

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

URRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2016 #8

March 4, 2016

Puerto Rico's Largest Blood Bank to Use Pathogen Reduction Technology

Banco de Sangre de Servicios Mutuos is the centralized transfusion service for ten hospitals in metropolitan San Juan, Puerto Rico, and distributes blood and blood products to another 30 hospitals throughout the island. This week, Cerus Corporation announced that it has finalized an agreement with Puerto Rico's largest blood provider (Banco de Sangre de Servicios Mutuos) to purchase and implement the INTERCEPT Blood System for platelets and plasma. The agreement comes at an ideal time as Puerto Rico works to maintain a safe, stable, and sustainable blood supply in the wake of the Zika virus (ZIKV) epidemic.

INTERCEPT is Cerus's photochemical pathogen reduction (PR) technology, which inactivates a host of bacteria and viruses in blood products. PR is a proactive approach to transfusion safety that the Food and Drug Administration (FDA) approved in 2014. Since that time, several ABC member blood centers have committed to use the system.

The FDA <u>guidance</u> aimed at reducing the risk of transmitting ZIKV by transfusion on Feb. 16 requires suspension of collections in Puerto Rico. "We are stopping local collections today at noon (Friday, March 4)," said Jose O. Alsina, vice president and chief operating officer of Banco de Sangre de Servicios Mutuos. Since Puerto Rico is an area with local transmission of ZIKV, FDA recommends that blood and components be obtained from areas without local transmission unless FDAapproved testing and/or PR technology is in place. Accordingly, the <u>guidance</u>, absent enforcement discretion, requires suspension of collections in Puerto Rico until donor testing and/or PR are implemented.

"We reached an agreement this week with Cerus," said Mr. Alsina. "We anticipate setting the INTERCEPT Blood System up Sunday to begin training Monday." That process will include performing validations and working PR into its blood processing procedures.

In addition to the immediate safety impact of PR, the use of INTERCEPT will allow Puerto Rico to continue to recruit their volunteer platelet and plasma donors within the recommendations of the FDA <u>guidance</u>, rather than being solely reliant on blood services on the mainland, and risking serious disruption of their self-sufficiency in the medium and long terms. That said, whole blood and RBCs

INSIDE:

Action2
ABC Proposed Bylaw Changes and Dues Structure Webinar Recordings Available4
Letter to the Editor – Re: "All Zika, All the Time!" .4
RESEARCH IN BRIEF6
BRIEFLY NOTED7
REGULATORY NEWS8
RECENT REVIEWS8
GLOBAL NEWS9
STOPLIGHT [®] : Status of America's Blood
Centers' Blood Supply .9
PEOPLE10
MEETINGS11
POSITIONS11





OUR SPACE

Abbey Nunes, ABC's Chief Member Experience Officer

Spring into Action

By the time February comes to a close, we here on the east coast are pretty much fed up with winter. March arrives with just enough sunshine to give us a glimmer of hope, and the wonderful promise of spring and warmer days ahead. Because of that, March, a usual underdog to months with summer vacations and holidays, is one of my favorite months of the year.

We in blood banking are also no stranger to being the underdog; much too often our cause is often overshadowed by much "sexier" philanthropic initiatives. But every year, America's Blood Centers (ABC) takes the time, in March none the less, to nationally recognize our leaders, advocates, and supporters both within the industry and community at the *Awards of Excellence* during the ABC Annual Meeting. From media partners, high school blood drives, to individuals who go the extra mile in support of the cause, the *Awards of Excellence* celebrates the many hardworking and dedicated individuals it takes to make our mission a success.

At the meeting itself, our association's leaders from across the country gather together to learn, network, share and discuss the latest trends and hot topics in blood banking. In addition, each year, the Foundation for America's Blood Centers (FABC) hosts a fundraiser in conjunction with the annual *Awards of Excellence* program. Last year's popular talent show, *ABC's Got Talent* gives way to "Rolling on the River," as we invite you to try your luck at FABC's Casino Night event. Proceeds will help support programs and initiatives aimed at helping our member blood centers continue to excel in serving their communities.

If you will be at this year's meeting and are not already planning on joining us for this year's event, set to take place on Monday, March 14 (in Jacksonville, Fla.), I encourage you to sign up today (contact Lori Beaston for registration details). The *Awards* program, paired with a casino-themed fundraiser benefitting the FABC, is truly an event not to be missed. After a work-filled week, the *Awards of Excellence*, much like March, provides our blood banking leaders an often much needed reminder of the dedication, hope, and promise that these individuals bring to our industry. Lastly, a special thank you to those blood centers who took the time out of their busy schedules to nominate their community partners; this event would not be possible without you. We look forward to seeing you in Jacksonville!

