

ABC Member Centers Impart Their Experiences with Zika Planning

Nearly 200 participants joined into the ABC Zika webinar on Tuesday, August 16, to listen to what presenters Louis Katz, MD, ABC's chief medical officer; Susan Rossmann, MD, president of ABC and chief medical officer of the Gulf Coast Regional Blood Center; Jill Evans, MT (ASCP), ASQ, CQA, vice president of quality at LifeSouth Community Blood Center; Rita Reik, MD, chief medical officer of OneBlood; and Galen Kline, CLSSBB, director of Quality Assurance and Regulatory Affairs at Heartland Blood Centers, part of Versiti, had to share on their experiences with Zika this summer. The presenters discussed initiatives to be considered at blood centers to maintain a safe and adequate blood supply in the face of Zika.

FDA on Zika

The Food and Drug Administration (FDA) guidance requires that all blood establishments who are not testing for Zika to defer donors who have traveled to Miami-Dade County in the last 28 days/four weeks. FDA has been asked to clarify the definition of "travel" and it is anticipated that an updated guidance will apply definitions used for malaria, which is 24-hours, to avoid deferrals for those driving through the country or for airport transfers. The area affected has seen a spike from an initial three individuals in late July to 30 locally-transmitted Zika infection cases, noted Dr. Reik; however, the area affected remains within Miami-Dade County (with five new locally-acquired cases reported at Miami Beach today, Friday, August 19).

Zika Testing

OneBlood, LifeSouth Community Blood Center, Gulf Coast Regional Blood Centers (GCRBC), SunCoast Blood Bank, Blood Systems, South Texas Blood & Tissue and

American Red Cross (ARC) are all performing Zika testing and the Blood Bank of Hawaii has reported they will start imminently. These centers went through a complex Investigational New Drug (IND) application process.

"It's a cumbersome submission with lots and lots of documentation," warned Ms. Evans. But "the risk of transfusion transmission weighs heavy on our minds..."



Roche cobas 6800 Zika testing equipment

circumventing that was a big motivator for us (in getting the testing up and running). We are a surveillance tool, we believe strongly in this one, because 80 percent of those infected are asymptomatic."

"It was relatively easy for us to get the machine up technically," said Dr. Rossmann. "We as a blood community, however, really need to work on our consent issues...particularly for minors. These tests are not gene therapy trials, there just doesn't seem to be a real evaluation of the risk."

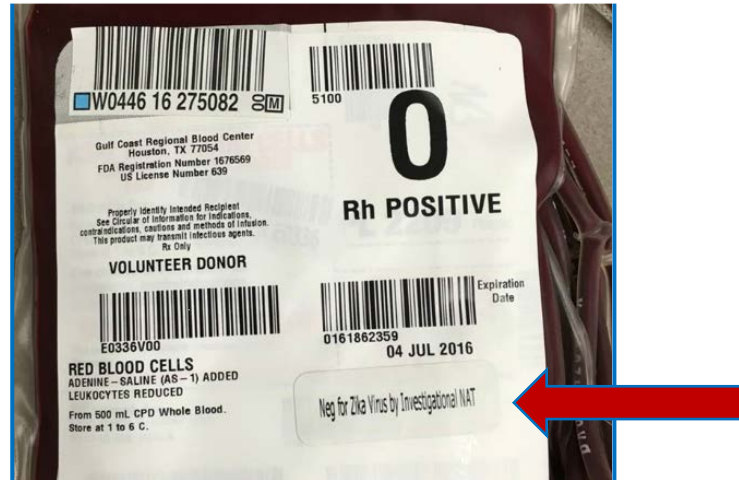
FDA had required, in the IND protocols, that some high-risk blood recipients give

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MEMBER CENTERS IMPART EXPERIENCES WITH ZIKA (continued from page 1)



Blood unit with Zika testing label

consent or acknowledgment to receive units that have been tested for Zika. However, with FDA concurrence, this process has already been changed, removing the requirement for special consent.

The Roche IND also required specific consent for testing from the donor, unlike the Hologic protocol that allowed the use of a donor information sheet without specific consent. Roche is considering amending their study to accommodate this much simpler approach.

Despite thousands of samples tested by GCRBC, OneBlood, LifeSouth Community Blood Centers, SunCoast Blood Bank, South Texas & Blood Systems, the *Newsletter* is aware of no positive results.

Cost recovery for testing and the new processes that accompany testing is allowed under IND and some member centers have reportedly been able to recover the testing costs from the hospitals they service.

Pathogen Reduction

The FDA guidance in February allows use of pathogen reduction on plasma and platelet donations to minimize the risk of Zika infections. The technology is not available for red blood cell donations.

Ms. Evans and LifeSouth leadership decided pathogen reduction could be beneficial to their center for use with their platelet donations, and are treating platelets using Cerus Corp.'s INTERCEPT system today, she said. SunCoast has been distributing INTERCEPT platelets since January 2016 and are distributing about 20 percent of their platelet inventory as pathogen reduced platelets now, said CEO Scott Bush.

