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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2016 #7 **February 26, 2016**

INSIDE:

Food and Drug Administration (FDA) publishes guidance on Zika virus for immediate implementation

The Food & Drug Administration (FDA) issued a final guidance aimed at reducing the risk of transmitting Zika virus (ZIKV) by transfusion on Feb. 16. This flavivirus was described in non-human primates in Africa in 1947. After the first descriptions of human infection in 1968, Zika was seen as a mild febrile illness without serious sequelae. It spread to the islands of the Pacific with an epidemic on Yap Island in 2007, and then to French Polynesia in 2013-14. Recognized transmission in the Americas occurred in 2015 and is spreading rapidly, with mosquito transmission in 28 areas to date according to information from the Centers for Disease Control and Prevention (CDC).

The virus is transmitted by *Aedes aegypti* (and other *Aedes sp*.) mosquitoes, as are dengue, chikungunya, and yellow fever viruses. *A. aegypti* is present from Florida to California in the southern U.S. and Hawaii. *A. albopictus*, in which the virus can replicate and may be transmissible, is present more broadly in the southeastern third of the continental U.S. Mosquito transmission has been recognized in the U.S. territories of American Samoa, Puerto Rico, and the U.S. Virgin Islands. Review of data from Polynesia identified an increased incidence of Guillain-Barre Syndrome with the epidemic there.

Current concerns in Brazil are centered on the explosive Zika epidemic being associated with an apparent increase in the serious neurodevelopmental syndrome, microcephaly. A causal relationship is unproven. The overlap in time and space of Zika and microcephaly along with the identification in brain and other tissues of affected fetuses of ZIKV proteins, nucleic acid sequences, and visualization of viral particles on electron microscopy suggest the relationship will be confirmed by pending studies. Eighty percent of Zika infections are clinically unapparent, and viral RNA was detected by PCR in the blood of 2.8 percent of healthy blood donors in French Polynesia.

Two credible cases of transfusion-transmission have been reported from Brazil in the media from the first quarter 2015. Sexual transmission has been recognized in two cases with one report published in 2011, one in the media Sexual transmission has been recognized in two cases with one report published in 2011, one in the media this year, and several more cases currently are under investigation by CDC. Their long-term implications for the blood community await a better

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OUR SPACE

ABC Chief Medical Officer Louis Katz, MD

All Zika, All the Time!

There is a scary aspect to protecting blood safety being brought into bright relief by expanding Zika epidemics in the Americas. We have generally considered sustainability of the blood supply over the medium- and long-terms in the context of the commoditization of blood, unrestrained competition, and declining margins, but Zika raises more acute concerns. The recent Food and Drug Administration guidance and its impact on the blood community in Puerto Rico are instructive, especially after talking to colleagues there. A quick read of the guidance tells us that the agency expects cessation of collections on the island by March 1 unless certain conditions are met; conditions that likely cannot be on that timeline. The expectation then, absent enforcement discretion, is that the island will import components from the mainland to cover need. I have no doubt the blood community will respond in the short run, regardless of financial considerations, because that is our mission. However, if Puerto Rico stands down for several weeks or months, where will the people now employed to collect, process, and distribute blood get their paychecks? After they have moved on to other jobs to support their families, how will their capacity be reconstituted when the crisis passes?

When local transmission of Zika lands in Florida, the Gulf Coast, or California, under what circumstances will we face the same issues here? Also, recall that a potentially competent Zika vector (*Aedes albopictus*) is present in fully the Southeastern third of the continental U.S. "Local transmission" seems like a straightforward concept—*Aedes* mosquitos on the mainland transmit Zika to people, which I fully expect will happen. But what constitutes "local transmission" in the context of the blood community? It is undefined in the guidance, and inquiries to public health have not yet been productive. It seems abundantly clear (to me at least) that we cannot shut down collections in Florida or Texas for one or a few cases of vector transmission of Zika virus—but how many are too many? What is missing in the guidance and the public discussion to date is an estimate of "acceptable risk" from Zika in blood that can be used to calibrate our response. The parameters used to calculate that threshold must include protecting not just the safety of the current blood supply, but also adequacy, and sustaining our infrastructure in potentially affected areas into the future.

