CEO and President of the GCRBC. "When you see those pictures of women holding their babies with microcephaly... looking at that little baby, you just know we have to do something."

Brian Gannon, CEO and President of GCRBC

Transfusion-transmitted ZIKV infection has been of great concern to the blood community in the face of the wide-spread epidemic in the Americas. A major driver of concern is that ZIKV has been causally linked to a

Brazilian epidemic of microcephaly, a severe neurodevelopmental abnormality in fetuses and infants, as determined by the U.S. Centers for Disease Control and Prevention (CDC) in a special report in *The New England Journal of Medicine*.

Testing at GCRBC is set to start as early as May 23, but could take until the first week of June, said Mr. Gannon. Until testing begins, staff at the Houston-based blood center will continue to screen donors based on their answers about travel and residence patterns and whether donors have had sexual contact in the last three months with someone at risk for ZIKV infection.

The costs for the added individual donor testing are not prohibitive, a 3 percent increase, said Gannon; yet his organization—which supplies blood components to more than 170 hospitals and health care centers in the Gulf Coast region of Texas—is pursuing financial options with local hospitals to decrease the burden on the blood center.

"I think we initiated the process earlier this year when Zika became a global emergency and everyone at the FDA was extremely interested around testing,"

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OUR SPACE

ABC President Susan Rossmann, MD, PhD

The Future Blood Industry Will Lag Behind, Not So

Recently, a thought-provoking commentary on the "Evolution of the nation's blood supply system" appeared in *Transfusion* online, ahead of print. The authors predict our current network of independent and American Red Cross blood centers will evolve to either a "consolidated" system of four to six independent suppliers or a single national system. Disturbingly, the authors predict a period of "temporary localized

independent suppliers or a single national system. Disturbingly, the authors predict a period of "temporary localized disruption of services" as we move to the new format, with shortages of certain products and a lack of full support for patients needing specialized products.

If such shortages are occurring now, they are not well-documented. Naturally, it's not in the best interests of the hospital nor the supplier to publicize any supply issues. However, in every recent disaster or emergency, the needs of patients have been met through the AABB Interorganizational Disaster Task Force or more informal networks. The recent shipment of thousands of blood units provisioned to Puerto Rico to cover during the Zika crisis is an excellent case in point.

Another disturbing note in this piece regards innovation by the blood community. "There has been wonderful innovation in transfusion medicine supported by blood centers, federal funding, industry, and universities...Industry is no longer willing to develop new products as there is little likelihood that the innovations will be implemented." The recent response to the threat from Zika virus, however, belies this statement, as one of the major nucleic acid amplicification test manufacturers already has a test under Investigational New Drug application, and the other is expected to launch one shortly. Interestingly, exactly 20 years ago, one of the authors published a similarly-titled piece in *American Journal of Clinical Pathology*. Dr. McCullough wrote, "Research in transfusion medicine and related fields is bringing potential new transfusion therapies and blood components closer to reality. The blood system and the organizations and people who compose it must continue to evolve in ways to implement these new therapies." Sadly, some of the promising products of that time, notably red blood cell substitutes, have not worked out. Pathogen reduction, however, is now a licensed product and available as another tool in the battle with Zika and other pathogens. We do move ahead, even as the rate of change sometimes seems glacial in the scientific and regulatory world but rapid in the organizational world.

Citations: Jeffrey McCullough, J. Mac McCullough and William J. Riley. Evolution of the nation's blood supply system, *Transfusion*. 2016 Apr 4. DOI: 10.1111/trf.13525. [Epub ahead of print]. PMID: 27041559

Jeffrey McCullough, The continuing evolution of the nation's blood supply system, <u>American Journal of Clinical Pathology</u>, 1996 Jun; 105(6):689-95. PMID: 865944

SusanRostmurk

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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. srossman@giveblood.org

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Gulf Coast Regional Blood Center First to Test Blood for Zika (continued from page 1)



said Tony Hardiman, Lifecycle Leader, Vice President, Blood Screening at Roche.

"Initially we got the instrumentation ready for Puerto Rico and then we looked at where else it would make sense in terms of preparedness. In the Southern states just seemed like a higher opportunity for Zika to be transmitted." *Aedes aegypti*, the principle vector for ZIKV, dengue, and chikungunya viruses is present in the southern tier of the U.S., including the

gulf coast region.

Last month, Tampa, Fla.-based Creative Testing Solutions began testing donated blood units from the Commonwealth of Puerto Rico for ZIKV with the cobas system.

No cases of mosquito-borne transmission have been recognized in the continental U.S. or Hawaii; however, 388 travel-associated ZIKV cases have been reported within the continental U.S. and another 500 cases were reported in U.S. territories like Puerto Rico, U.S. Virgin Islands, and American Samoa, according to the CDC.

Other blood centers are interested in participating in the IND, said Mr. Hardiman. "We've had more than 20 inquiries to enroll in the IND. As we speak, we're in the process of moving forward and performing installations on instrumentation at other centers," he noted, although confidentiality agreements precluded him from saying exactly which centers were about to implement testing.

Citation: Rasmussen SA, Jamieson DJ, Honein MA, Peterson LR. Zika virus and birth defects — reviewing the evidence for causality, *The New England Journal of Medicine*. 2016 April. DOI: 10.1056/NEJMsr1604338

(Source: <u>FDA Press Release</u>, 3/30/16; <u>Roche Press Release</u>, 3/31/16; Creative Testing Solutions Statement, 4/7/16) ♦

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 Lisa Spinelli at <u>newsletter@americasblood.org</u>. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.





