



# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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This issue of the *ABC Newsletter* is being published early due to the AABB Annual Meeting in Anaheim, Calif. The *Newsletter* will not be published next Friday, Oct. 30. Regular publication will resume Nov. 6.

## STRIDE Study Illuminates Effective Iron Deficiency Mitigation Strategies

It is well established that regular blood donation can cause iron deficiency in blood donors and research has shown that providing blood donors with iron supplements may help mitigate this problem. The highly anticipated results of the Strategies to Reduce Iron Deficiency (STRIDE) study, to be presented at the AABB Annual Meeting in Anaheim, Calif., later this week (Abstract S34-030E), provide blood centers options for donor education and iron (Fe) supplementation dosing that may effectively reduce donor iron deficiency.

While previous [research](#) has shown that iron supplementation can speed hemoglobin recovery, an imperfect indicator of donor iron stores, questions remain regarding how best to implement this strategy. To answer some of these questions, Alan Mast, MD, PhD, of the BloodCenter of Wisconsin's Blood Research Institute, and REDS-III investigators conducted a randomized, blinded, placebo-controlled study investigating the effects on blood donor iron stores of providing varying levels of iron supplementation or post-donation written information.

Frequent blood donors from three blood centers were randomly assigned to one of five study arms over two years. Three arms consisted of providing iron supplementation for 60 days after each donation, either 38 mg, 19 mg, or 0 mg (placebo) of elemental Fe. The other two arms consisted of providing an iron status letter vs. one encouraging frequent donation. The iron status letter provided donors with their ferritin level and recommended continued frequent donation for donors with ferritin >26 mg/L, while donors with ferritin ≤26mg/L were recommended to take self-purchased iron pills and/or delay donation for six months. Ferritin, soluble transferrin receptor (sTfR), and complete blood count (CBC) were measured at each donation.

Of 692 donors enrolled, 393 completed a final visit. By the study's end, the prevalence of a ferritin <26mg/L was unchanged in the control groups but had declined by 50 percent in the three intervention groups (19 and 38 mg Fe and iron status letter). The prevalence of a ferritin level <12mg/L was unchanged in the two control groups, but had declined by 70 percent in the three intervention groups.

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## OUR SPACE

**Abbey Nunes, ABC's Chief Member Experience Officer**

### **Where We've Been and Where We're Going – The ABC Professional Institute**

It is amazing how quickly a calendar year flies by. Here we are almost at the end of October and preparations for the holidays and end of the year have already begun. It is also hard to believe that just a year ago at this time is when we started planning the first stages of the ABC Professional Institute (API) – a one-stop-shop for all of ABC's educational offerings. Reflecting on that first year of bringing the API from a concept to a tangible item, it is exciting to look back on what has been accomplished:

- The creation of the API Curriculum Development Committee – a group of volunteer ABC members who help lead the direction of the project, as well as the creation and development of API programs;
- The development and launch of the API Capital Campaign, which has raised nearly \$300,000 to date to help sustain this program;
- The standardization of educational offerings to ensure that whether it is an online offering or a face-to-face meeting, all educational opportunities meet and exceed the learner's expectations;
- The development, implementation, and launch of the ABC mobile event application, a simple yet effective mobile app that allows attendees to easily access meeting/workshop information from their smartphones or tablets both prior to and during events;
- The launch of the new [ABC Member Site](#), providing members a user-friendly experience to access all of ABC resources and information, including all educational offerings through the API;
- The creation of a new position at ABC – the director of Education Programs & Grants to develop and manage education programs and processes to drive a learning and continuing education culture that delivers member value and satisfaction via the API; and
- The first newly designed offering of the API, Blood Banking 101, is in the initial stages of development. Blood Banking 101 is an introductory e-learning tool aimed at providing the learner with a foundational knowledge of the blood banking industry.