There is informative experience at our ABC member OneBlood that clinical surveillance at the level of zip code and county can be used "on the fly" to mitigate blood risks from chikungunya and dengue. I suspect a similar geographic approach is appropriate for Zika, but that it will not be perfect. As I have asked before where trade-offs are considered, "how safe is safe enough?"

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The *ABC Newsletter* (ISSN #1092-0412) is published 46 times a year by America's Blood Centers® and distributed by e-mail.

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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FDA Publishes Guidance on Zika (continued from page 1)

understanding of the frequencies of these events. To mitigate an unquantified risk of transfusion-transmitted ZIKV infection, the FDA recommends distinct approaches for FDA-regulated centers in areas with and without active (i.e. vectorial) transmission.

In areas *without* local transmission, the entire continental U.S., collection facilities are to amend donor educational materials and the donor questionnaire to inform and/or query donors about potential exposure (including sexual contact) in areas where Zika transmission is occurring. Centers are to *formally defer* those with travel or residential exposure for four weeks after leaving the risk area. Donors with Zika infection or two or more signs and symptoms after potential exposures are to *self-defer* for four weeks after symptom resolution.

Female donors are to *self-defer* for four weeks after their last sexual contact with a man with Zika, or a partner who traveled or resided in an area with local transmission, in the three months before the sexual contact. Travel surveys reported at the AABB Annual Meeting in 2015, suggest that travel deferrals will affect minimally around 2.25 percent of donors nationwide, but we are aware of much higher rates along the U.S.-Mexican border at ABC member facilities that have already intervened.

In areas *with* local transmission, the guidance is more prescriptive, recommending procurement of blood and components from areas without local transmission unless FDA-approved testing and/or pathogen reduction (PR) technology are in place. No FDA-approved donor screening tests are available, and PR has been cleared only for platelets and plasma, not for whole blood and red cells that constitute two-thirds or more of all transfusions. The guidance notes that testing under Investigational New Drug (IND) and PR under Investigational Device Exemption (IDE) may be permissible where licensed processes are not available.

Further recommendations for the elicitation of and response to post-donation information, product disposition, and labeling are provided. Implementation is required by March 15, 2016 in areas without local transmission and by March 1 in areas with local transmission.

In an AABB sponsored webinar on Feb. 17 and an ABC Scientific, Medical, and Technical (SMT) Committee conference call on Feb. 19, important questions were raised that are to be clarified by FDA in subsequent communications. The most critical is the definition of local transmission. The CDC provides information for areas outside the continental U.S., but due to issues with the granularity and timeliness of surveillance data, this is published only at the country level. Accordingly, the guidance, absent enforcement discretion, requires suspension of collections in Puerto Rico until testing and/or PR are implemented. Testing will not be available under IND until April at the earliest, in a format that is not available on approved donor screening Nucleic Acid Testing platforms, We are aware that independent centers on the island are concerned about their ability to operate effectively in that interval. Sourcing blood from the mainland is an obvious potential solution, but it is not clear that centers or hospitals in Puerto Rico have the resources to do so without federal support. ABC and others have advocated for a federal contract to assure adequate blood reaches Puerto Rico from the mainland and U.S. blood centers do not need to provide the resources at a loss. The long-term recovery and sustainability of blood collection after any such disruption in Puerto Rico or on the mainland is a topic of discussion. The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, which includes blood services representatives from AABB, ABC, the American Red Cross, Blood Centers of America, and federal agencies, released a press release and is engaged on these issues.

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FDA Publishes Guidance on Zika (continued from page 3)

Concern is being expressed that if a granular definition of local transmission is not available (more granular i.e. than the state level), it is possible that similar issues will arise when the virus establishes itself on the mainland. In the continental U.S., the ABC SMT committee, informed by prior experiences with dengue and chikungunya activity at ABC member blood center OneBlood, prefers use of either the county, zip code of residence, or a similar geographic parameter, which are now available for donor addresses.