Abbey Nunes

anunes@americasblood.org

The *ABC Newsletter* (ISSN #1092-0412) is published 46 times a year by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2016 by America's Blood Centers. Reproduction of the *ABC Newsletter* is forbidden unless permission is granted by the publisher. (ABC members need not obtain prior permission if proper credit is given.)

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. **America's Blood Centers**

President: Susan Rossmann CEO: Christine S. Zambricki ABC Publications Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$390

Send subscription queries to <u>Imaundy@americasblood.org</u>. America's Blood Centers 725 15th St. NW, Suite 700, Washington, DC 20005 Phone: (202) 393-5725 Send news tips to <u>newsletter@americasblood.org</u>.

-2-



Puerto Rico Blood Bank to Use PR Technology (continued from page 1)

will need to be imported until testing is in place, and/or a PR process is available for those products. Provisions are being made to supply blood products from the mainland in the short term while work continues to develop a donor screening test .To date, members America's Blood Centers, the American Red Cross, and Blood Centers of America have been meeting the needs of Puerto Rico and stand ready to continue.

The INTERCEPT treatment is effective against established transfusion threats, e.g. hepatitis B and C, HIV, West Nile virus, malaria and babesia, as well as emerging pathogens such as chikungunya and dengue viruses. PR will reduce the risk of bacterial contamination of platelets, currently the most frequent serious transfusion-transmitted infectious risk to the blood supply. Published data has demonstrated its activity against ZIKV in plasma.



ABC Newsletter

REGISTRATION NOW OPEN

America's Blood Centers' Human Resources & Employee Training/Development Workshop

San Antonio, TX - April 26-28, 2016

Hosted by **We South Texas** Blood & Tissue Center

Marriott Plaza San Antonio

Negotiated hotel room rate: \$149 + tax* www.marriott.com/hotels/travel/satpl-marriott-plaza-san-antonio/ *Group rate available through April 1.

2016 Workshop Schedule

Human Resources topics: April 26 Joint HR & Employee Training/Development topics: April 27 Employee Training/Development topics: April 28

2016 Workshop Fees (early bird/regular)

2-day registration: \$410/\$465 3-day registration: \$485/\$540 South Texas Blood & Tissue Center is excited to host ABC members in San Antonio for the 2016 Human Resources & Training/Development Workshop. We look forward to a dynamic exchange of new ideas and best practices from across the country. I hope to see you in San Antonio in April!

> Linda Myers, Chief Executive Officer South Texas Blood & Tissue Center

Sponsorship opportunities available. Contact Leslie Maundy at *lmaundy@ americasblood.org* for details.

The America's Blood Centers Professional Institute Scholarship Program offers scholarship opportunities to ABC members to cover the cost of registration fees and help with travel expenses. Application form and details will be made available once registration opens.









San Antonio International Airport (SAT) is served by all major US airlines, including discount carrier Southwest. It offers non-stop service to/from 27 major and secondary US airports; check *www.sanantonio.gov/SAT* for more information.



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. **•**

ABC Proposed Bylaw Changes and Dues Structure Webinar Recordings Available

A vote will take place at the upcoming 54th ABC Annual Meeting, in Jacksonville, Fla. hosted by OneBlood, regarding proposed bylaw changes and a new dues structure for member blood centers. America's Blood Centers held webinars to provide members with additional details and answer any questions on the impact of the proposed changes for member blood centers. For those who missed the webinars, ABC members can access the slides and audio for both the proposed bylaws and dues structure. If you are a member voting representative and will not be in attendance, you will find instructions for voting by proxy in MCN 16-021 and MCN 16-022.



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

-4-



Letter to the Editor - Re: "All Zika, All the Time!"

Dear Dr. Katz:

The <u>ABC Newsletter (2016, #7)</u> highlighted the impact of the Zika virus (ZIKV) epidemic on blood transfusion safety. The Food and Drug Administration (FDA) <u>Guidance</u> "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus" contained specific recommendations for active and inactive ZIKV regions including the use of licensed pathogen reduction technology (PRT) to make platelet and plasma components available.

Your <u>commentary</u> focused on importation, noting the impact on local self-sufficiency and the lack of clarity to define an active region for cessation of blood collections. The other option, PRT, offers substantial benefits that importation does not. While currently limited to plasma (P) and platelet components (PC), application of PRT to PCs provides retention of local collections, preservation of donors, retention of skilled blood center personnel and infrastructure, and potentially safer PCs due to possible lag between classifying an inactive region as an active region. PRT is of special relevance for PC since importation will result in older PC with an increased risk of transfusion-transmitted bacterial infection. The duration of the need for importation, and availability, efficacy and price of testing are further uncertainties that favor PRT, for which these parameters are established.