The accomplishments achieved thus far are much thanks to you, our supporters: the membership, volunteer committee members, and the generous contributions of industry partners. We would not be where we are in this project without each and every one of you. But our work is not done. The [API Capital Campaign](#) runs through the end of March, and with it comes a goal of nearly tripling the amount raised thus far. As mentioned above, the launch of the Blood Banking 101 program, as well as additional e-learning offerings, are just around the corner.

So whether it's a financial contribution or donation of your time and resources, we look forward in continuing to work with you on the goal of making the API a recognized premiere learning platform. Contact [Rachelle Fondaw](#) to learn more about how you can get involved. And just think – with your support – what accomplishments we will be able to look back on this time next year.

*Abbey Nunes*

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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STRIDE Results (continued from page 1)

The prevalence of  $\log_{10}(\text{sTfR}/\text{ferritin}) \geq 2.07$  was unchanged in the two control groups, but declined by 30 to 50 percent in the three intervention groups.

Essentially, all measures of iron deficiency observed at the study's end were equivalent among the three iron intervention groups, and were statistically different from the two control groups. The three intervention groups had venous hemoglobin 0.3 to 0.4 g/dL higher than the two control groups at the study's end. Subjects receiving an iron status letter were deferred at 4.1 percent of visits vs. 9.8 percent deferrals for those receiving letters without iron status information. Donors receiving placebo pills were deferred at 6.1 percent of visits vs. 2.7 percent of those receiving 19 or 38 mg Fe. This is important because low hemoglobin remains the most common reason for blood donor deferral in the US.

“All of them [the three interventions] worked, and all of the three intervention groups had greatly improved iron status over the control groups. This gives blood centers a lot of options as to how they can design or manage a program to mitigate iron deficiency in blood donors ... There are lots of different things that can work and blood centers have to decide what's best for them in terms of operations and costs,” Dr. Mast told the *ABC Newsletter*.

This study supports the growing notion that blood centers must implement measures to mitigate iron deficiency in donors. In fact, the Food and Drug Administration final rule published new [regulations](#) in May that when they go into effect in May 2016 will alter the minimum hemoglobin level to protect donors from iron deficiency and to potentially permit more female donors to give blood.

The rule changes the minimum hemoglobin for males from 12.5 g/dL to 13.0 g/dL. The minimum requirement for female donors remains 12.5 g/dL, however, female donors will be permitted to donate at 12.0g/dL provided that additional steps are taken to assure donor safety with regard to iron status. It remains unclear exactly what mitigation strategies meet this new requirement, but may include assessment of iron stores and/or iron supplementation.

A handful of America's Blood Centers' member centers have implemented donor iron supplementation programs and other iron deficiency mitigation strategies, suggesting that such interventions are feasible. Those attending the AABB Annual Meeting should head to the 2 p.m. Hot Topics session (9116-S) on Saturday, Oct. 24 to hear from Dr. Mast and other experts about how blood centers might design and implement such programs. Another session (9228-TC-HEM) at 4 p.m. on Sunday, Oct. 25 will explore the integration of ferritin testing into donor screening.

**Citation:** Mast AE. Iron status of donors in STRIDE, a randomized, blinded, placebo-controlled study of education and iron supplementation for mitigation of iron deficiency in frequent blood donors. *Transfusion*. Oct;55(3S):20A. ♦

### ABC Webinar Slides Available on FDA 600 Series Final Rule

The Food and Drug Administration published on June 5 the final rule, “Requirements for Blood Components Intended for Transfusion or for Further Manufacturing Use.” This final rule, set to go into effect May 23, 2016, updates the 600 Series of the Code of the Federal Register (CFR) – the regulations that govern blood collection and manufacturing. America's Blood Centers held a webinar this week to answer some of the many questions that have arisen about how the updated regulations will impact blood center operations. For those who missed the webinar, ABC members can access the slides and audio [here](#).

## Blood Centers Offer Transfusion Safety Officer Educational Programs

OneBlood, headquartered in Florida, announced on Tuesday that it will join the growing number of blood centers offering educational opportunities for transfusion safety officers (TSOs). The center will offer a unique TSO and patient blood management (PBM) seminar, which will allow attendees to earn Continuing Medical Education (CME) and Continuing Education Units (CEU).