An updated AABB Association Bulletin on ZIKV is being drafted by members of the AABB Transfusion Transmitted Diseases committee. Also, the AABB Donor History Questionnaire task force has been working on revisions to the uniform Donor History Questionnaire(s) and accompanying support materials that will be referenced in the Association Bulletin. These materials are forthcoming. Representatives from ABC member blood centers are on each committee respectively. Further, an ABC working group convened to discuss scenarios for responding to ZIKV, including the FDA guidance, on the assumption that local transmission will occur on the U.S. mainland.

The ABC SMT committee has discussed the potential impact of the deferral of female sexual contacts of males with risk for ZIKV infection in the past three months on top of the pending loss of around 5 percent males with hemoglobin <13 g/dL as a result of changes in the Donor Final Rule. That impact is unknown.

A library of relevant references on the evolving Zika situation is available for ABC members at: https://members.americasblood.org/api/api-tools-and-resources-smt, and is being updated as new information is published. ♦

We Welcome Your Articles

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

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RESEARCH IN BRIEF

Although liberal transfusion thresholds are not beneficial following noncardiac surgery, it is unclear if higher thresholds are appropriate for patients with postoperative myocardial infarction (MI). A retrospective cohort study of patients at Veterans Affairs facilities from Jan. 1, 2000 to Dec. 31, 2012 evaluated the association between postoperative blood transfusion and mortality in patients with coronary artery disease and postoperative MI following noncardiac surgery. Patients with coronary artery disease (CAD) who underwent inpatient noncardiac surgery and had a nadir postoperative hematocrit between 20 percent and 30 percent were included, and stratified by postoperative nadir hematocrit and the presence of postoperative MI. The primary outcome was the 30-day postoperative mortality rate. Of 7,361 patients, 2,027 patients (27.5 percent) received at least 1 postoperative blood transfusion. The primary outcome occurred in 267 (3.6 percent) and 30-day MI occurred in 271 (3.7 percent). Among the 5,334 patients without postoperative blood transfusion, lower nadir hematocrit was associated with an increased risk for mortality (hematocrit of 20 percent to <24 percent: 7.3 percent; 24 percent to <27 percent: 3.7 percent; and 27 percent to 30 percent: 1.6 percent; $P < .01$). In patients with postoperative MI, blood transfusion was associated with lower mortality, for those with hematocrit of 20 percent to 24 percent (15.4 percent vs. 42.9 percent, OR, 0.28; 95 percent CI, 0.13-0.64). In patients without postoperative MI, transfusion was associated with significantly higher mortality for those with hematocrit of 27 percent to 30 percent (4.6 percent vs. 1.5 percent, OR, 3.21; 95 percent CI, 1.85-5.60). The authors concluded that these findings support restrictive postoperative transfusion in patients with stable coronary artery disease after noncardiac surgery, but also suggest a potential role for higher hematocrit transfusion thresholds in patients with postoperative MI. Frank, et al. note in an editorial that, other than two very small pilot studies in patients with MI who were randomized to higher or lower transfusion triggers (one supporting liberal and the other a restrictive transfusion) the ideal hemoglobin trigger in the setting of MI (perioperative or nonperioperative) remains unknown. They recommend prospective studies should assess the impact of both transfusion triggers and targets, particularly among at-risk patients with known CAD. The editorial concluded by stating that the central tenet of any patient blood management program should be to give the right product at the right dose to the right patient for the right reason and at the right time.

Citation: Hollis RH, Singletary BA, McMurtie JT, et al., Blood transfusion and 30-day mortality in patients with coronary artery disease and anemia following noncardiac surgery. JAMA Surg 2016; 151 (2): 139-145.

Frank SM, Ejaz A, Pawlik T. Optimal transfusion trigger in surgical patients with coronary artery disease. JAMA Surg 2016; 151 (2): 146.