ABC Newsletter

ABC is pleased to announce Sameer Ughade will start as the Director of Information Technology (IT) and Business Intelligence for the organization on May 9. Mr. Ughade brings with him 10+ years of experience in designing and developing IT systems and managing and leading IT departments and teams. His areas of expertise include, IT Infrastructure Design, Network and Security Management, Virtualization and Cloud Computing, Design and Development of Business Intelligence Systems, and Information Systems.

With a strong penchant for designing and implementing IT strategies and technology roadmaps, Mr. Ughade's past experience includes successful integration and migration of major data repositories, providing

analytic and business intelligence capabilities, bringing an outsourced IT service model in-house, creating and managing IT budgets for operational and capital project support, and establishing information security policies and programs including payment card industry-compliance.

In his most recent position, Mr. Ughade lead a large complex project responsible for converting multiple information systems to a single health care enterprise technology platform for a business opportunity expected to generate \$50 million in revenue. The project involved leading a cross functional team of 50+ resources, three geographic locations, four business units, and 550+ business users with a \$1.1 million budget.

Sameer earned a Master of Science in Computer Engineering from George Washington University and holds a Bachelor of Engineering in Electronics Engineering from the Visvesvaraya National Institute of Technology in India. He and his wife Sonal have a 2-year-old daughter and living in Maryland. Sameer will provide valuable strategic direction to the technology needs of ABC, including the data warehouse project, as well as many other critical, member-facing IT initiatives.

ABC SUMMER MEETING

Honolulu, Hawaii, August 1-4, 2016

Share, learn, network, and discover the latest trends in blood banking. The ABC summer meeting begins with the 6th Annual Links for Life Golf Tournament, followed by key sessions including the Medical Directors Workshop; Scientific, Medical & Technical Forum; and the Blood Center Leadership Forum. Come for the education – stay for the experience.



Register here.



America's Blood Centers^{*} INSIDE ABC It's About *Life*.

ABC Newsletter

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

Advocacy Update: ABC at Work for Members

The ABC Board of Directors recently approved the <u>ABC advocacy agenda</u> for fiscal year 2017, which contains several issues impacting community blood centers that ABC will address. A key component remains the development of a long-term reimbursement model for the sustainability of the U.S. blood collection and distribution system that accounts for the full value of a robust blood supply and encourages investment in innovative blood safety measures. Over the previous fiscal year that ended in March 2016, ABC had several "wins" including an announcement from the Department of Health and Human Services (HHS) that they have selected Rand Corporation to conduct an HHS-funded study investigating the current U.S. blood system model and future alternatives in collaboration with ABC, AABB, the American Red Cross, and other experts.

Another major milestone featured ABC activating its member blood centers for a grassroots advocacy campaign in opposition to proposed cuts to Medicare reimbursement for blood products outlined in the Centers for Medicare & Medicaid Services' (CMS) Hospital Outpatient Prospective Payment System (OPPS) proposed rule for 2016. Below are some outcomes of that campaign:

- 44 of ABC's 64 member blood centers participated in the campaign (sent letters to their legislators, CMS, or both);
- 48 letters were sent to CMS from member blood centers and other partner organizations (e.g., regional health associations);
- 130 members of Congress were contacted by ABC blood centers and partner organizations; and
- Eight of those legislators contacted CMS on ABC's behalf.

Additionally, as a part of these efforts, ABC met with HHS and advocated for the inclusion of Healthcare Common Procedure Coding System (HCPCS) codes to cover the transfusion of pathogen-reduced platelet and plasma products. ABC, AABB, and the American Red Cross submitted a joint <u>statement</u> to CMS expressing the importance of creating new P-codes to allow for appropriate billing of pathogen-reduced platelets and plasma to provide patients with access to these new products that can improve patient safety. The new codes are described in the <u>final rule</u> and took effect in January 2016 (outlined in the table below). ABC will continue to advocate on behalf of its member blood centers to eliminate other tests with the adoption of pathogen reduction technology. Updates on ABC's advocacy activities are available on the <u>ABC member site</u>.

New CY2016 HCPCS P-code	New HCPCS P-Code Long Descriptor	Final CY 2016 OPPS Payment Amount
P9072	Platelets, pheresis, pathogen reduced, each unit	\$641.85
P9071	Plasma (single donor), pathogen reduced, frozen, each unit	\$72.56
P9070	Plasma, pooled, multiple donor, pathogen reduced, frozen, each unit	\$73.08

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ABC Newsletter

Christine Zambricki, ABC CEO; Kari Aranko, EBA Executive Director; Sally Thomas, ABO Secretariat.

On April 5 through 8, ABC CEO Christine Zambricki traveled to Zagreb, Croatia to attend the European Blood Alliance (EBA) 37th Board Meeting and the Alliance of Blood Operators (ABO) Chief Executives Meeting.

ABO members, an alliance of blood operators from North America, Europe, and Australia—including members of the EBA and ABC, discussed updates on high risk deferrals, fresh product demand change, and the impact of plasticizers like di(2-ethylhexyl) phthalate in transfusion consumables, as well as trends in regenerative medicine and the production of plasma for fractionation. The ABO Donor Engage-

ment and Relationship Group is heavily engaged in promoting the <u>Missing Types Campaign</u>, a global effort to increase donor awareness involving over 30 countries.