OneBlood's team of physicians who are board certified in blood banking and transfusion medicine will lead the interactive seminars and provide a broad range of content for a diverse audience. Four seminars will be presented throughout Florida in 2016, beginning in January. Basic and advanced classes are available and participants have the options of a one- or two-day seminar, as well as virtually viewing the seminar online if they are unable to attend in person.

The seminars offer something for everyone," said Richard Gammon, MD, medical director at OneBlood. "Whether your hospital is looking to establish a patient blood management program or already have a program in place, the OneBlood seminars are tailored to meet the specific needs of the audience," said Dr. Gammon.

OneBlood established the program because the center felt it was important to provide their hospital partners an educational venue on current transfusion thresholds, alternatives to allogeneic transfusions, and PBM, added Dr. Gammon.

"The growing number of TSOs is driven by two factors," said Dr. Gammon. Those factors are patient safety and cost. He explained that clinicians need to learn how to balance administering enough blood to maximize patient outcomes with avoiding unnecessary transfusions, which may expose the patient to both infectious and non-infectious risks. Further, the process of acquiring, testing, and transfusing blood causes the hospital to incur significant costs. "The TSO acts as the liaison between the clinicians, the transfusion service, and the blood center. These individuals can perform data analysis, education, and increase the level of awareness of PBM at their institutions," he said.

OneBlood's TSO and PBM seminars are scheduled for Jan. 20, April 19-20, July 27, and Nov. 8-9, 2016. Registration costs \$125 per day for each attendee, or online participation is a flat fee of \$300. There is no limit to the number of people at an organization that can view the online program once it is purchased. Those interested in learning more about this opportunity can contact Dennie Gilbert at [Denise.Gilbert@oneblood.org](mailto:Denise.Gilbert@oneblood.org) or (727) 568-1134.

OneBlood is one of a number of blood centers that offer some variety of TSO training, including Blood Systems, Inc. (BSI), which offers a three-day on-site intensive TSO training program, consisting of lectures, workshops, interactive case studies, and group interaction. Launched in January 2012, the program is designed to train TSOs in building, implementing, and improving transfusion safety and PBM at their institutions. At the conclusion of the program, students receive 20 CEUs, a certificate of attendance, and ongoing support from the training faculty.

Alumni from the program have contributed abstract posters to past AABB Annual Meetings on successful patient blood management programs, pre-surgical anemia clinics, and transfusion safety initiatives. The program is now held twice a year, in May and October. Information on the next TSO Training Program session in May 2016 can be found [here](#). Contact Buddy Nguyen at [bnguyen@bloodsystems.org](mailto:bnguyen@bloodsystems.org) with questions.

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Transfusion Safety Officer Training (continued from page 4)

Similarly, BloodSource, Sacramento, Calif., offers an array of blood management resources including educational opportunities, transfusion guidelines, and consultations to its hospital customers through its formalized PBM program, [BloodSmart](#). These are just a few examples the growing trend among blood centers to offer TSO and PBM training and education. (Sources: OneBlood press release, 10/20/15; Blood Systems submission, 10/21/15) ♦



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

### **Nominations Open for ABC's 19<sup>th</sup> Annual Awards of Excellence, 2015 FABC Awards**

America's Blood Centers is now accepting nominations for the 19<sup>th</sup> Annual Awards of Excellence. This program provides ABC's member blood centers the opportunity to offer national recognition to local individuals, civic groups, media, and corporations for their commitment to community blood programs.

Award recipients will be announced in January 2016. The Awards of Excellence ceremony will be held on Monday, March 14, 2016 at the Hyatt Regency Jacksonville Riverfront in conjunction with ABC's 54<sup>th</sup> Annual Meeting in Jacksonville, Fla. Similar to the 2015 Awards of Excellence, the format will be a "rolling dinner," providing guests the opportunity to mingle and network before the ceremony. A Casino Night Fundraiser for the Foundation for America's Blood Centers (FABC) will take place after the ceremony.