Contributed by Richard R. Gammon, MD, Medical Director, OneBlood

A study from Brigham and Women's and Providence Hospitals describes a home-brew fluorescent resonance energy transfer (FRET) assay with rapid turnaround time (rTAT) that resulted in avoidance of unnecessary plasmapheresis by quickly ruling out thrombotic thrombocytopenic purpura (TTP). The diagnosis of TTP is not always straightforward for teams providing therapeutic apheresis. Patients almost never have the classical pentad of symptoms, the peripheral blood smear can be equivocal, and multiple other entities, especially sepsis, remain in differential diagnosis. Plasmapheresis is started as an emergency procedure, but is expensive, invasive, labor intensive, and involves large volume plasma transfusion. Rapid measurement of ADAMTS 13, the enzyme that cleaves large Von Willebrand's multimers that are pathogenic and deficient in most classic cases of TTP, and normal in

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RESEARCH IN BRIEF (continued from page 5)

other entities being considered, should be very useful. However, the standard assay must be sent to reference laboratories and the long TAT, usually days, requires continuous plasma exchange. The assay evaluated uses cleavage of a synthetic Von Willebrand factor substrate covalently bonded to appropriate fluorescent probes and quenchers in a commercially available system. Results were available in as little as six and always within 24 hours. In the 18 months after implementation of the rTAT ADAMTS13 assay, there was a significant reduction in plasma utilization per patient suspected of having TTP (mean, 144.5 vs. 63.3 units of plasma). The mean number of exchanges per patient and mean number of exchanges after achieving a platelet count of at least 150,000 were lower in the rTAT cohort. There was no significant difference in 30-day mortality. An rTAT assay seems valuable especially for those blood centers and hospitals seeing TTP patients with reasonable frequencies. ADAMTS13 assays suffer from assay variabilities and lack of international reference preparation. A broader study comparing assays using an international reference preparation will be needed to confirm the applicability of any rTAT.

Citation: Connell NT, Cheves T, Seeney JD. Effect of ADAMTS13 activity turnaround time on plasma utilization for suspected thrombotic thrombocytopenic purpura. *Transfusion*. 2016. 56:354-59.

Contributed by Yasuko Ericson MD, Medical Director, Mississippi Valley Regional Blood Center

The major human platelet antigens are encoded in multiple alleles, most of which differ by only a single amino acid. These polymorphisms can elicit an immune response resulting in the formation of antibodies that can cause rapid platelet clearance from the circulation after transfusion in certain clinical conditions, e.g. neonatal alloimmune thrombocytopenia (NAIT) that affects approximately 1 in 1,000 births. NAIT occurs when the mother makes alloantibodies to the platelet specific antigen of the fetus that cross the placenta and destroy the fetus or infant's platelets. Intracranial hemorrhage and intrauterine death are NAIT's most serious consequences. Difficulty identifying the less common platelet specific antibodies makes the diagnosis and treatment of NAIT and related conditions problematic. Platelet antibody detection is hampered by the lack of availability of platelet antigens for assay development, antigen instability in serological testing, and interference in interpretation when HLA antibodies are present, a common finding in pregnant females. In a Plenary Paper in *Blood*, N. Zhang at the Blood Research Institute of ABC member the BloodCenter of Wisconsin (Versiti) and colleagues have developed a novel method to avoid these problems. They have used the CRISPR/Cas9 (clustered regularly interspaced short palindromic repeats/CRISPR associated protein 9) gene editing technique on induced pluripotent stem cell-platelet technologies to create human platelet progenitors expressing low frequency platelet alloantigens for diagnostic, investigative and even, potentially, future therapeutic use. Using the HPA-1b / HPA-b (Pl^{A1}/Pl^{A2}) alloantigen system, often involved in NAIT, as a prototype, the authors generated Pl^{A1} and Pl^{A2} expressing progenitor cells and used them in a flow cytometric assay to detect antibodies. Their future intent is to provide polymorphisms that define each of the major human platelet antigens to provide a replenishable source of alloantigen progenitors for use in platelet antibody identification. This has the potential to greatly improve the diagnosis and care of newborns with NAIT.

Citation: Zhang N, Zhi H, Curtis BR et al. CRISPR/Cas9-mediated conversion of human platelet alloantigen allotypes. Blood. Early Online. http://dx.doi.org/10.1182/blood-2015-10-675751.