PRT inactivates multiple pathogens including other flaviviruses (WNV); and as shown by the French Polynesia blood service with universal PRT for PC and P to preserve self-sufficiency, and to reduce the risk of ZIKV, dengue virus (DENV) and chikungunya virus (CHIKV) as documented by robust PRT. PRT has been successfully used in the La Réunion Island CHIKV epidemic since 2007; and is currently used in the French Antilles blood centers to deal with CHIKV, DENV, and ZIKV in the absence of licensed donor screening tests.

Blood center economics are critical due to continuing burdens on blood safety inflicted by emerging pathogens. Licensed PRT offers a compelling economic rationale for preservation of local self-sufficiency, retention of blood collection infrastructure including donors and trained personnel, broad spectrum pathogen reduction to allow replacement of other procedures (irradiation, bacterial detection, CMV serology), and treatment of double dose PC to manage costs while providing earlier release of PC with potentially reduced expiration rates.

FDA <u>Guidance</u> allowing use of PRT merits consideration as an option to manage ZIKV not only in active regions, but also for inactive regions under imminent threat for active ZIKV due to travel exposure and the presence of endemic mosquito vectors.

Sincerely,

Laurence Corash, MD, Chief Scientific Officer Cerus Corporation

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 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.



RESEARCH IN BRIEF

ABC Newsletter

In a 2016 article in Vox Sanguinis, A. Shandler and colleagues attempt to answer the question of what is the true cost of transfusing a unit of fresh frozen plasma (FFP) using an activity-based costing (ABC) methodology. The authors examined patient records from Englewood Hospital, Englewood, N.J. covering calendar year 2012 from 246,624 patients, 136 combined medical and surgical inpatients who were transfused FFP only or FFP and other blood products. These patients were charged for 577 units of FFP but 534 were transfused. An average of 4.2 units were charged per patient compared to 3.9 transfused. Surgical patients received 40.1 percent of the units transfused. Including the expense of product acquisition, overhead and transfusion-related expenses they estimated it costs \$409.62 per unit of FFP transfused or \$1,608.37 per transfused patient. The average acquisition cost for a unit of FFP was \$41.95. From an annual expenditure of \$218,738.33, the bulk of the expenses were related to direct and indirect overhead \$103,981.20 (47.5 percent), followed by administration and monitoring the transfusion \$51,376.50 (23.5 percent) and pre-transfusion processes and patient blood testing \$33,466.21 (15.3 percent). The acquisition cost and waste accounted for \$22,400.00 (10.2 percent) and \$1,800.00 (0.8 percent) respectively. The remaining \$5,714.41 (2.7 percent) expense was distributed among transfusion logistics, hospital blood bank supply management, and issuing and delivering the components. Managing acute transfusion reactions and hemovigilance contributed no additional expense. The authors are the first to use an ABC methodology to map the true cost of administering FFP in a U.S. inpatient setting, concluding that it is nearly 10 times the cost of purchasing it. These data may encourage more judicious FFP use especially given the wide variability in FFP transfusion practice and the paucity of evidence for clinical efficacy. The ABC methodology may also be useful for comparing the cost of using other therapies for managing coagulation disorders to the cost of using FFP.

Citation: A. Shandler, S. Ozawa, A. Hoffman. Activity-based costs of plasma transfusions in medical and surgical inpatients at a U.S. hospital. *Vox Sanguinis*. 2016. DOI: 10.1111/vox.12386

Contributed by D. Kip Kuttner, DO, Medical Director, Miller-Keystone Blood Center

A study in *Transfusion* suggests that, despite the implementation of Patient Blood Management interventions, the use of allogeneic transfusion in total joint arthroscopy (TJA) in the U.S. increased from 1993 to 2011. This study used ICD-9-CM codes in the nationwide inpatient sample (NIS) data to identify TJA cases, RBC transfusion, predonation autologous transfusion and cell salvage over the study period. There were 2,225,054 TJA cases identified, (2,025,894 primary and 199,160 revision surgeries) including total hip arthroplasty (THA) and total knee arthroplasty (TKA); bilateral TJA were coded twice and analyzed separately. Patient comorbidities were calculated using the Charlson comorbidity index; ICD-9 codes identified associated preexisting anemia due to chronic blood loss, and nutrient deficiency anemia (all nutrient deficiencies except iron). The likelihood of allogeneic red blood cell (RBC) transfusion increased modestly between 1993 and 2011 (odds ratio, 1.049; 95 percent confidence interval, 1.048-1.050; p<0.001). Bilateral TJA, anemia of chronic blood loss, deficiency anemias, and Charlson comorbidity index were independent predictors of allogeneic RBC transfusion. Over the same period, the rate of presurgical autologous transfusion declined and the rate of intraoperative and postoperative cell salvage remained low but stable. Although the use of presurgical autologous transfusion was associated with lower allogeneic RBC use, this practice was characterized as wasteful and not cost-effective and was discouraged by the authors. Finally, the study showed that RBC transfusion was associated with an increased risk of in-hospital mortality (unspecified) in TJA patients. The database does not allow access to important data such as preoperative hemoglobin level, the most important predictor of transfusion, perioperative blood loss, the number of units transfused or details on surgical techniques that may have impacted blood use. Further, the study analysis did not include surgeries occurring after 2011 and thus likely excluded many procedures in which antifibrinolytic agents such as tranexamic acid were