During the meeting with EBA, the association of European nonprofit blood organizations discussed topics included complex immunohematology testing, donor deferral policies for use of non-steroidal antiinflammatory drugs, automated collection systems, human leukocyte antigen matched platelets, Hepatitis E virus testing strategies, and pathogen reduction. The National Health Service Blood and Transplant from Great Britain presented their strategy in Regenerative Medicine, including a discussion about issues related to donor information and donor biobanks as a resource for research. The group was very interested in hearing about the American experience with Zika as the EBA is actively working with the European Centre for Disease Prevention and Control on Zika and HEV mitigation.

The opportunity for knowledge sharing and benchmarking for individual ABC members is a great resource. For more information on opportunities ABC members have to partake in ABO and EBA activities, please contact <u>Christine Zambricki</u>.

RESEARCH IN BRIEF

Pathogen reduction with riboflavin and ultraviolet (UV) light reduces transfusion-transmitted malaria (TTM) from whole blood in a blinded, randomized, controlled clinical trial (RCT). In a landmark RCT, pathogen reduction treatment of whole blood with riboflavin (vitamin B2) and UV light significantly reduced the incidence of TTM. A common cause of childhood mortality, malaria claimed almost 500,000 lives last year worldwide, most in sub-Saharan Africa, according to the World Health Organization. While malaria usually spreads from mosquitoes, transfusions are a serious risk especially for those living in sub-Sahara Africa. Because a high proportion of donors have asymptomatic parasitemia resulting from extensive exposure and partial immunity, TTM is a major concern in this section of the world. Two hundred and twenty-seven patients were enrolled in this RCT in Ghana, specifically powered to assess TTM in non-parasitemic (by sensitive polymerase chain reaction assay) recipients who received parasitemic transfusions. The combination of riboflavin and UV treatment (Mirasol, Terumo BCT, Lakewood, Colo.), reduced the incidence of Plasmodium transmission in that critical group to 4 percent (1/28 patients) from 22 percent, (8/37 patients) in controls receiving untreated units. Adverse events were clinically and statistically similar in the control and treated whole blood recipients groups. A particular strength of the study was the use of a stringent sequencing technique called parasite allelic matching that allowed attribution of transmission to a specific donor in support of the diagnosis of TTM. In an accompanying comment, Sheila O'Brien, PhD, from Canadian Blood Services stated "Evidence that transfusion-transmitted infections in whole

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<u>RESEARCH IN BRIEF</u> (continued from page 6)

blood can be safely addressed by pathogen reduction technology while maintaining the clinical benefit of the transfusion underscores the potential for this treatment to revolutionise transfusion safety in Africa where it is most needed." Trials of this nature are not feasible in the developed world where rates of transmission by transfusion are too low to assess infectious endpoints. (Source: World Health Organization. <u>World Malaria Report 2015</u>.)

Citations: Allain J-P, Owusu-Ofori AK, Assennato SM *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. *Lancet.* 2016. 387:1753-61.

O'Brien SF. Transfusion-transmitted malaria: is hope around the corner? Lancet. 2016. 387:1701-3.

A prospective study measuring the 10-year mortality of adults after transfusion took place in the United Kingdom. Physicians and professionals working in the blood community understand blood transfusions can be lifesaving for some patients, but for other patients they are less clearly beneficial. Mortality from the underlying process necessitating transfusion is substantial in the short, medium and long terms, but precise measurements will facilitate the crafting of clinical guidance, and especially where costbenefit studies of safety interventions is lacking. Investigators from National Health Service Blood and Transplant in the United Kingdom performed a prospective analysis of patients transfused in 2001 to 2002 to determine the long-term survival of recipients older than 16 years, transfused with red blood cells (RBC), platelets or fresh frozen plasma. This study found that more than 70 percent of all recipients die within the decade after transfusion, broadly consistent with other, largely retrospective, studies in the developed world. Survival was associated strongly with age at transfusion, with younger RBC recipients (16 to 39 years old) having a survival rate of over 80 percent. Diagnosis, e.g. cancer vs. no cancer and medical vs. surgical indications, was also associated with survival and both medical and surgical patients with malignancy had the shortest survival. Analyses stratified by the product transfused are also provided. The authors conclude that given high survival in young recipients, and for some older patients as well, continued vigilance for transfusion-transmitted infection-and presumably other adverse effects from blood—is "essential."

Citation: Morley SL, Hudson CL, Llewelyn CA *et al*. Transfusion in adults: 10-year survival of red cell, plasma and platelet recipients following transfusion. *Transfusion Medicine*. 2016. Early online. DOI: 10.1111/tme.12307.