Contributed by Jerry Gottschall, MD, Senior Medical Director, BloodCenter of Wisconsin (Versiti)

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RESEARCH IN BRIEF (continued from page 6)

Investigators at the University of California Irvine Medical Center (UCIMC) have poised themselves to derive substantial improvements in perioperative red blood cell (RBC) transfusion ordering practices, using tools created as part of their recently enhanced review of electronic surgical data. The authors have used an anesthesia information management system (AIMS) to examine relevant, transfusion-related surgical data over a recent three-year span (2011-2013). The data were first stratified according to surgical specialty and operative site, which led to the identification of 9,377 discrete types of surgical procedures. For reasons of practicality, these ultimately were condensed to 119 broader "case categories" across nine surgical disciplines (e.g., cardiac surgery, orthopedic, etc.). For each of these 119 categories, actual RBC use was reviewed to create a MSBOS (maximum surgical blood ordering schedule) according to methods previously described by Frank SM, et al. (Optimizing preoperative blood ordering with data acquired from an anesthesia information management system. *Anesthesiology*. 2013; 118: 1286-97). The authors then examined the appropriateness of preoperative RBC transfusion-related orders (e.g., "type and crossmatch," "type and screen," and "no blood sample") by UCIMC clinicians comparing the clinicians' ordering practices to the MSBOS. They found substantial divergence between actual (clinician-driven) practices and the ideal (MSBOS-recommended) state, supporting their hypothesis that, by "using the MSBOS we could show a reduction in unnecessary preoperative blood testing and associated costs [estimated at over $50,000 per year of potential savings for their facility]." They closed their discussion by stating, "[a]s a result of this investigation, we have implemented the MSBOS at UCI Health and are currently monitoring subsequent transfusion patterns and results with interest."

Citation: Rinehart JB, *et al*. Perioperative blood ordering optimization process using information from an anesthesia information management system. *Transfusion*. 2016 February 14. [Epub ahead of print]

Contributed by Christopher Gresens MD, Senior Medical Director, BloodSource.

REGULATORY NEWS

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. ISBT 128 Standard Technical Specification v5.5.0, which describes the rules surrounding the use of ISBT 128 as well as guidance in the interpretation of these rules, includes the following key changes: option of encoding a nationally specified value for the Special Testing RBC Antigens, addition of Hepatitis E Virus to Table RT019, and the addition of a definition field to the Special Testing General Database. The Version Control Table in Section 1.7. provides a full list of changes. The document can be downloaded here. In addition, ICCBBA released **ST-013 ISBT 128 Standard Labeling of Human Milk Banking Products v1.0.0.** This new standard provides ISBT 128 requirements for information that shall appear on the final label for human milk banking products, can be downloaded here.

ABC Proposed Bylaw Changes and Dues Structure Webinar Recordings Available

A vote will take place at the upcoming 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 earlier this week 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.

THE WORD IN WASHINGTON

This week, America's Blood Centers CEO Christine Zambricki, DNAP, CRNA, FAAN represented ABC members at two Congressional Hearings as legislators responded to public concerns and the media attention surrounding the threat of Zika virus (ZIKV) expanding in the U.S. She attended the full hearing of the Senate Health, Education, Labor and Pensions Committee (HELP) entitled "Zika Virus: Addressing the Growing Public Health Threat."

Former Health and Human Services Secretary Louis Sullivan and ABC CEO Christine Zambricki, DNAP, CRNA, FAAN following a meeting on the Hill.

The Senate HELP Committee is responsible for overseeing public health policy and Chairman Lamar Alexander (R-Tenn) focused much of the discussion on funding for current and future prevention, testing, and treatment of ZIKV. They are fast tracking two bills that will include substantial funding for Zika related programs and research. These bills are expected to be voted on in late spring.

Dr. Zambricki also attended the House Committee on Oversight and Government Reform's Subcommittee on Transportation and Public Assets hearing entitled "The Zika Virus: Coordination of a Multi-Agency Response." During the hearing, Chairman John Mica (R-Fla) raised concerns about the possibility of transmitting ZIKV through blood donations. Centers for Disease Control and Prevention Principal Deputy Director Anne Schuchat, MD responded by discussing the recent FDA guidance. Ranking Member Tammy Duckworth (D-Ill) expressed concern about the cases of Zika identified in Illinois and the need to fast track research to prevent its spread.