(continued on page 7)



RESEARCH IN BRIEF (continued from page 6)

used. The authors concluded that the increased use of allogeneic transfusion despite widespread emphasis on conservative blood use is a worrisome trend given the alleged associations of transfusion with adverse consequences in surgical patients, including surgical site and periprosthetic joint infection. Increased use of transxamic acid could reverse this worrisome trend.

Citation: Rasouli MR, Maltenfort MG, Erkocak OF. Blood management after total joint arthroplasty in the United States: 19-year trend analysis. *Transfusion*. 2016. Early Online. doi:10.1111/trf.13518.

Contributed by Mary Townsend MD, Medical Director, Blood Systems and Senior Medical Director, Coffee Memorial Blood Center

Anemia, but not red blood cell (RBC) transfusion, is independently associated with necrotizing enterocolitis (NEC) in very low birthweight (VLBW) infants. Some data have suggested that RBC transfusion may contribute to pathogenesis of the severe syndrome, NEC, in neonates and infants. A prospective, multicenter, observational study at three level III neonatal ICUs was conducted in Atlanta, Ga., enrolling 600 VLBW neonates (\leq 1500 grams) investigating transfusion transmission of cytomegalovirus, and a secondary analysis of the records of 598 of the enrolled infants was performed. The primary exposure was RBC transfusion, and the secondary exposure was severe anemia (hemoglobin \leq 8 grams/dL). The primary outcome was the cumulative incidence of predefined NEC at eight weeks. In univariate analysis, RBC transfusion was associated with a 9.9 percent incidence of NEC, compared to 4.6 percent in untransfused neonates. On multivariate analysis, adjusted for the presence of severe anemia, RBC transfusion was not predictive of NEC (hazard ratio, 0.44, [95 percent confidence interval, 0.17-1.12]). Further, severe anemia was temporally associated with NEC, (hazard ratio, 5.99 [95 percent CI, 2.00-18.0] for severe anemia in a given week). These results conflict with data from retrospective studies and the authors conclude that "further studies are needed to evaluate whether preventing severe anemia is more important than minimizing RBC transfusion" for reducing the risk of NEC.

Citation: Patel RV, Knezevic A, Shenvi N, et al. Association of Red Blood Cell Transfusion, Anemia, and Necrotizing Enterocolitis in Very Low-Birth-Weight Infants. JAMA. 2016. 315(9):889-897.

Together, we can transform a life





BRIEFLY NOTED

ABC Newsletter

AABB recently released <u>Association Bulletin #16-04</u>, Zika, Dengue, and Chikungunya Viruses. This updated bulletin published on March 1 replaces Association Bulletin #16-03 from Feb. 1. According to the *AABB Weekly Report* from Feb. 26, the updated bulletin features "self-deferral recommendations and post-donation information to facilitate compliance with the February Food and Drug Administration Zika guidance." Additionally, ABC members can access a library of relevant references on the evolving Zika situation <u>here</u> and may direct questions or concerns to Louis Katz, MD. (Source: AABB Weekly Report, 2/26/16) ◆

REGULATORY NEWS

The Food and Drug Administration (FDA) recently published a Final Guidance document regarding human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance "Donor Screening Recommendations to Reduce Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue Based Products" was issued March 1 with implementation no later than March 30. Its recommendations apply to living and cadaveric (non-heart beating) donors. The guidance states that living donors should be considered ineligible for HCT/Ps donations if any of the following apply to the donor: diagnosed with Zika virus (ZIKV) infection in the past six months, resided in, or traveled to, an area with active ZIKV transmission in the past six months, or had sex in the past six months with a male who was diagnosed with or resided/traveled to an area of active transmission. Birth mother donors of umbilical cord blood, placenta, or other gestational tissues should be considered ineligible if any of the following apply: diagnosed with ZIKV infection at any point during the pregnancy, resided in, or traveled to, an area with active ZIKV transmission at any point during the pregnancy, or had sex at any point during the pregnancy with a male who was diagnosed with or resided/traveled to an area of active transmission in the preceding six months. Cadaveric donors should be considered ineligible for HCT/Ps donations if the donor had a medical diagnosis of ZIKV infection in the previous six months. Section 1271.65(b) of 21 CFR allows limited use of HCT/Ps, when appropriately labeled, from ineligible donors in the following circumstances: allogeneic use only, reproductive cells or tissue from directed reproductive donors, documented urgent medical need, or non-clinical use. Similarly, Section 1271.90 allows exemption for donor eligibility for autologous use or reproductive cells/tissues from a sexually intimate partner of the intended recipient. Comments on the guidance can be submitted anytime at: <u>http://www.regulations.gov</u>. (Source: FDA Final Guidance, 3/1/16)