A study in *Emerging Infectious Diseases*, identifies viruses in malaria-free Canadians who reported an illness after returning from travels outside the country. The study included travelers from May 2006 to April 2007 and February 2013 to March 2014. The 1,304 anonymized samples, from the malaria biobank at the Public Health Ontario Laboratory, were negative for malaria and tested using real-time polymerase chain reaction (PCR) assay for herpes simpex virus (HSV) type 1, HSV-2, Epstein-Barr virus (EBV) and cytomegalovirus (CMV), and by real-time reverse transcription PCR for dengue, a panflavivirus assay, hepatitis A (HAV), and chikungunya. A "travel-associated" virus was found in more than 20 percent of these malaria negative samples; dengue was found in 2.1 percent; and chikungunya in 0.4 percent. A substantial number of HAV infections were attributed to inadequate use of pre-travel immunization. The herpesvirus positive samples were attributed to a variety of possible causes, including acquisition before or during travel or reactivation of chronic latent infection. The authors noted that the role of travel in herpesvirus infections will require a prospective evaluation since the lack of clinical linkage or control groups for these specimens are important shortcomings of the study. The authors conclude that vector-borne pathogens (not endemic in Canada) were emerging during the study among Canadian travelers. The relevance of these findings to blood donors is not clear. Dengue transmission from well donors is rarely

<u>RESEARCH IN BRIEF</u> (continued from page 7)

recognized despite millions of infections worldwide and chikungunya, an epidemic in large parts of the world, from transfusion has not been recognized and reported, despite its biological plausibility.

Citation: Kariyawasam R, Lau R, Eshaghi A *et al*. Spectrum of viral pathogens in blood of malaria-free ill travelers returning to Canada. *Emerging Infectious Diseases*. 2016. 22:854-61.

BRIEFLY NOTED

The <u>American Society for Apheresis</u> (ASFA) and the Board of Certification (BOC) at the American Society for Clinical Pathology (ASCP) have teamed up to offer a <u>qualification in apheresis</u> for eligible apheresis professionals. To receive the qualification, medical professionals will first have to prove eligibility to the BOC and then take a self-administered computer-based test. The 90-minute test consists of 50 multiple choice questions and carries a \$240 application fee. The qualification lasts for three years and can be re-validated for an additional \$50 application fee along with proof of six continuing education hours or other apheresis activities. A dedicated room at the ASFA meeting in early May at the Westin Mission Hills Golf Resort & Spa in Palm Springs, Calif., is available for testing as well.

Workshop examined key priorities in blood banking and transfusion medicine. The Scientific Priorities in Pediatric Transfusion Medicine workshop, organized by the <u>National Heart, Lung, and Blood</u> <u>Institute</u> (NHLBI) and held in Bethesda, Md. from April 5 to 6, was called to identify key research questions and priorities in blood banking and transfusion medicine that need to be addressed in the next five to 10 years to optimize transfusion care in neonate and pediatric patients and advance the health of teenage blood donors. The two-day workshop split scientific and medical participants into six focus groups and put forward 26 research questions. The biggest theme that arose was the lack of epidemiological databases in transfused neonates and children in all clinical settings. Without baseline data, participants felt mired to propose robust clinical trials that would lead to level I evidence. The workshop did produce some other themes, including understanding alloimmunization and management of alloimmunized patients and mothers; the best use and management of blood products to achieve clinical benefit in cancer, surgery, and for patients on extracorporeal circuits, and the safety of blood donation for 16 year-old children. NHLBI and the National Institutes of Health will be partnering to present funding opportunities inspired by the workshops. **•**

REGULATORY NEWS

The Food and Drug Administration (FDA) has moved the date for the <u>public hearing on "Draft</u> <u>Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Prod-</u> <u>ucts</u> (HCT/Ps) at the Masur Auditorium on the National Institutes of Health Campus in Bethesda, Md., from April 13 to September 12 and 13, 2016. The hearings are a chance to give input and comments on four draft guidances regulating various aspects of HCT/Ps. Comments for the guidances are now due by September 27, after the hearing. Additionally, the FDA has announced a <u>public workshop titled</u> <u>"Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval</u>," to identify and discuss scientific considerations and challenges regarding the development of HCT/Ps subject to premarket approval, including stem cell-based products, on September 8 at the FDA White Oak Campus in Silver Spring, Md.

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<u>REGULATORY NEWS</u> (continued from page 8)

Please participate in Bureau of Labor Statistics (BLS) survey. The BLS will soon be visiting blood centers and organ banks to update their listing of services that comprise the Producer Price Index (PPI). ABC, AABB and BLS encourage your participation in this survey that is used to measure prices related to the collection, storage and distribution of blood and blood products, and the storing and distribution of body organs. According to the North American Industry Classification System (NAICS), blood and organ services are grouped into one industry—blood and organ banks. The continued success of the PPI for blood and organ banks depends on industry participation. These valuable statistics are made possible through the participation of blood centers such as yours. ●

THE WORD IN WASHINGTON



Karen DeSalvo, Acting Assistant Secretary of HHS

ABC CEO Christine Zambricki, DNAP, CRNA, FAAN, and Dr. Louis Katz, ABC CMO, met with Dr. Karen DeSalvo, Acting Assistant Secretary of Health and Human Services (ASH) and her team this week in Washington, D.C, to discuss the blood system's sustainability. Dr. DeSalvo requested the meeting to obtain first-hand information from blood operators about current challenges in the community and their impact on accessibility to an adequate and safe blood supply in the future.

ABC representatives used this opportunity to brief these key leaders on the chilling impact of dropping transfusion rates and intense competition on blood centers' ability to adopt quality and safety innovations and surge in response to a national threat. Discussion emphasized the central role of the current reimbursement paradigm in which payment for blood and blood products is made to hospitals, who, viewing blood as a commodity in their quest to reduce cost, have little incentive to recognize changes in our cost structures. Lastly, the team explored the topic of alternative models, in-

cluding direct payment for blood system infrastructure and an antitrust exemption that would allow competing blood programs to collaborate to set quality and safety standards and charges for new technology in the interest of public health. Dr. DeSalvo also acknowledged the blood community's effective and efficient coordination of services to Puerto Rico in response to the Zika crisis.