Partnering with Public Health

Reflecting what was heard at the summer meeting about dengue in Hawaii from BBH and the Hawaii Department of Health, an important lesson the presenters imparted was the necessity of partnering with local health departments (DOHs).

“We have a model relationship with the Florida state public health department. And I agree, it’s wonderful to have a collaborative relationship with them,” said Dr. Reik, agreeing with Ms. Evans on the matter.

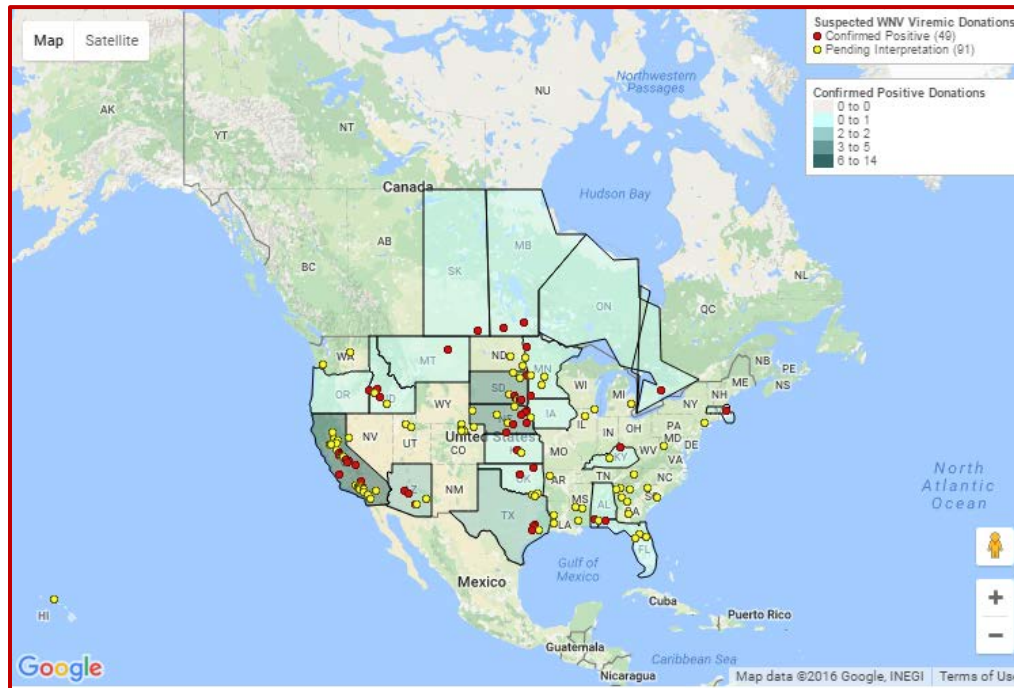
Having a healthy, long-term, partnership with the local DOH can help ensure a blood center’s crisis plans are swiftly put into action immediately following the emergence of viable risks to the blood supply. The local DOHs can take weeks, if not longer, to conduct their own investigations, so blood centers with those open lines of communication can benefit and get the information needed for appropriate interventions should an outbreak of any kind occur.

“They (DOHs) love blood centers, because we’re a pretty effective surveillance system for the healthy human population and they appreciate us very much for that,” said Dr. Reik. “Their (FDA) lessons learned is having the local department of health making the final decision (on blood donor deferrals during an outbreak) is crucial; having that authority temporarily revoked was probably not wise and a bit of an over-reaction.”



West Nile Virus Still a Threat

With fears abounding with Zika and the U.S. blood supply, not as much attention has been placed on West Nile Virus (WNV) this year. The [AABB's WNV Biovigilance Network](#), shows 91 pending cases of WNV infected donations since the beginning of this year in the North America continent. Confirmed infected donations this year have reached 49, with the number climbing daily. The AABB map below demonstrates the geographic distribution of those confirmed and pending interpretation cases. WNV brings serious neurological illnesses to about one percent of those infected and can be transmitted via transfusion. 📌



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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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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.

Missing Type Campaign Reaches Thousands



Thank you to all participating member centers for your hard work in making the Missing Type Campaign a success! Thousands of social media users have liked, shared, and favorited messages across the globe with the #MissingType and helped spread awareness of much-needed blood donations. We started on August 15 with our own social media efforts and are trying to keep the momentum going for another week—until August 26.



The American Red Cross helped spread the messaging through, amongst other things, a celebrity portion of the campaign that kicked off Wednesday, August 16. Some of the celebrities that participated so far have been Jamie Lee Curtis, London Fletcher, and Hunter Hayes. ABC has created a [Flickr album](#)—some of the photos are posted here—to capture the spirit of the campaign. We encourage you to [send us your photos](#) to add to the collection.



Remember to keep up the great work posting, sharing, liking, and favoriting images using #MissingType to your social media channels!