RECENT REVIEWS

In a systematic review and meta-analysis, Canadian investigators explore a topic that will engage the blood community increasingly as the ability to characterize donors in multiple dimensions, e.g. demographics, phenotypes, genotypes and "omics" continues to expand. That is, the impacts on transfusion outcomes of donor characteristics beyond Red Blood Cell (RBC) antigen phenotypes and infectious diseases risks and testing. The authors describe our current understanding of how donor characteristics like donor age and gender, white blood cell antibody status, human leukocyte antigen D-related (HLA-DR) status and others influence short and long-term outcomes of RBC transfusion. Associations are described for donor gender and post-transfusion survival, blood donor HLA-DR and transplant alloimmunization, the presence of donor anti-HLA antibodies and transfusion-related acute lung injury and donor RBC antigen selection and risk for alloimmunization. However, perhaps the most

(continued on page 9)

RECENT REVIEWS (continued from page 8)



informative finding reported is the low quality (using GRADE criteria) of the available studies and their high risks of bias and confounding. The latter should color acceptance of the associations between donor characteristics and outcomes from the 59 studies that qualified for inclusion in the review, and, especially, should influence the design of future inquiries into how blood donors influence transfusion outcomes.

Citation: Chassè M, McIntyre L, English SW et al. Effect of blood donor characteristics on transfusion outcomes: a systematic review and meta-analysis. *Trans. Med. Rev.* 2016. [Article in press]

GLOBAL NEWS

The <u>American Friends of Magen David Adom</u> (AFMDA) received a \$25 million donation from the Marcus Foundation to assist Magen David Adom (MDA) with the construction of a new blood center. It will be named the Marcus National Blood Services Center. MDA is Israel's blood and emergency medical service providing nearly all of the country's blood needs. In 2008, America's Blood Centers (ABC) signed a contingency agreement that ABC would help facilitate the provision of blood from member centers should Israel experience a catastrophic disruption to its blood supply, for example, following a major disaster. Since that time, several ABC members have partnered locally with AFMDA chapters in their respective communities. (Source: Jewish Times, 3/3/16) ◆

STOPLIGHT[®]: Status of America's Blood Centers' Blood Supply



Percent of Regional Inventory at 2 Days Supply or Less, March 3, 2016



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

Daily updates are available at: www.AmericasBlood.org



PEOPLE

Ward Carter has been named chief operating officer at QualTex Laboratories, a subsidiary of BioBridge Global. He brings more than 30 years of experience within the diagnostic division of Abbott Laboratories, most recently as the director of strategic products, inventory manager at Abbott Diagnostics Division U.S. commercialization. "Ward has been intensively customer-focused throughout his career, building relationships with businesses from coast to coast," said Linda Myers, Chief Executive Officer of BioBridge Global." He is closely aligned with our commitment to increasing our levels of customer service across the organization." Mr. Carter graduated from Stephen F. Austin University and was recognized as the 2011 recipient of Abbott's Chairman's Award. "I am thrilled to be joining an organization like BioBridge Global and QualTex Labs," said Mr. Carter. "We're poised for significant growth throughout the enterprise, and especially in QualTex." (BioBridge Global press release 3/1/16)



Verax Biomedical announced Paul D. Mintz, MD as Senior Vice President and Chief medical Officer. According to a news release, Dr. Mintz will act as the clinical liaison to the transfusion medicine community in his new role. "We are extremely pleased to have Dr. Mintz join our team," said Jim Lousararian, Verax Chief Executive Officer. "His unique combination of knowledge, experience and leadership within the blood banking community, firmly grounded in the concepts of patient safety and best transfusion practices. perfectly matches our core values." He previously served as director of the Division of Hematology Clinical Review in the Office of Blood Research and Review at the Food and Drug Administration's Center for Biologics Evaluation and Research, which was responsible for the clinical review of blood-derived medical products and their recombinant or transgenic analogues. Dr. Mintz is a former president of AABB and served on the AABB's Board of Directors for nine years. He has also served as a member of the Board of Trustees of the National Blood Foundation. Dr. Mintz was a member of the faculty of the University of Virginia School of Medicine from 1979 until 2011 where he was a tenured Professor of Pathology and Internal Medicine. He also served as Chief of the Division of Clinical Pathology and medical director of the Clinical Laboratories and Transfusion Medicine Services at the University of Virginia Health System. He was also co-medical director of Virginia Blood Services from 2008 until 2011. (Source: Verax Biomedical press release 2/22/16)