Other attendees at the meeting from the Office of the Assistant Secretary (OASH) included: Jewel Mullen, MD, MPH, MPA, Principal Deputy Assistant Secretary for Health; Thomas Novotny, MD, MPH, HHS Deputy Assistant Secretary for Science and Medicine; Dr. Richard Wolitski, HHS Acting Director for HIV/AIDS Policy; Elizabeth Phelan, MD, MS, the OASH ORISE Blood and Tissue Fellow; and Dr. Karen Scott, OASH Medical Director. Also in attendance were Jim Berger, MS, MT, ASCPS, SBB, Senior Advisor for Blood Policy, Advisory Committee on Blood and Tissue Safety and Availability; Shaun Gilmore, President of the American Red Cross Biomedical Services; and Chris Hrouda, Executive VP of Biomedical Services at the American Red Cross.

In the past two years, HHS established a Subcommittee on Blood Sustainability within the Advisory Committee on Blood and Tissue Safety and Availability. Louis Katz and Christine Zambricki are members of that sub-committee. This year, HHS funded the RAND study, originally conceived by the ABC Committee on the Value of Blood, to study the gap that exists in the blood economy and, if appropriate based on their findings, to make recommendations for system and reimbursement models that will protect future availability of a robust, safe blood supply. The study is expected to be completed within the next year.



GLOBAL NEWS

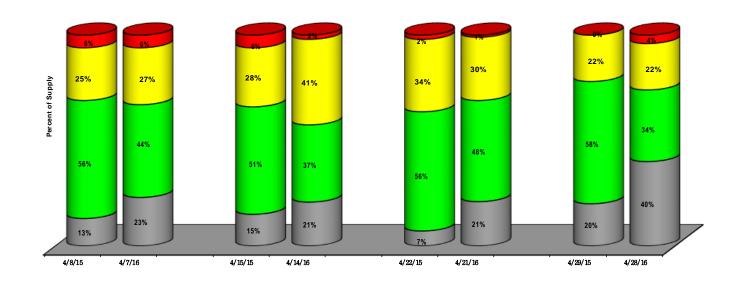
No Response

ABC Newsletter

The International Plasma Fractionation Association (IPFA) announced the Australian Red Cross Blood Service (ARCBS) as its newest member last week. With 78 fixed collection sites and 25 mobile, the ARCBS collects over 1.2 million blood, platelet, and plasma donations from almost half a million voluntary donors annually. As the only collector of blood donations in Australia, the over 80-year-old blood donation organization meets approximately 60 percent of the demand for plasma-derived products in Australia. The Amsterdam-based IPFA acts as a liaison between its collection centers, plasma suppliers and plasma fractionation centers. (Source: IPFA news release, 1/21/16)

INFECTIOUS DISEASE UPDATES

A new case of dengue virus (DENV) infection was confirmed April 22 on the Island of Hawaii, making the total number of confirmed Hawaiian residents and visitors infected at 264 since September 2015. However, data suggests the epidemic is waning. DENV is spread from mosquitoes to humans, but there is a small risk of transfusion transmission. ABC member, the Blood Bank of Hawaii, has taken steps to avoid drawing donors in the most affected area. (Source: Hawaii State Department of Health, Dengue Fever FAQs)



STOPLIGHT®: Status of the ABC Blood Supply

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

Yellow: 2 Days

Red: 1 Day or Less

Green: 3 or More Days



MEMBER NEWS



The **Rhode Island Blood Center** has partnered with Chicago-based Abbott Laboratories to kick off a new young donor campaign called **BE THE 1TM**. The partnership looks to leverage the influencing power of soccer star Cristiano Ronaldo as their global ambassador for the campaign. **BE THE 1TM** launched in April using the Real Madrid and Portugal national team soccer player, who has been a long supporter of blood donation and a regular donor since he was 24 years old. The campaign uses "pledges" that post to personal social media accounts in order to entice Centennials, or post-Millennials, to follow through on their promise to donate blood and plasma.

Heartland Blood Centers has announced a partnership with the <u>Sickle Cell Disease Association</u> of Illinois to launch the "Red is Life" program. The program aims to help drive awareness for sickle cell disease and the need for African-American blood donors, provide accurate education, and increase the amount of blood available for treatment of sickle cell disease. Sickle cell disease is an inherited disorder affecting the hemoglobin in red blood cells. There are more than 700,000 sickle cell patients in America, many of whom require numerous blood transfusions during their lifetime due to the lack of healthy red cells in their own body. Studies have shown that blood donated from someone of the same ethnicity as the patient reduces the risk of complications during and after transfusion—especially for those patients receiving multiple transfusions. Currently, less than 1 percent of national annual blood donations come from persons of African-American descent. Heartland Blood Centers urges all ethnicities to donate on behalf of those in your communities who are in need.