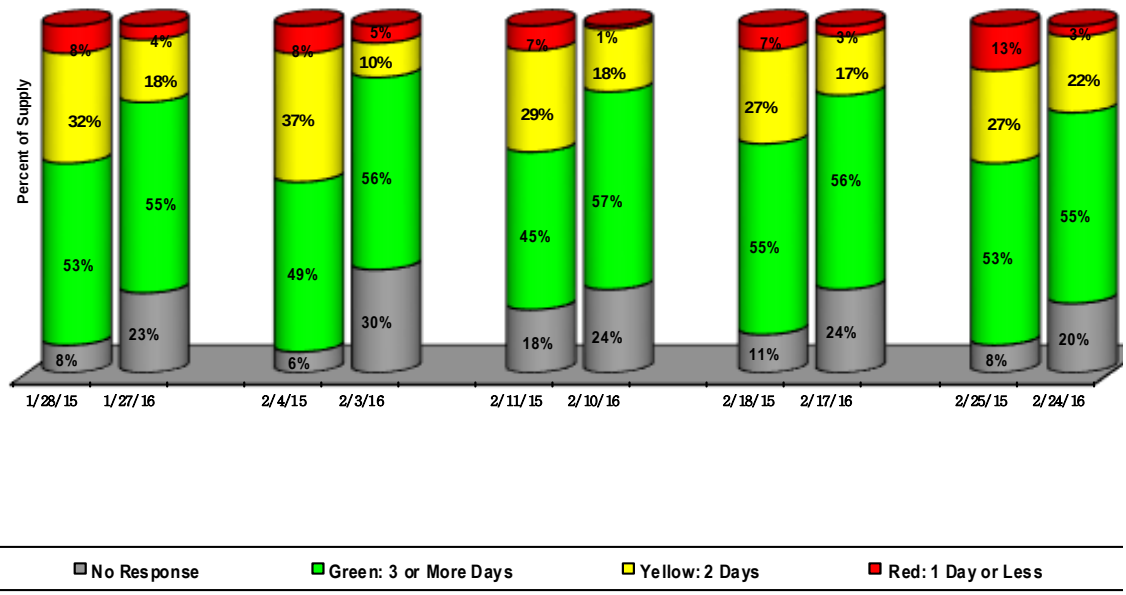
ABC will continue to track Zika related activity on the Hill in conjunction with extensive advocacy efforts in the regulatory domain. Congressional hearings represent an opportunity to understand the intersection between the regulatory and legislative arenas, while developing relationships that may serve ABC and its member blood centers in supporting population health by providing a safe and adequate blood supply.

Lastly, Dr. Zambricki had the opportunity to meet with former Health and Human Services Secretary Louis Sullivan, MD to discuss issues impacting both community blood centers and ABC. Dr. Sullivan expressed interest in having further discussions regarding the need to increase African-American donor recruitment and strategies to assist in the treatment of sickle cell patients.

We Welcome Meeting Notices

Do you have a symposium, conference, workshop, or annual meeting that you would like to publicize in the *ABC Newsletter*? If so, please send a meeting notice, press release, or an announcement to the editor, Mack Benton at newsletter@americasblood.org. Notices should contain the following information: the exact date(s) of the meeting; the formal title of the meeting; the sponsoring organization or agency; the location of the meeting; a short (fewer than 35 words) description of the curriculum, agenda, or topics to be covered; a contact person or a website address with more information. Notices will be published at the discretion of the editor in the Meetings section of the Newsletter.