The following awards will be presented during the Awards ceremony: Media of the Year Award, Corporation of the Year Award, Larry Frederick Award, National Partner of the Year Award, Outstanding Humanitarian Service Award, Creative Blood Drive Award, Productive Blood Drive Award, School Blood Drive Award, Thomas F. Zuck Lifetime Achievement Award, and the William M. Coenen President's Award. (Travel and hotel expenses of award recipients are the responsibility of the nominating blood center.)

The following Foundation for America's Blood Centers (FABC) awards will also be presented during the Awards ceremony: Terumo BCT Award of Excellence in Donor Recruitment and the ITxM Award for Excellence in Technical Operations

ABC encourages its member blood centers to take advantage of this opportunity to recognize their supporters and colleagues by submitting nominations **before Friday, Nov. 20**. ABC members can find more information in [MCN 15-088](#). Please direct questions to Jodi Zand at [jzand@americasblood.org](mailto:jzand@americasblood.org). ♦



## RESEARCH IN BRIEF

**The results of a donor travel survey to be presented at the AABB Annual Meeting in Anaheim, Calif., on Oct. 26 suggest that a travel-related donor deferral to mitigate the risk posed by chikungunya and dengue virus could result in deferral of 2 to 4 percent of donors annually.** The results of the survey, conducted jointly by America's Blood Centers, AABB, and the American Red Cross, will be presented during the Scientific Oral Abstract Plenary Session on Oct. 26 at 8:30 a.m. (Abstract P1-030A). Nearly 20 percent of US residents travel abroad annually, often to areas where dengue and chikungunya viruses are endemic. There are currently no screening tests for these viruses, and as such a travel-related donor deferral has been considered; the impact of such a deferral is unknown. Researchers from the three national blood organizations asked successful donors at centers representing about 70 percent of the US blood supply to complete anonymous, self-administered surveys about recent travel. Comparable data were collected from donors by a paper survey in the summer of 2014 and a web-based survey in the winter of 2015 to assess the impact of a short deferral and seasonal differences in travel patterns. Information on destination and the interval between the return to the US and donation allowed the researchers to estimate the impact on collections for different configurations of travel-based deferral. More than 33,000 donors completed the summer of 2014 survey, with 2.6 percent reporting travel outside the US and Canada  $\leq 28$  days before donation. Mexico and Caribbean destinations were most common, accounting for  $>85$  percent of travel in the Americas. A deferral of 28 days was estimated to impact 1.2 percent of donation. Limiting the deferral to 14 days reduces the impact to 0.4 percent of donations. The winter 2015 online survey was completed by about 20,000 donors with 4 percent reporting foreign travel with 2.2 percent reporting travel to the Americas within 28 days of donation. These data suggest that the size of the donor population subject to a tropical deferral policy is potentially several-fold higher than the 0.5 to 0.75 percent of presenting donors currently deferred for malaria risk. A 28-day deferral encompassing all sites outside the US, Canada, and Western Europe might impact 2 to 4 percent of presenting donors annually. The researchers note that the impact would be mitigated by prospective donor education on waiting the specified minimum before presenting to donate after international travel and/or by establishing the deferral period at 14 days.

**Citation:** Spencer BR, *et al.* Survey to estimate donor loss to 14- or 28-day travel deferral for mitigation of CHIKV, DENV, and other acute infections. *Transfusion*. Oct;55(3S): 3A.