Newsletter Survey to End

The newsletter [survey](#) is almost complete. We have had some good feedback so far, but would still like to hear from more of our readers. We will end the survey submissions on Friday, August 26, and report on the findings the following week. If there are any of you left that have NOT participated in the newsletter survey, please do not be shy and do not worry, the survey will not take but three minutes to complete. We would love to hear from you on your preferences for how you like to receive the newsletter as well as your preferences on content. Feel free to share any and all thoughts, all comments are welcome! ♦

Register Today!

ABC SMT Journal Club Webinar
August 23, 1:00 - 2:00 p.m. EDT
SMT Journal Club Committee members will review three key scientific//medical articles followed by open discussion by participants.
To register [click here](#).

RESEARCH IN BRIEF

In a prospective study at the Houston Methodist Hospital, doctors determined ultrasound-guided peripheral venous access reduced the need for establishing central venous catheters in patients undergoing therapeutic apheresis. The study ran from July 1, 2015 until September 30, 2015 and evaluated 186 patients who underwent 831 procedures, including peripheral stem cell collections, peripheral plasma exchanges, and red blood cell exchanges. Using ultrasound-guided peripheral access prevented the need for a central venous catheter in 37 (20 percent) patients.

Citation: Eric Salazar, Garcia S., Miguel R., *et al.* Ultrasound-guided peripheral venous access for therapeutic apheresis procedures reduces need for central venous catheters. *Journal of Clinical Apheresis*. August 10, 2016. DOI: 10.1002/jca.21493

Bone marrow (BM) recipients had better overall outcomes than those receiving peripheral blood stem cells (PBSC) for hematopoietic cell transplantation in a new study. In a follow-up of a multicenter randomized clinical trial, 551 patients received either unrelated donor BM or PBSC in hematopoietic cell transplantation for hematologic neoplasms. Patient outcomes were assessed at enrollment, six months, one, two, and five years after transplantation. The recipients of unrelated donor BM had higher Mental Health Inventory Psychological Well-Being scores (78.9 [1.7] vs 72.2 [1.9]), had less burdensome chronic graft versus host disease scores (13.1 [1.5] vs 19.3 [1.6]), and were more likely to return to work than recipients of PBSC at five years after transplantation (odds ratio, 1.5; 95 percent confidence interval, 1.2-2.0). However, there was no measurable difference in survival rate. The researchers concluded that bone marrow was the optimal choice and should be the standard of care for these types of transplants.

Citation: Lee S.J., Logan B., Westervelt P., *et al.* Comparison of Patient-Reported Outcomes in 5-Year Survivors Who Received Bone Marrow vs Peripheral Blood Unrelated Donor Transplantation: Long-term Follow-up of a Randomized Clinical Trial. *JAMA Oncology*. August 11, 2016. Online First. DOI:10.1001/jamaoncol.2016.2520.

Two probable Zika virus (ZIKV) transmission by transfusion cases were reported in Brazil. Both transfusion recipients received platelets from a single apheresis donor in January. The donor called back five days after donating and self-reported symptoms consistent with Zika infection: rash, and joint and eye pain. An investigation by the hospital that transfused both patients—one a patient with primary myelofibrosis syndrome and the second a leukemia patient who had undergone bone marrow transplantation—showed that while pre-transfusion samples were negative for ZIKV, samples post-transfusion (six and 51 days in patients one and two, respectively) were positive for ZIKV by polymerase chain reaction assay. Further molecular sequencing and phylogenetic analysis of the ZIKV RNA strongly suggest the identity of the donor and two patients' ZIKV strains to be the same. Both recipients remained asymptomatic.

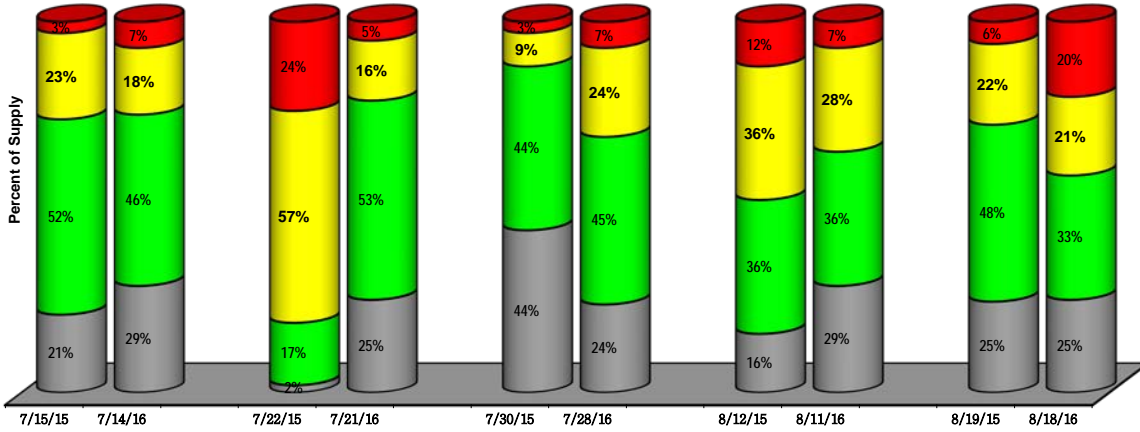
Citation: Motta I., Spencer B., Cordeiro da Silva S., *et al.* Evidence for Transmission of Zika Virus by Platelet Transfusion. *NEJM*. August 17, 2016. DOI: DOI: 10.1056/NEJMc1607262. ♦