STOPLIGHT®: Status of the ABC Blood Supply, 2015 vs. 2016



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MEMBER NEWS

New York Blood Center (NYBC) and Community Blood Center of Greater Kansas City (Kansas City, Mo.) recently announced the establishment of the National Center for Blood Group Genomics. According to a press release the laboratory will "specialize in providing precise-matched blood products to avoid complications, properly screen patients for the suitability of various transfusion treatment regimens, and improve the overall practice and safety of transfusion medicine. The National Center for Blood Group Genomics will use genomics, in accordance with its mission, to combat blood cancer autoimmune diseases, and acquired anemias. It is a continuation of NYBC's longstanding commitment to innovative research in transfusion medicine, genomics, and immunohematology. "This is a very exciting time for the New York Blood Center, for our Kansas City Community partner, and for the field of blood group genomics nationwide," said Howard P. Milstein, Chairman of the Boards of Trustees for NYBC. "We have extraordinary experience and capability in blood group genomics and will harness this talent as a resource for the nation in cancer treatment and personalized precision medicine – each recognized as advancing the frontiers of medicine." (Source: New York Blood Center press release, 2/24/16)

Upcoming ABC Webinars – Don't Miss Out!

- **"World Blood Donor Day 2016 – Nexcare Give Webinar"** – Feb. 29; 4 to 5 p.m. ET. Additional information available in MCN 16-018 or Contact: Mack Benton at mbenton@americasblood.org

PEOPLE

Bloodworks Northwest (BloodworksNW) Chief Financial Officer (CFO) **Bob Gleason** recently earned recognition from the Puget Sound Business Journal as one of their "CFO of the Year" awardees for non-profit organizations in the state of Washington. He will receive the award at a ceremony on March 10. Given annually, these awards honor financial professionals that display outstanding performance in demonstrating excellent financial acumen to accompany superb leadership within the company and the community. Mr. Gleason has been with Bloodworks NW since 2003 and has more than 35 years of financial management expertise with previous roles at Omnicare Ohio, Voca Corporation, and PricewaterhouseCoopers in New York and Ohio.

Chad A. Douglas has been named Chief Executive Officer at LifeShare Blood Centers. He brings more than 15 years of blood center leadership experience to position most recently serving as the Executive Director of Blood Operations at LifeSource in Chicago, Ill. Mr. Douglas succeeds Margaret E. Wallace who is retiring after decades of service to the blood banking community. "While filling the shoes left behind by Margaret Wallace may be difficult, the Board is confident we have found the right person, with the right experience, at the right time for LifeShare, said John Matessino, Chairman of LifeShare Blood Centers' Board of Trustees. "No doubt, not only will Chad be an asset to the Shreveport area but also a good ambassador and leader in all the communities LifeShare serves." Mr. Douglas earned a Masters of Health Administration from the University of Central Florida, Orlando, Fla., and served in the U.S. Air Force. (LifeShare Blood Centers press release 2/22/16)

AdvaMed announced that **Scott Whitaker** will be their next President and Chief Executive Officer. Mr. Whitaker will begin April 4. His previous roles include Chief Operating Officer of Biotechnology Innovation Organization and Chief of Staff at the Department of Health and Human Services. "We are very pleased that Scott has agreed to lead AdvaMed at a time of unprecedented change in health care," said AdvaMed Board Chairman Vincent A. Forlenza, chairman, CEO and president of Becton Dickinson. "Medical technology companies are at the forefront of developing solutions that improve patient outcomes and enable the delivery of high-quality, cost-effective care. However, continued progress in these areas depends on ensuring a strong innovation ecosystem. Scott has a proven track record as an association leader, and we believe he has the vision to set the course for AdvaMed's future." (AdvaMed press release 2/18/16)

IN MEMORIAM - Joseph Bove, MD, 89

Joseph Bove, MD, the first director of the Yale-New Haven Hospital Blood Bank passed away on Feb. 1. Dr. Bove was professor emeritus of laboratory medicine and founded Yale's blood bank in 1959. He received his medical and bachelor's degrees from the University of Maryland after serving in the U.S. Navy. During his distinguished 30-plus year career at Yale, Dr. Bove made many contributions to the advancement of blood banking, publishing many papers, while receiving numerous honors including both the John Elliott Award and the Distinguished Service Award from AABB. Considered a pioneer of blood banking, he chaired the AABB committee on Transfusion Transmitted Diseases and the Food and Drug Administration's Blood Products Advisory Committee. A memorial service will take place at the Unitarian

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RESEARCH IN BRIEF (continued from page 10)

Society of New Haven in Hamden, Connecticut on Saturday, Feb. 27 at 3 p.m. The family asks that donations be made in lieu of flowers to the Unitarian Society of New Haven, 700 Hartford Tpke, Hamden, Conn. 06517, or to the Columbus House, 586 Ella T. Grasso Boulevard, New Haven, Conn.