On April 4, Stephen McMeeken donated hit the 150 gallon mark at the **San Diego Blood Bank**'s East County Donor Center in El Cajon, Calif. The story made national headlines and was broadcasted to over 17 cities from <u>San Diego</u> to Albany, New York. Mr. McMeeken started donating blood in 1976 when his wife was pregnant with their first child. For the last 40 years, he has been regularly donating blood and also donates platelets 24 times per year. Mr. McMeeken is raising a legacy of donors by getting his two sons involved, both of whom are now also blood donors. ●



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 <u>newsletter@americasblood.org</u> 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.



PEOPLE



Dr. Nora V. Hirschler is retiring this week from Blood Centers of the Pacific (BCP), where she has been President and CEO since 1999. During her tenure, Dr. Hirschler oversaw the organization as it grew from serving 30 hospitals to 52; led the merger of BCP with Blood Bank of the Redwoods in 2011; and played an instrumental role in the January 2016 merger of BCP and Blood-Source. A Clinical Professor in Laboratory Medicine at the University of California San Francisco Medical School, Dr. Hirschler was previously the Medical Director at the American Red Cross in Northern Ohio and, subsequently, the Medical Director at the Irwin Memorial Blood Center (now BCP). She is a former member of the AABB Board of Directors and currently chairs the Nominating Committee. Blood Systems President and CEO Dan Connor

praised Dr. Hirschler's leadership and her compassion. "Nora has provided superlative leadership of BCP in a very competitive environment and served as a key leader in the Blood Systems network for more than 15 years. As a physician, she is a strong advocate for patients. She cares deeply for the employees who do the day-to-day work of saving lives," he said.

MEETINGS

May 10 – 11	ABC Board Meeting		
	The ABC Board Meeting will take place May 10 to 11 in Rosemont, Ill. Contact <u>Lori Beaston</u> for more information.		
June 9 - 11	14 th International Cord Blood Symposium, San Francisco, Calif.		
	AABB, with support from the Cord Blood Association, will host the 14 th Interna- tional Cord Blood Symposium from June 9 to 11 in San Francisco, Calif. The scientific program brings all of the umbilical cord blood related fields of hemato- poietic stem cell transplantation, banking, and potential in regenerative medicine together in one interactive three-day conference. The <u>program</u> , registration details, and other information can be found <u>here</u> .		
August 1 - 4	ABC 54th Summer Meeting Honolulu, Hawaii		
	Registration has begun for the ABC 54 th Summer Meeting in Honolulu, Hawaii, hosted by Blood Bank of Hawaii, will take place August 1 to 4, 2016 at the Hilton Waikiki Beach. It will feature the ABC Medical Directors Workshop and the Foundation for America's Blood Centers Golf Tournament. <u>Click to register</u> .		
September 8	FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.		
	This free, first-come-first serve, public workshop titled the <u>Scientific Evidence in</u> <u>the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products</u> <u>Subject to Premarket Approval</u> was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells,		



<u>MEETINGS</u> (continued from page 12)

tissues, and cellular and tissue-based products (HCT/Ps) subject to premarket approval, including stem cell-based products. The workshop will take place at White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room in Silver Spring, Md.

September 12 - 13 FDA Public Hearing on HCT/Ps, Bethesda, Md.

Early registration for this public hearing to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products will last until June 1. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found <u>here</u>.

POSITIONS AVAILABLE:

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 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) 393-1282; e-mail: <u>lmaundy@americasblood.org</u>.

Medical Technologist or Medical Laboratory Technician, PT. Blood Bank of Hawaii is seeking a state licensed MT or MLT. Performs ABO/CMV testing, all general lab procedures including work in components, blood inventory and the blood releasing section of the Laboratory. Must possess an understanding and working comprehension of the scientific, technical and procedural aspects laboratory testing, general comprehension of immunologic and genetic factors that affect health and disease. Must have a practical understanding of quality control and be able to perform simple instrument maintenance. Must be able to report test results, quote ranges and specimen requirements. All tests and procedures are performed with the highest standard of professional performance and in accordance with established standards of ethic and medical technology. Has an appreciation of the roles of paramedical and other health related fields, keeping the benefit of the donor, patient, physician and community in mind. Apply online at www.BBH.org.

Compliance & Regulatory Affairs Specialist (16000300). Blood Systems is searching for a Compliance & Regulatory Affairs Specialist to join its quality team in sunny Phoenix, AZ! Under minimal supervision, this position is responsible for supporting compliance activities for Blood Systems and its business units. This position drives change in policies and procedures to align with changes in industry based on regulations, best practice, etc. This position serves as a

resource to quality and operations for quality and regulatory issues. Requirements: Bachelor's degree; knowledge of blood banking industry standards and regulations; four years related experience in a regulated industry to include two years of experience quality, regulatory, and/or auditing. Preferred: COA, COE, and/or CMQOE certification; Certification as a Medical Technologist or Specialist in Blood Banking (SBB) by a recognized certifying agency or RN licensure. For immediate consideration, please apply on our website www.bloodsystems.org no later than Friday, May 6, 2016 - req. # 16000300. Blood Systems offers a competitive benefits package such as: affordable medical, vision, and dental coverage, matched 401(k), education assistance and much more! Pre-employment background check and drug screen is required. Visit our website at: www.bloodsystems.org. Blood Systems Inc. is an equal opportunity employer. EEO/Minorities/Females/Disabled/Veterans