The U.S. Senate confirmed **Robert Califf, MD**, as commissioner of the Food and Drug Administration. Dr. Califf joined the agency in January 2015. A statement released by the FDA on Feb. 24 said "Dr. Califf has demonstrated a long and deep commitment to advancing the public health throughout his distinguished career as a physician, researcher, and leader in the fields of science and medicine. He understands well the critical role that the FDA plays in responding to the changes in our society while protecting and promoting the health of the public, across the many areas we regulate – and I am confident that our public health and scientific contributions will further grow under his exceptional leadership," said Acting Commissioner Stephen Ostroff, MD. He was nominated by President Obama in September and has been a leading cardiologist and researcher. Dr. Califf replaces Dr. Ostroff, who has served as acting commissioner since Margaret Hamburg, MD, stepped down last year. (Source: FDA statement release, 2/26/16)



MEETINGS

March 12 - 14 ABC 54th Annual Meeting, Jacksonville, Fla.

The ABC 54th Annual Meeting in Jacksonville, Fla., hosted by OneBlood, will take place March 12 - 14 at the Hyatt Regency Jacksonville Riverfront. Contact <u>Lori Beaston</u> for registration information.

April 26 -28 ABC Human Resources and Employee Training/Development Workshop, San Antonio, Texas

The ABC Human Resources & EmployeeTraining/Development Workshop, hosted by ABC member South Texas Blood & Tissue Center, in San Antonio, Texas, April 26-28 will be held at the Marriott Plaza San Antonio. *P.A.C.E. and HRCI credits will be offered.* Online registration is open and invitations were emailed; register by April 1. View details including agenda, fees, hotel, travel, and scholarships via your invitation, or contact Lori Beaston.

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) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Client Support Technician. The Client Support Technician is responsible for supporting the company's goals by providing excellent customer service and maintaining quality relationships with accounts. Reports to the Soft-Client Support Manager. ware and Primarv Responsibilities: Identify, diagnose and resolve software issues by thorough analysis and customer communication; Establish and maintain good customer relations; Log all customer communications and interactions; Prioritize and resolve problems as they arise and notify management of potential problems when necessary: Mitigate customer complaint situations and take appropriate action; Administer help desk software. Knowledge, Skills and Abilities: Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists; Microsoft SQL Server and JasperSoft Reporting; Proficient with Word Processing, Spreadsheets, Internet and Database software; Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists; Must be self-directed. College degree preferred and three to five years relevant experience. Offers the ability to work at home. Please direct inquiries to Managing Director, tim@itsynergistics.com or call (509) 587-3110.

Transfusion Medicine Specialist. The Department of Laboratory Medicine at Cleveland Clinic is seeking a dynamic Transfusion Medicine specialist to join the professional staff as a member of the Section of Transfusion Medicine. Consisting of a transfusion service, perioperative transfusion service, cellular therapy laboratory, and transfusion services at main campus and eight affiliated regional hospitals, the Section of Transfusion Medicine is an integral and essential service provider for the Cleveland Clinic's World Class clinical and research programs. With over 175,000 blood components transfused and approximately 500 stem cell products processed annually, the Section provides a stimulating environment for clinical service, teaching and academic productivity. The successful applicant will be board-certified or eligible in blood banking and transfusion medicine and demonstrate interest in teaching, and research or quality management. Clinical responsibilities will be divided between Cleveland Clinic Main

(continued on page 12)

(continued from page 11)

Campus and one or more regional hospital transfusion services. Scholarly activity in support of our educational and research missions is also expected and supported. An opportunity for academic appointment in the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University is available, commensurate with experience and qualification. Priscilla Figueroa, M.D.; Head, Section of Transfusion Medicine; Department of Laboratory Medicine. Interested candidates should submit an application online at: www.clevelandclinic.org/physicianrecruitment. Equal Employment/Affirmative Action Employer Min/Fem/Disability/Vet

Executive Director. The Community Blood Bank of Erie, Pennsylvania is a successful, growth-oriented, independent, not-for-profit organization serving hospitals in Northwestern Pennsylvania and Western New York. The incumbent will provide overall leadership, direction, and general management and will work closely with the organization's Board of Directors and its senior leadership to advance the organization's vision and to design and implement strategies to achieve those goals. Responsibilities include delivery of the blood bank's mission while maintaining the organization's financial viability. Requirements for this position include a bachelor's degree with five years' experience in a leadership position in blood banking, health care, life science or related field in a managerial capacity would be accepted. Candidates with an MBA or MHA are preferred. Candidates must possess exceptional strategic planning abilities coupled with strong interpersonal, financial and human resource skills. To be considered for this opportunity, email a resume with cover letter, a five year salary history and three professional references to sbeeler@fourhearts.org. CBB is an equal opportunity employer.