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, 2015 vs. 2016



■ 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

AMERICA'S BLOOD CENTERS' Information Technology Workshop

Minneapolis, MN – September 13-14, 2016

Hosted by

Memorial BLOOD CENTERS

A Division of Innovative Blood Resources

Innovative Blood Resources and our Minnesota Division, Memorial Blood Centers, are pleased to host the 2016 ABC Information Technology Workshop near our headquarters in St. Paul, Minnesota. Attendees will benefit from the shared knowledge of fellow IT professionals while exploring topics impacting our changing and interconnected healthcare environment. We look forward to seeing you in September!

– Donald C. Berglund, CEO, Innovative Blood Resources

Negotiated hotel room rate: \$199 + tax
http://bit.ly/renaissance_minneapolis

2016 Workshop Fees (early bird/regular)
2-day registration: \$410/\$465

Registration opens **July 13**. Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation, registration fees and information.

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

Sponsorship opportunities available. Contact Jodi Zand at jzand@americasblood.org for details.

✈ Minneapolis–Saint Paul International Airport (MSP) is served by most major US airlines. Visit www.mspairport.com.



BRIEFLY NOTED

The International Council for Commonality in Blood Banking Automation (ICCBBA) announced updates to ISBT 128, the international identification, labeling, and information processing system for products of human origin. Version 6.19.0 of the ISBT 128 Product Description Code Database is now available to licensed facilities. The new database can be downloaded as a Microsoft Access database and all updates are listed on the [version control sheet](#). New product description codes can be provided once request forms from the website have been submitted. An updated Product Lookup Program that is populated with the new codes is also available. The **Standard Terminology for Medical Products of Human Origin v6.19 has also been released**. It provides definitions to all ISBT 128 terminology and should be used in conjunction with the ISBT 128 Product Description Code Database. (Source: ICCBBA, August 15, 2016.)



The AABB has published Association Bulletin (AB) #16-06, “[Blood Center and Public Health Actions to Reduce the Risk of Zika Virus Transfusion Transmission](#).” This bulletin is a supplement to the information provided in the AB #16-04 “[Zika, Dengue, and Chikungunya Viruses](#).” The AB recommends altering the donor history questionnaire for active or inactive areas to include Zika Additional Questions, recommendations on how to facilitate self-deferrals from donors on travel to affected Zika areas or sexual relations with someone who has traveled to a Zika area, or has any Zika-related symptoms. The AB also discusses post-donation materials and recommendations as well as clinical outcomes, reported cases and actions to be taken in case a local-transmission occurs. (Source: AABB, August 16, 2016.)

The AABB has released its “Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens, 3rd edition.” The publication helps to “provide requirements for using molecular methods to predict ABO, Rh and other blood group antigens on red cells, platelets and neutrophils. It also contains quality system requirements, operational standards and a detailed list of inventory resources needed to identify targeted nucleotides that encode these antigens.” The standards go into effect on October 1 and are available for [purchase online at AABB](#).

The genetically-modified mosquitoes from Oxitec overcame their first hurdle in the Florida Keys. The Food and Drug Administration (FDA) released a final environmental assessment on August 5 stating it does not believe field trials of the genetically-altered mosquitoes will significantly impact Key Haven’s environment. The final assessment does not mean that Oxitec’s mosquitos are approved for commercial use in the Keys just yet, however. The Oxitec male mosquitoes, which we reported in the *ABC Newsletter* from last week were released in parts of the Grand Cayman island in July, are genetically altered to be self-limiting. When the genetically-modified males mate with wild *Aedes aegypti* female mosquitoes the offspring are passed a self-limiting trait and die before they fully mature into adults. The Florida Keys Mosquito Control District will first have to gain residential approval in the fall to release the mosquitoes before any further advancement is made in their release. Open field trials of the OX513A genetically engineered mosquito have also been conducted in Brazil, Panama, and Malaysia. (Source: FDA, [Oxitec Mosquito](#). August 5, 2016.) ♦



RECENT REVIEWS

The *American Journal of Medicine* (AJM) released a special issue this month providing information and clinical guidance on the rationale of using specific reversal agents for thromboembolic patients

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RECENT REVIEWS (continued from page 7)

taking direct oral anticoagulants (DOACs). DOACs are used as alternatives for Vitamin K anticoagulants (VKAs) to treat thromboembolic events in patients with nonvalvular atrial fibrillation. Studies showed DOACs lead to lower intracranial hemorrhaging and have a shorter half-life than VKAs. There is one reversal agent that has been on the market in the U.S. since 2015 for use on DOACs, idacruizumab, with two others in development: andexanet alfa and ciraparantag. In this *AJM* issue, clinical data on DOAC-associated bleeding from phase three clinical trials and post-marketing trials of the reversal agents are reviewed, as are current assessment and management strategies of bleeding events, and perioperative management in the setting of DOAC therapy, as well as re-initiation of DOAC therapy after a bleeding event.