**More US troops survived life-threatening injuries in Afghanistan after Defense Secretary Robert Gates ordered evacuation helicopters to extract wounded personnel within 60 minutes, a period known in emergency medicine as the “gold hour”.** In a study published Sept. 30 in *JAMA Surgery*, researchers found the number of wounded troops who died on the battlefield in Afghanistan dropped by more than 6 percentage points after the policy went into effect in 2009. The case fatality rate – the proportion of total deaths among all wounded troops – declined as well. According to the study, which reviewed the outcomes of 21,089 cases of battlefield wounds in Afghanistan from September 2011 to March 2014 – 386 of 2,411 (16 percent) severely injured troops died on the battlefield before the mandate, while 964 of 9,755 (9.9 percent) injured personnel died after. The case fatality rate declined from 13.7 percent before the mandate to 7.6 percent after. Lead author and retired Army Col. Russ Kotwal told the *Military Times* that the researchers initially examined the data to determine whether the services succeeded in adhering to Secretary Gates' mandate. They found that the average air response time declined from 90 minutes to 43 minutes and the percentage of missions achieving pre-hospital helicopter transport within 60 minutes rose from nearly 25 percent to 75 percent. “Time of transport certainly makes a difference. But so do treatment capabilities. It's not just the time getting to the hospital, it's about pushing out treatment capabilities,” said Col. Kotwal. The researchers estimated that the policy change mandating helicopter removal of wounded personnel within 60 minutes likely means that 359

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**RESEARCH IN BRIEF** (continued from page 6)

troops who would have died from their combat wounds prior to the policy change lived. Improvements in blood replacement and transfusions immediately after injury and the use of tourniquets – by medics, corpsmen, or anyone responding to a casualty – contributed greatly to improving survival times, said Col. Kotwal. More information can be found in the [Military Times](#) article. (Source: *Military Times*: 9/30/15)

**Citations:** Kotwal RS, *et al.* The effect of a golden hour policy on the morbidity and mortality of combat casualties. *JAMA Surg.* 2015 Sep. 30:1-10. [Epub ahead of print] ♦

**BRIEFLY NOTED**

AABB recently published a [detailed summary](#) of the Sept. 21 meeting of Food and Drug Administration staff with AABB's FDA Liaison committee. The committee includes liaisons from America's Blood Centers, AABB, the Advanced Medical Technology Association, the American Red Cross, the American Society for Apheresis, the Armed Services Blood Program, and the College of American Pathologists. The meeting, described briefly in the *ABC Newsletter* on Oct. 2, covered a myriad of topics including the FDA's [final rule updating the 600 series of the CFR](#), the burdensome requirements for freezing source plasma, and regulations regarding the sale of plasma to fractionators to be made into plasma protein therapeutics. (Source: AABB website, 10/21/15)

The Centers for Disease Control plans to update the Hemovigilance Module of the National Healthcare Safety Network (NHSN), according to the [September NHSN newsletter](#). The revised version will include information about products treated with pathogen-reduction technologies (PRT). As of Jan. 1, the denominator reporting form will include a new section for reporting the total numbers of PRT-treated units and aliquots by product type and collection method. In addition, CDC will add a question to the Annual Facility Survey and instructions to the denominator form on how to report pooled products. CDC offers customizable [Hemovigilance Module forms](#) online that can be downloaded and incorporated into the facilities' internal data collection process. Questions may be addressed to [nhsn@cdc.gov](mailto:nhsn@cdc.gov); include Hemovigilance in the subject line for a faster response. (Sources: AABB Weekly Report, 10/16/15; CDC NHSN e-Newsletter, 9/30/15) ♦

**REGULATORY NEWS**

The Food and Drug Administration [announced](#) Oct. 16 that it granted accelerated approval to idarucizumab (Praxbind) to reverse the anticoagulant dabigatran (Pradaxa) in emergency situations. Dabigatran was approved in 2010 to prevent stroke and systemic blood clots in patients with atrial fibrillation, as well as to treat and prevent deep venous thrombosis and pulmonary embolism. However, in the case of emergency surgery and hemorrhage there is often a need to reverse the effects of the blood thinner. Idarucizumab is the first reversal agent approved specifically for dabigatran. The safety and effectiveness of idarucizumab were studied in three trials involving a total of 283 healthy volunteers given dabigatran (i.e., people who did not require an anticoagulant). In these volunteers after administration of idarucizumab, there was an immediate reduction in the amount of dabigatran in participants' blood (measured as unbound dabigatran plasma concentration) that lasted for a period of at least 24 hours. The most common side effect from use of idarucizumab was headache. Idarucizumab is approved under the FDA's accelerated approval program, which allows the agency to approve drugs for serious