Donor Suitability and Quality Specialist (Memorial Blood Center). (Department: Collections Quality; Location: St. Paul, MN; Status: Full-Time, 1.0FTE, and Exempt; Benefits: Medical, Dental, Vision, 401K, PTO and EST to name a few!) Position Summary: To ensure quality systems are maintained and monitored in Collections Department. Qualification: RN or LPN degree required. To apply please go directly to our website with an updated resume: <u>https://home2.eease.adp.com/recruit2/?id=19081382&t=1</u>

Automation Specialist II (AS2) (Phlebotomist III / Senior Phlebotomist) (Memorial Blood Center). Location: Metro Donor Centers- Plymouth Location; Status: Full-Time, 1.0 FTE (40 hours per week), Non-Exempt; Shift: Will include some weekends and varying am and pm shifts; Benefits: Medical, Dental, Vision, 401K, PTO and EST to name a few!) Responsibilities will be focused on automation collections of platelet donors, double red cells, and or Auto-C. Attention is paid to accurate and concurrent documentation, taking blood samples, working with blood donors automation/whole blood and staff,



and ensuring compliance with Quality Assurance standards, cGMP, Standard Operating Procedures (SOPs), and regulatory standards. Maintains a professional appearance and attitude while ensuring excellent customer service. May be scheduled to collect Whole Blood as needed. The Automation Specialist performs all routine functions in platelet apheresis, double red cell apheresis, and or Auto-C plasmapheresis and helps draw whole blood donors as needed. To apply please go directly to website with our an updated resume: https://home2.eease.adp.com/recruit2/?id=19080712&t=1

Automation Specialist I (ASI) (Phlebotomist II / Double Red Cell Donations) (Memorial Blood Center). (Location: Metro Donor Centers (Plymouth and Coon Rapids); Job Type: Full-time, 1.0 FTE (40 hours per week), Non-Exempt; Schedule: Varies; Shift: Will include weekends and varying shifts covering day and evening shifts; Benefits: Medical, Dental, Vision, 401K, PTO and EST just to name a few!) Responsibilities will be focused on automation collections of double red cells. Attention is paid to accurate and concurrent documentation, taking blood samples, working with blood donors automation/whole blood and staff, and ensuring compliance with Quality Assurance standards, cGMP, SOP's, and regulatory standards. Maintains a professional appearance and attitude while ensuring excellent customer service. May be scheduled to collect Whole Blood as needed. The Automation Specialist performs all routine functions in double red cell apheresis and helps draw whole blood donors as needed. To apply please go directly to our website with an updated resu-me: https://home2.eease.adp.com/recruit2/?id=19080702&t=1.

Operational Lead (Memorial Blood Center). (Department: Collections Vans & Mobiles Metro; Location: Southeast Territory; Shift: Varies; Status: Full-Time, 1.0 FTE, Non Exempt; Schedule: (Monday-Friday and every 3rd week), Varying shifts; Benefits: Medical, Dental, Vision, 401K, PTO and EST to name a few!) The Operational Lead works with the assigned Team Supervisor to ensure compliance with Quality Assurance standards, cGMP, SOPs, regulatory standards and Memorial Blood Center (MBC) policies. Responsibilities will include open/close and running of the operation at a blood drive or donor center when the Team Supervisor is not present. Ensures all QC is acceptable at the start of operation and reviews all records to ensure accuracy and completeness. Acts as Team Supervisor designee. Observes recently role released staff. Performs above a

(continued on page 13)



POSITIONS (continued from page 12)

CS2 level. Maintains a professional appearance and attitude while ensuring excellent customer service. To apply please go directly to our website with an updated resume: <u>https://home2.eease.adp.com/re-</u> cruit2/?id=19080692&t=1

Reference Lab Med Tech (\$5,000+ Sign-On Bonus Depending On Experience; Benefits Start at Date of Hire!). Our Reference Laboratory is one of only 55 AABB accredited Immunohematology Reference Laboratories in the country. Come join a dynamic team in performing molecular immunohematology testing, performing routine and complex transfusion service testing, and assisting area hospitals in saving lives by resolving unexpected serologic results. Position requires excellent organizational, communication and computer skills with a certification by a recognized certifying agency and a LA CLS license. The Blood Center pays a competitive starting wage and full benefits package including paid holidays, health, dental and life insurance on date of hire, paid time off after six months and an employer contributed retirement plan. If you meet the above qualifications and would like to work for a company that cares about its employees and the community please apply for the Reference Lab Med Tech position online at www.thebloodcenter.org. EOE/AAE