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 Lori Beaston for registration information.

April 7 **Centers for Patient Safety 10th Annual Patient Safety Conference St. Louis, Mo.**

The Centers for Patient Safety will hold its 10th Annual Patient Safety Conference will take place on April 7 at the Crowne Plaza Hotel & Convention Center in St. Louis, Mo. from 8:15 a.m. to 4:15 p.m. The theme of this year's conference is "A Culture at the Crossroads" More information is available 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 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.

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: https://home2.eease.adp.com/recruit2/?id=19081382&t=1

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

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POSITIONS (continued from page 11)

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 our website with

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 resume: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 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:
https://home2.eease.adp.com/recruit2/?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 immune-hematology during these shifts. Provides adequate training and performance appraisals. To apply please go directly to our website with an updated resume: https://home2.eease.adp.com/recruit2/?id=19080682&t=1

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 include 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

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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 postdoctoral 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 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://obi.org/careers/.

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; as-sessing, 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 complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has

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POSITIONS (continued from page 13)

facilities. CBC is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing. Apply at www.carterbloodcare.org.

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 man-agement 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.

Director of Collections. The director of collections (DC) provides effective leadership, supervision and direction for the operations of collections. Oversee the direction, coordination, and evaluation of collections, providing direction for subordinate management team members to ensure excellent services and an adequate, safe, pure and potent blood supply. Responsible for developing tissue related operational procedures and tasks that comply with core current good tissue practice (cGTP) requirements. Ensures all procedures and processes are performed as designed to prevent circumstances that increase the risk of the introduction, transmission, or spread of communicable diseases through the use of human cells, tissue and cellular and tissue-based products (HCT/Ps). Effectively monitor production, inventory and performance in areas within the scope of assigned departments; develop, implement, monitor, and determine the effectiveness of department processes and plans; take appropriate corrective measures when necessary; and identify new applications, innovations, quality and/or safety improvements; report findings/results to the CFO and medical director, as appropriate. Employer will assist with relocation costs. Additional Salary Information: TBD. Please apply at www.BBH.org.

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail* (lmaundy@americasblood.org) *or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2016

March 3. **Advisory Council on Blood Stem Cell Transplantation Meeting, audio conference and web conference.** More information and registration details can be found in the Federal Register notice.

March 8-9. **IPFA Asia Pacific 2016 Workshop on Plasma Quality and Supply, Taipei, Taiwan.** More information is available at www.ipfa.nl.

Mar. 12-14. **Annual Meeting, America's Blood Centers, Jacksonville, Fla.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

March 14-16. **12th Annual FDA and the Changing Paradigm for HCT/P Regulations, Bethesda, Md.** More information and registration details can be found here. Register by Oct. 30 for a $200 discount.

Apr. 7. **10th Annual Patient Safety Conference, St. Louis, Missouri.** For more information or to view the full agenda of speakers and topics visit here.

Apr. 26-28. **Human Resources & Training/Development Workshop, America's Blood Centers, San Antonio, Texas.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

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

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

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

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

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

July 28-29 **FDA Blood Products Advisory Committee Meeting.** More information can be found here.

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

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

Sept. 21. **6th Annual Symposium Red Cell Genotyping 2016: Clinical Steps, Bethesda, Md.** Registration can be found here: www.bcw.edu/rcg2016. Contact: Phyllis Kirchner, Phyllis.kirchner@bcw.edu.
Sept. 22. **35th Annual Immunohematology and Blood**

Transfusion Symposium, Bethesda, Md. Registration can be completed here. Contact: Karen Byrne, kbyrne@cc.nih.gov.

2017

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