Citation: Charles V. Pollack, Jr. Introduction to Direct Oral Anticoagulants and Rationale for Specific Reversal Agents. *AJM*. August 9, 2016. DOI: <http://dx.doi.org/10.1016/j.amjmed.2016.06.002>. ♦

INFECTIOUS DISEASE UPDATES

One of the biggest vaccination projects in Africa has started in Angola as part of the World Health Organization's (WHO) efforts to control the yellow fever outbreak that has killed over 400 people. The WHO, working with Ministries of Health in the Angola and the Democratic Republic of Congo, are attempting to vaccinate more than 14 million people against yellow fever in more than 8000 locations in 12 provinces of Angola. This emergency vaccination program comes after the six million Yellow Fever vaccine stockpile was exhausted early on this summer. [An Associated Press \(AP\) article](#) claimed one million vaccines had mysteriously disappeared and the WHO was calling for an 80 percent dilution of the vaccine in an attempt to keep up with the demand. The current campaign looks to be complete by the beginning of the rainy season, in late September, but could still be millions short of what is needed to contain the spread of the virus. (Sources: WHO, [Mass vaccination campaign to protect millions against yellow fever in Angola and Democratic Republic of the Congo](#). August 2016; AP, UN bungles response to Africa's yellow fever outbreak. August 5, 2016.)

A case of a man with Zika virus (ZIKV) still detectable in his semen after 188 days of onset of symptoms was reported in Italy. The man returned from a two-week trip from Haiti to Italy in January 2016. He presented symptoms consistent with ZIKV infection. Laboratory tests detected ZIKV RNA by Reverse transcription polymerase chain reaction in his plasma nine days after symptom onset (ca. 100 copies/mL), and in urine (ca 25,000 copies/mL) and saliva (58,700 copies/mL) up to 15 and 47 days, respectively. The RNA was present in his semen (175 copies/mL) at 188 days, but the infectivity is not known since virus isolation was not reported.

Citation: Barzon L., Pacenti M., Franchin E., et al. Infection Dynamics In A Traveller With Persistent Shedding Of Zika Virus Rna In Semen For Six Months After Returning From Haiti To Italy, *Eurosurveillance*. August 11, 2016. DOI: <http://dx.doi.org/10.2807/1560-7917.ES.2016.21.32.30316>.

The U.S. Health and Human Services Department (HHS) declared a public health emergency in Puerto Rico on August 12 due to the Zika outbreak. The Department of Health in Puerto Rico (PR) confirmed [10,690 Zika cases](#), with over 1,000 being pregnant women, two deaths, and 23 cases of Guillain-Barré health officials attributed to Zika infections. However, the Centers for Disease Control and Prevention (CDC) believe these figures are severely lower than the actual number of those infected in PR, with as many as thousands more, and 50 pregnant women, becoming infected per day. While only one microcephaly case was suspected, infection rates for the island have not hit the levels of those found in Brazil, cases of Zika infection are expected to keep rising through October, said Dr. Lyle R. Petersen, the CDC chief of vector-borne diseases and director of its fight against Zika. (Sources: *New York Times*, [U.S. Declares Zika an Emergency in Puerto Rico](#). August 12, 2016; CDC, [Update: Ongoing Zika Virus Transmission](#). August 5, 2016.) ♦



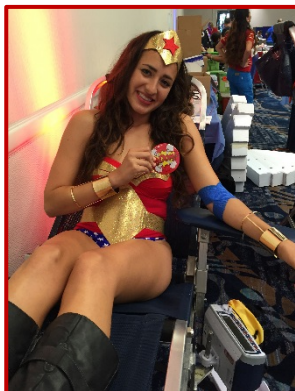
REGULATORY NEWS

The Food and Drug Administration (FDA) issued a non-binding guidance titled the [“Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus \(HBV\) from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\).”](#) In this guidance, the FDA recommends testing HCT/P donors for hepatitis B antigen, IgM and IgG antibodies to hepatitis B, and anti-HBc to help thwart the spread of HBV in HCT/Ps donations. They also recommend using FDA-licensed nucleic acid testing for HBV to confirm cases. The guidance expounds upon test interpretation recommendations and suggests a six-month window for implementation of the guidance after date of issue. (Source: FDA, August 17, 2016.) ♦

COMPANY NEWS

Merck & Company gained European Commission approval to sell its new hepatitis C virus (HCV) treatment **Zepatier in the European Union.** The company cites [published studies on Zepatier](#), which the Food and Drug Administration approved for use within the U.S. in January, showing it to be an effective treatment for patients with HCV genotype (GT) 1, GT4, and GT6 infection receiving opioid agonist therapies like methadone and buprenorphine. (Source: [Merck press release](#), July 29, 2016.) ♦

MEMBER NEWS



The San Diego Blood Bank hosted their 40th annual Robert A. Heinlein Blood Drive at this year's Comic Con convention at the San Diego Convention Center. A total of 1,288 units were collected over a four-day period, with donors receiving an exclusive Captain America T-shirt in coordination with Marvel Comics.