Assistant Manager Donor Testing (Memorial Blood Center). (Department: Donor Testing Laboratory; Reports To: Manager Donor Testing Lab; Status: Full-time, 1.0FTE, Exempt; Schedule: Monday – Friday, 2nd Shift) Manages testing laboratory 2nd shift staff and coordinates operations associated with testing blood donors for infectious disease and immunohematology during these shifts. Provides adequate training and performance appraisals. To apply please go directly to our website with an updated resume: <u>https://home2.eease.adp.com/recruit2/?id=19080682&t=1</u>

Manager of Education & Quality. The Rhode Island Blood Center is hiring a manager of Education & Quality within the Donor Services department. In this position, you will work closely with department staff to ensure quality blood collection and services. This position coordinates the SafeTrace and Vista information systems with the IT department to in-clude validation, training and hardware maintenance and collaborates with QA/Compliance regarding change control and CAPAs. Supervisory role includes planning, assigning, and directing the activities of direct reports as well as the recruitment, selection, and training of staff. You will also evaluate job performance/competency and resolve employee issues. Bachelor's degree or equivalent in medical technology, Nursing or other relevant science required. Broad blood bank or QA and compliance knowledge in lieu of education may be considered. Three to five years of blood banking or relevant QA/Compliance experience is required. A minimum of five years in a leadership role is also required. Please apply at www.ribc.org. JOIN

THE TEAM THAT GIVES THE GIFT OF LIFE!!! We are an Equal Opportunity Employer.

Post-Doctoral Fellow. Hoxworth Blood Center/University of Cincinnati is searching for a post-doctoral research fellow with an interest in one or more of the following: signal transduction, hematopoietic stem cells, pluripotent stem cell based disease modeling in hematopoiesis, mouse cancer genetic models, inflammation in hematopoiesis and hierarchical organization of hematopoiesis in health and disease. The applicant should have a doctoral degree in Biology, Molecular Biology, Genetics, Immunology, or related field, and a strong interest in blood/cancer research. The applicant should also be highly self-motivated and have a track record of publications (first-authored publications in respected journals). Applicants with experience in hematology, immunology, mouse genetics, flow cytometry and/or bioinformatics analyses are a plus. Contact: Jose A. Cancelas MD, PhD; E-mail: jose.cancelas@uc.edu.

Account Consultant I (Tulsa, Oklahoma). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customerfocused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: http://obi.org/careers/.

(continued on page 14)

POSITIONS (continued from page 13)

Account Consultant I (Little Rock, Arkansas). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: http://arkbi.org/careers/.

Manager IS Compliance. Accomplished IT quality assurance candidate with in-depth knowledge and experience in the areas of: quality control, internal and external audit, blood banking regulations and compliance, implementing change control, SOPs, implementing preventive measures, preparing validation plans, risk analysis, test plan, test cases, test matrices, conducting testing, and developing summaries, performing system upgrades, managing projects, acting as point person for FDA, AABB, LFB, CSL, and other regulatory agencies, managing staff and collaborating with various departments, providing technical support and performing data administration for blood banking applications and business applications. Education: Med-Tech or bachelor's degree in Quality Programs. Any of the following certifications are a plus: SBB Certification, ISO 9000 or AABB Quality Program implementation and maintenance. Carter BloodCare (CBC) is an EEO/Affirmative Action employer. CBC provides equal employment opportunities (EEO) to all employees and applicants and will not discriminate in its employment practices due to an employee's or applicant's race, color, religion, sex, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare com-plies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. CBC is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace



and perform pre-employment substance abuse testing. Apply at <u>www.carterbloodcare.org</u>.

Director of Quality Assurance. Blood Bank of Hawaii, a medium-size blood center (50,000 RBC distribution annually), is looking for a director of quality assurance to join our senior management team. Reporting to the president/CEO, this position's responsibilities include ensuring organizational compliance with applicable regulatory requirements, accreditation standards (FDA, CLIA, AABB, state, international), and industry practice standards; serving as Management Quality Assurance representative to the Board of Trustees Medical Committee, apprising the Committee of organizational quality performance indicators, regulatory updates, and significant potential compliance risks; acting as internal quality management consultant to operations to provide subject matter expertise, education, and advice on process excellence, process improvement and cGMP; oversight for quality and regulatory performance, quality systems and sustaining a culture of quality. The ideal candidate will have a BA/BS degree in a math or science related field and demonstrate strong leader-ship and communication skills with direct experience in regulatory and quality assurance in a blood banking, plasma center, or biotechnology related organization. Experience in a blood center highly desirable. At least five years of experience in planning departmental strategy, budgets, goals and implementation tactics. Progressive supervisory experience required. Please apply online at www.BBH.org.

6