Clinical Lab Manager (HLA) (16000290). Blood Systems Laboratories is searching for a Clinical Lab Manager to support its Histocompatibility Lab in sunny Tempe, AZ! Under limited direction, this position is responsible for managing the overall activities and providing skilled technical oversight in the laboratory. Works with other team members to ensure timely, quality, test results. Requirements: Bachelor's degree; CLIA

POSITIONS (continued from page 13)

requirements for high complexity testing; SBB or CHS certification; seven years clinical laboratory experience. Preferred: Master's degree; previous experience in molecular techniques, immunohematology techniques, automated testing and computerization; previous experience with supervision of laboratory for both solid organ and bone marrow transplant support; CHS certification. For immediate consideration, please apply on our website www.bloodsystems.org no later than Wednesday, May 4, 2016 - reg. # 16000290. Blood Systems offers a competitive benefits package such as: affordable medical, vision, and dental coverage, matched 401(k), education assistance and much more! Pre-employment background check and drug screen is required. Visit our website at: www.bloodsystems.org. Blood Systems Inc. an equal opportunity employer. is EEO/Minorities/Females/Disabled/Veterans

Clinical Lab Specialist (CTL) (16000291). Blood Systems Laboratories is searching for a Clinical Lab Specialist to support its Cellular Therapy Lab in sunny Tempe, AZ! Shift Assignment Hours: SHIFT 2. Under direct supervision, this position is responsible for performing routine testing of biological specimens. This position also provides skilled technical support in the laboratory. Works with other team members to ensure timely, quality, test results. Requirements: Bachelor's degree; CLIA requirements for high complexity testing; CA testing requirements must be met within one year; valid driver's license; meet and maintain company driver eligibility; two years clinical lab experience. For immediate consideration, please apply on our website www.bloodsystems.org no later than Wednesday, May 4, 2016 - req. # 16000291. Blood Systems offers a competitive benefits package such as: affordable medical, vision, and dental coverage, matched 401(k), education assistance and much more! Pre-employment background check and drug screen is required. Visit our website at: www.bloodsystems.org. Blood Systems Inc. opportunity an equal employer. is EEO/Minorities/Females/Disabled/Veterans

Quality Manager (UBS-AZ) (16000296). Blood Systems is searching for a Quality Manager to support its UBS division in sunny Scottsdale, AZ! Under minimal supervision, this position is responsible for assisting in managing the review of quality systems and compliance in all areas of technical and clinical operations. This position serves as a resource to operations on quality issues. Participates in performance improvement initiatives through data and process analysis. Requirements: Bachelor's degree; four years of related experience in a regulated industry to include two years in quality, regulatory, and/or auditing environment. Certification as a Medical Technologist or Specialist in Blood Banking (SBB) by a recognized certifying agency or RN licensure; six months supervisory experience preferred. For immediate consideration, please apply on our website www.bloodsystems.org no later than Wednesday, May

4, 2016 – req. # 16000296. Blood Systems offers a competitive benefits package such as: affordable medical, vision, and dental coverage, matched 401(k), education assistance and much more! Pre-employment background check and drug screen is required. Visit our website at: <u>www.bloodsystems.org</u>. Blood Systems Inc. is an equal opportunity employer. EEO/Minorities/Females/Disabled/Veterans

Quality Manager (BSRI-Denver) (16000299). Blood Systems is searching for a Quality Manager to support its research division at its newest location in Denver, CO! Under minimal supervision, this position is responsible for assisting in managing the review of quality systems and compliance in all areas of technical and clinical operations. This position serves as a resource to operations on quality issues. Participates in performance improvement initiatives through data and process analysis. Requirements: Bachelor's degree; four years of related experience in a regulated industry to include two years in quality, regulatory, and/or auditing environment. Certification as a Medical Technologist or Specialist in Blood Banking (SBB) by a recognized certifying agency or RN licensure; six months supervisory experience preferred. For immediate consideration, please apply on our website www.bloodsystems.org no later than Friday, May 13, 2016 - req. # 16000299. Blood Systems offers a competitive benefits package such as: affordable medical, vision, and dental coverage, matched 401(k), education assistance and much more! Pre-employment background check and drug screen is required. Visit our website at: www.bloodsystems.org. Blood Systems Inc. is an equal opportunity employer. EEO/Minorities/Females/Disabled/Veterans

Medical Director. The Plasma Protein Therapeutics Association (PPTA) is seeking a Medical Director to serve as the primary source of medical/clinical expertise for the association, its member companies and other industry stakeholders. Excellent opportunity for an M.D. with five plus years' clinical experience and research or pharmaceutical industry experience to make an impact. PPTA places key emphasis on protecting the health and safety of donors and patients, increasing global access to plasma protein therapies, therapeutic efficacy, and development of industry standards. Successful candidate will advise PPTA staff and member company representatives on clinical implications of industry activities; collaborate with association staff on communications and initiatives; participate in industry and regulatory meetings; track research and publish in peer reviewed journals; assist in the development of policy and industry standards; present to industry and regulatory groups. Medical training should include specialization in internal medicine, hematology, pathology, infectious diseases, immunology, or related. Position based fulltime in Annapolis, MD. Please visit http://idgsearch.com/active-searches for full position



POSITIONS (continued from page 14)

announcement or contact Julie Goodyear at (301) 340-2210. Interested candidates please send CV and letter of interest to <u>goodyear@jdgsearch.com</u>. Applications received by May 13 will receive priority consideration.