One highlight from the drive was a visit from [Ryan Wilcox](#), a San Diego high school student who is battling cancer. Earlier this year Wilcox was visited by on-screen Captain America, Chris Evans along with co-stars Robert Downey Jr. and Gwyneth Paltrow. ♦



WORD IN WASHINGTON

The U.S. Department of Health and Human Services will shift \$81 million in funds to continue developing Zika vaccines, wrote HHS Secretary Sylvia Burwell in a letter last week.

Ms. Burwell said she would move \$34 million from the National Institutes of Health and \$47 million from the Biomedical Advanced Research and Development Authority (BARDA) to work on Zika vaccines. The letter, addressed to Minority Leader of the U.S. House of Representatives Nancy Pelosi, comes just weeks after Congress has gone on recess for the remainder of the summer, without passing any Zika-funding bill. (Source: *Washington Post*, [Obama administration to shift \\$81 million to fight Zika](#). August 11, 2016.) ♦



GLOBAL NEWS

A fund structured by JPMorgan Chase and backed by the Bill and Melinda Gates Foundation invested about \$3.3 million in an infectious disease testing company from Australia. The Global Health Investment Fund, a U.S. fund which finances global health initiatives, purchased a 8.4 percent stake in Atomo Diagnostics, an Australian-based company which creates rapid diagnostic devices and services to test for HIV, malaria and ebola. Atomo's latest valuation after the last round of investment is at around \$30 million. (Source: [Atomo press release](#), August, 11, 2016; *BBC News*, [Bill Gates fund invests in Australian start-up Atomo](#). August 12, 2016.)

Kyoto University's Center for Induced Pluripotent Stem (iPS) Cell Research and Application has produced iPS cells for stockpiled use in regenerative medicine from the umbilical blood of a newborn baby. The iPS cells derived from the baby's cord blood were created in July and will be made ready for other research institutes soon, *Japan Today* reported on Thursday. The center has been aiming to stockpile these kinds of stem cells, which can be reprogrammed to grow into various human tissues and organs, in the hopes of having enough inventory for 30 to 50 percent of the entire Japanese population by the end of fiscal year 2017. (Source: *Japan Today*, [Kyoto University team produces quality stem cells from umbilical blood](#). August 18, 2016.) ♦

MEETINGS

- Sept. 8 **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.**
- This free, first-come-first serve, public workshop titled the "[Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval](#)" was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products 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.
- Sept. 12 - 13 **FDA Public Hearing on HCT/Ps, Bethesda, Md.**
- This public hearing was created to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found [here](#).
- Sept. 13 – 14 **ABC IT Workshop, Minneapolis, Minn.**
- Experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.
- Sept. 21 **Red Cell Genotyping 2016: Clinical Steps, Bethesda. Md.**
- The BloodCenter of Wisconsin (BCW) and the Department of Transfusion Medicine at the National Institutes of Health (NIH) Clinical Center, are co-hosting the 6th

MEETINGS (continued from page 10)

Annual Red Cell Genotyping Symposium at Lister Center Auditorium, National Library of Medicine, NIH Building 38A, 8600 Rockville Pike, Bethesda, Md., from 8:25 a.m. to 4:15 p.m. This symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. For information, program fee and advance registration visit BCW's [website](#) or contact Phyllis Kirchner phyllis.kirchner@bcw.edu.

Oct. 31 – Nov. 1

FDA 510(k) Submissions Workshop, Washington, D.C.

AdvaMed hosts FDA and industry experts to teach the basics of 510(k) submissions. Learn about the FDA's updates to the 510(k) process, considerations for determining a product's regulatory route to market, factors to consider when planning and assembling a 510(k) submission. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register [here](#).

Nov. 2

FDA IDE Submissions Workshop, Washington, D.C.