Director of Donor Recruitment. Blood Assurance, a regional blood services provider based in Chattanooga, TN, is seeking a director of Donor Recruitment to lead a team of donor recruiters who cover multi-state territories. Minimum qualifications for success in this new role will include a bachelor's degree with at least five to 10 years prior related experience managing a recruitment team in the blood banking industry. Other job requirements are advanced skills in influence and negotiation, communications, interpersonal relations with the public, creative problem solving, analytics and reporting, customer service, multi-task prioritizing, organizing and public speaking. This is a management-level position that reports to an Operations Executive and requires multi-state travel up to 70 percent of the time. Primary job responsibilities will involve building new and existing business relationships, developing team goals and holding staff accountable for meeting the blood collection goals set for multiple mobile and facility locations. Additional responsibilities include expanding business opportunities, executing the company's strategic business initiatives and developing staff skills in influence/negotiation, customer service and managing relationships. Key success factors will be executing with responsive leadership, effective internal partnerships and the ability to consistently set and attain collection goals that meet operational needs. For consideration, please submit a resume and salary expectations to: bbankdirector@yahoo.com.

AP/CP or CP Trained Pathologist. The Department of Pathology is seeking an AP/CP or CP trained pathologist (board certified), with subspecialty training in Transfusion Medicine (board certified or eligible). The candidate will share responsibility with one other medical director for supporting the Transfusion Service at the University of Utah Hospital, the Huntsman Cancer Institute and Primary Children's Hospital. The position will also support the Associated Regional and University Pathologists (ARUP) Blood Donor Cen-

ter and Immunohematology Reference Laboratory. The successful candidate will be expected to support laboratory and hospital quality improvement, compliance, and accreditation initiatives, and to provide consultation to clinicians. Participation in teaching of medical students, pathology residents, and hematology fellows is also expected. Research in the area of applied transfusion medicine is encouraged. Academic rank and salary will be commensurate with experience. Applicants should submit electronically a curriculum vitae, a brief cover letter, and the names and addresses of three references here. The University of Utah is an Affirmative Action/Equal Opportunity employer and does not discriminate based upon race, national origin, color, religion, sex, age, sexual orientation, gender identity/expression, status as a person with a disability, genetic information, or Protected Veteran status.

Corporate Account Executive (South Texas Blood & Tissue Center). BioBridge Global (BBG) is a nonprofit company that oversees and supports the South Texas Blood & Tissue Center (STBTC), QualTex Laboratories, GenCure, and The Blood and Tissue Center Foundation. The successful candidate will have solid business-tobusiness sales, account management experience and blood bank knowledge. This individual will be responsible for protecting and growing annual sales revenue from the distribution of STBTC blood components to hospital customers. Will also provide routine and appropriate education to external customers who use, purchase, or distribute our products/services. Will be responsible and accountable for the ongoing maintenance and accuracy of customer records in the database. Bachelor's degree in related field or equivalent combination of education and work experience. Minimum of three years of outside sales experience in blood-banking, medical device or pharmaceutical hospital sales. Familiarity with the use of SalesForce as a CRM is preferred. Offering competitive salary and benefits. For information, call Human Resources at (800) 292-5534, ext. 1559. For further information, visit our website: http://bit.lv/1SSpieh. BioBridge Global and its subsidiaries are proud to be an EEO-AA employer M/F/D/V and maintain a Tobacco and Drug-Free Workplace.



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f **Y** 2016

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 Maundy by e-mail (<u>lmaundy@americasblood.org</u>) or by fax to (202) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)

2016

May 25-26. **IPFA/PEI 23rd International Workshop**, **Lisbon**, **Portugal: "Surveillance and Screening of Blood Borne Pathogens"** More information is available at <u>www.ipfa.nl</u>.

June 2-5. 2016 SCABB Annual Meeting & Exhibit Show, Houston, Texas. Contact: scabb@scabb.org . More information available here.

June 5-6. South Central Association of Blood Banks Advanced Immunohematology & Molecular Symposium (AIMS), Houston, Texas. Contact: scabb@scabb.org. More information available here.

July 13-15. **2nd European Conference on Donor Health & Management, Cambridge, England.** Registration can be found here: <u>www.ecdhm.org</u>. Contact: Clare Beach, <u>ecdhm2016@azuraevents.co.uk</u>.

July 24-28. WFH World Congress, Orlando, Fla. Contact: jbungardt@wfh.org. More information available <u>here</u>.

Aug. 1-4. Summer Meeting, MD Workshop & Golf Tournament, America's Blood Centers, Honolulu, Hawaii. Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: <u>meetings@americasblood.org</u>.

Sept. 8. **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.** Contact: <u>FDA</u> for more information.

Sept. 12-13: FDA Public Hearing on HCT/Ps Comments, Bethesda, Md. Contact the FDA for more information.

Sept. 13-14. **IT Workshop, America's Blood Centers, Minneapolis, Minn.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: <u>meet-ings@americasblood.org</u>.

Sept. 21. 6th Annual Symposium Red Cell Genotyping 2016: Clinical Steps, Bethesda, Md. Registration can be found here: <u>www.bcw.edu/rcg2016</u>. Contact: Phyllis Kirchner, <u>Phyllis.kirchner@bcw.edu</u>.

Sept. 22. **35th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** Registration can be completed <u>here</u>. Contact: Karen Byrne, <u>kbyr-ne@cc.nih.gov</u>.

2017

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