Learn the regulatory and practical guidelines governing when an investigational device exemption is required during this interactive AdvaMed workshop. The workshop will take place at Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register [here](#). ♦

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

Advanced Clinical Lab Specialist (Part-time IRL). Blood Systems is one of the nation's oldest and largest comprehensive transfusion medicine organizations. We serve blood centers, hospitals and health systems, offering shared management and support services, quality excellence and effective contracting. Under minimal supervision, this position is responsible for 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. Knowledge/ Education: Bachelor's degree required. Must satisfy CLIA requirements for High Complexity Testing required. California testing requirements must be met within one year required. Licenses/ Certifications: Immunohematology Reference Laboratory (IRL); Certification as a Medical Technologist or Blood Banking Technologist (BB) by a recognized certifying agency required. Experience: Immunohematology Reference Laboratory (IRL); Three years clinical laboratory testing

required. One year of transfusion service experience required. One year IRL experience preferred. Blood Systems, Inc. is an Equal Opportunity Employer. Apply at: <http://www.bloodsystems.org/careers.html/Req16000310>. EOE/Minority/Female/Disability/Vets

Medical Director (Denver-based). Blood Systems is one of the nation's oldest and largest comprehensive transfusion medicine organizations. We serve blood centers, hospitals and health systems, offering shared management and support services, quality excellence and effective contracting. Knowledge/Education: MD or DO or equivalent degree required. Licenses/Certifications: Medical license in the state(s) of work within six months required. Transfusion Medicine board certification (or eligibility followed by certification within two years of employment) OR board certification in Hematology required. Board certification in Clinical Pathology, Internal

(continued on page 12)

POSITIONS (continued from page 11)

Medicine, or Pediatrics preferred. Experience: Fellowship training or equivalent experience in blood banking/transfusion medicine required. Experience at a blood center and/or hospital transfusion service including provision of education, clinical consultations, and some combination of therapeutic apheresis, cell therapy, laboratory, immunohematology, etc. experience required. Two years of experience in the field of Transfusion medicine preferred. Blood Systems, Inc. is an Equal Opportunity Employer. Apply at: <http://www.bloodsystems.org/careers.html/>
Req. 16000321.
EOE/Minority/Female/Disability/Vets

Technical Director. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a non-profit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Technical Director. Under the direction of the Administrator and Medical Director, the Technical Director has overall 24-hour responsibility for the Laboratory and all activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Technical Director oversees component production, inventory, product distribution, reference immunohematological testing, 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 CA license as a Clinical Laboratory Scientist. Experience as a technologist performing high complexity testing in a clinical laboratory and familiarity with standard laboratory methods and techniques. Demonstrated ability to perform standardized routine testing, specialized testing in blood donor processing, and immunohematology is preferred. Must meet the CLIA defined General supervisor qualifications (42 CFR 493.1461). To Apply: Contact Tom Schallert (TomSchall@aol.com; Northern California Community Blood Bank, 2524 Harrison Avenue, Eureka, CA 95501; (707) 443-8004).

Outside Sales Representative/Event Planner (Amarillo, Texas). This position must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain their support in meeting community needs for volunteer blood donors. Responsibilities will include providing service excellence in organizing and promoting mobile and donor center blood programs and blood donation events; assessing, developing and implementing strategic and tactical plans to achieve blood donor recruitment objectives and goals. They are expected to develop a customer-focused culture that will result in successful community partnerships and blood donor awareness. Job duties include scheduling blood drives in established territory to meet established goals, including major and minor holidays. Identify opportuni-

ties for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Solicit and recruit new groups and organizations for mobile drives within established territory/region. Rebook recurring blood drives for the following year. Develop and maintain collaborative working relationships with key accounts. Give presentations and represent Coffee Memorial Blood Center in order to promote blood collection. Qualifications: Associate's or bachelor's degree preferred, one to three years sales experience, and valid driver's license. Salary: Competitive salary, commission plan, and excellent benefits package. To apply, please visit <https://obi.org/careers>.

Director of Accounting/Controller. We have an opportunity for an experienced Director of Accounting/Controller who would be responsible for the financial operations of Bloodworks including accounts payable, billing, payroll, cash management and external reporting functions. Requirements for this position include: Bachelor's degree in Finance or Accounting; CPA or Master's degree preferred. Five or more years' experience in a Controller or Assistant Controller role. Five or more years supervising and developing staff. Healthcare/not for profit experience preferred. This is a full-time exempt position based at our Central location in Seattle's First Hill Neighborhood. Salary is DOE, DOQ. **Application Deadline: Open Until Filled.** Interested Applicants should send their application materials to HumanResources@bloodworksnw.org or fax to (866) 286-8495. All correspondence must reference job number 7885. The application can be found at: <http://www.bloodworksnw.org/careers/employment.pdf>. Bloodworks Northwest is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law. Should you have a disability that requires assistance and/or reasonable accommodation with the job application process, please contact the Human Resources department at HumanResources@bloodworksnw.org, or at (206) 292-6500, or at 921 Terry Avenue, Seattle, WA 98104.

Lab Quality Specialists. Currently, Cleveland Clinic is seeking Lab Quality Specialists for our East, West and South Regions. These positions are responsible for driving operational standardization throughout our laboratories and ensuring daily activities comply with regulatory and accrediting agencies. This will involve the collection and review of quality metrics, the evaluation of compliance gaps, and the continuous implementation of process improvements. Qualifications: Bachelor's degree in Clinical Laboratory Science or a chemical, physical or biological science; Three or more years of experience in quality systems development, implementation and assessment, or in regulatory affairs focused on the manufacturing of biologics or pharmaceu-

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ticals; At least three years of experience as a Medical Technologist; A minimum of three years' experience within a blood bank/transfusion service/blood center; and data management experience. To apply, please visit www.ecentralmetrics.com/url/?u=22906184778-215.

Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

Lead Laboratory Technologist – Blood Bank. The Lead Laboratory Technologist performs various duties that drive the continued success of our Blood Bank and other areas of our lab. From basic to advanced patient and donor testing, to the interpretation and validation of results, your work will determine donor-recipient compatibility as well as solutions for identified irregularities. You'll also be responsible for conducting instrument and equipment qualifications, managing reagent inventory, tracking quality metrics, recommending improvements, and serving as an educational resource for employees, residents and students. Qualifications: Associate's degree in Medical Laboratory Technology or another laboratory science, or a bachelor's degree in Medical Technology or a relevant chemical, physical, biological or clinical laboratory science; two years of blood bank experience; and one year of supervisory or quality assurance experience. To apply, please visit www.ecentralmetrics.com/url/?u=64006184865-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

Supervisor – Blood Bank. Currently, Cleveland Clinic is seeking Blood Bank Supervisors. In this highly visible role, you'll be responsible for supervising blood bank staff at multiple hospitals for our East, West and South Regions. This will involve overseeing the performance of basic and advanced patient and donor tests, helping train new employees, tracking and reporting on quality metrics, and leading performance improvement initiatives. Through these and many other contributions, you'll build on the continued success of our blood banks while moving forward in your career. Qualifications: Bachelor's degree in Medical Technology or a chemical, physical, biological or clinical laboratory science; Three years of blood bank experience; At least one year of management experience; and Working knowledge of Quality System Essentials. To apply, please visit www.ecentralmetrics.com/url/?u=32946184866-215. Cleveland Clinic

strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE.

Assistant Director, Planning Operations. Under the direction of the Executive Director, Blood Operations you will be responsible for developing and implementing logistical support for the optimal blood donor group schedule, assuring consistent achievement of annual, monthly and daily collection goals. The Assistant Director will assure the department directs customer-driven decisions, focused on an even input of blood, while emphasizing cost controls. This position is responsible for facilitating cross-functional communication as it relates to the production plan to assure strategic initiatives are consistently achieved (cost/revenue, customer, and people). Requirements: Bachelor's degree required, preferably in Business, Finance, or Logistics; Two year supervisory experience; Experience with computer applications and data base management required; One-year of metrics-based decision-making preferred; Hemasphere, e-Donor, and Crystal Reports desirable; and Texas Operators driver's license. South Texas Blood & Tissue Center, a subsidiary of BioBridge Global, is proud to be an Equal Opportunity Employer committed to providing employment opportunities to minorities, females, veterans, and disabled individuals. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, protected veteran status, genetic data, sexual orientation, gender identity, or any other legally protected characteristics. For more information please apply at: <http://bit.ly/2aPA9FW>.

Outside Sales Representative/Event Planner (Lawton, Oklahoma). This position must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain their support in meeting community needs for volunteer blood donors. Responsibilities will include providing service excellence in organizing and promoting mobile and donor center blood programs and blood donation events; assessing, developing and implementing strategic and tactical plans to achieve blood donor recruitment objectives and goals. They are expected to develop a customer-focused culture that will result in successful community partnerships and blood donor awareness. Job duties include scheduling blood drives in established territory to meet established goals, including major and minor holidays. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Solicit and recruit new groups and organizations for mobile drives within established territory.

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or region. Rebook recurring blood drives for the following year. Develop and maintain collaborative working relationships with key accounts. Give presentations and represent Oklahoma Blood Institute in order to promote blood collection. Qualifications: Associate's or bachelor's degree preferred, one to three years' sales experience, and valid driver's license. Salary: Competitive salary, commission plan, and excellent benefits package. How to apply: <http://obi.org/careers/>.

Outside Sales Representative/Event Planner (Fort Smith, Arkansas). This position must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain their support in meeting community needs for volunteer blood donors. Responsibilities will include providing service excellence in organizing and promoting mobile and donor center blood programs and blood donation events; assessing, developing and implementing strategic and tactical plans to achieve blood donor recruitment objectives and goals. They are expected to develop a customer-focused culture that will result in successful community partnerships and blood donor awareness. Job duties include scheduling blood drives in established territory to meet established goals, including major and minor holidays. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Solicit and recruit new groups and organizations for mobile drives within established territory/region. Rebook recurring blood drives for the following year. Develop and maintain collaborative working relationships with key accounts. Give presentations and represent Arkansas Blood Institute in order to promote blood collection. Qualifications: Associate's or bachelor's degree preferred, one to three years' sales experience, and valid driver's license. Salary: Competitive salary, commission plan, and excellent benefits package. How to apply: <http://arkbi.org/careers/>. ♦