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**REGULATORY NEWS** (continued from page 7)

conditions that fill an unmet medical need based on an effect on a surrogate or an intermediate clinical endpoint that is reasonably likely to predict a clinical benefit in patients. The company is required to submit additional clinical information after approval to confirm the drug's clinical benefits. (Source: FDA press release, 10/16/15)

**Rebiotix, based in Roseville Minn., [announced](#) on Oct. 21 that the Food and Drug Administration has granted breakthrough therapy status for its lead product RBX2660 to treat *Clostridium difficile* (*C. difficile*) infection.** Fecal transplants are being used to treat *C. difficile* infections by reconstitution of gastrointestinal flora disturbed by antibiotic therapy. RBX2660 is one of two microbiome treatments currently seeking FDA approval. The designation entitles Rebiotix to early and frequent support from FDA senior managers and reviewers in designing a drug development plan that will speed the approval timeline. RBX2660 works by delivering human-derived microbes into a patient's intestinal tract. *C. difficile* causes more than 29,000 deaths in the US annually. "A number of blood centers have expressed interest in facilitating fecal transplants, reflecting their skill in cGMP handling of substances of human origin. However, that niche seems likely to be short-lived with the development of pharmaceutical grade products," said America's Blood Centers Chief Medical Officer Louis Katz, MD, an infectious diseases specialist. (Source: Rebiotix press release, 10/12/15)

**The Food and Drug Administration [announced](#) Oct. 20 that it approved Coagadex, Coagulation Factor X (Human), for hereditary Factor X deficiency.** Until FDA's orphan drug approval, no specific coagulation factor replacement therapy was available for patients with hereditary Factor X deficiency. This is an inherited disorder, affecting men and women equally, in which the blood does not clot properly. Patients with the disorder are usually treated with fresh-frozen plasma or plasma-derived prothrombin concentrates to stop bleeding. The availability of a purified Factor X concentrate increases treatment options for patients with this rare bleeding disorder. Coagulation Factor X, which is derived from plasma, is indicated for individuals 12 years and older with hereditary Factor X deficiency for on-demand treatment and control of bleeding episodes, and for perioperative management of bleeding in patients with mild hereditary Factor X deficiency. The safety of Coagulation Factor X was evaluated in a multi-center, non-randomized study involving 16 participants (208 bleeding episodes) for treatment of spontaneous, traumatic and heavy menstrual (menorrhagic) bleeding episodes. It was demonstrated to be effective in controlling bleeding episodes in participants with moderate to severe hereditary Factor X deficiency. Orphan drug designation is given to drugs intended to treat rare diseases in order to promote their new development. (Source: FDA press release, 10/20/15)

**The American Society for Apheresis (ASFA) recently posted an update regarding the Centers for Medicare & Medicaid Services (CMS) proposed removal of the 1992 National Apheresis Coverage Determination Document (NCD) to be replaced by a system where coverage determination is performed by local Medicare Administrative Contractors.** AFSA, AABB, and the American Society of Hematology (ASH) jointly recommended this change in public comments to CMS due to the recognition that the current NCD contains antiquated indications and is silent on many proven current indications for apheresis. CMS received 55 comments during the 30-day public comment period but elected not to remove the 1992 Apheresis NCD Document. The indications for and technology of apheresis have changed considerably in the ensuing 23 years since the current NCD was issued. The request from the three associations sought a more rational approach to payment for apheresis services that would allow for consideration of new clinical knowledge. The refusal of change to the method for determining coverage may translate into less interest in providing and developing apheresis services for patients. Public comments to the CMS proposed rule can be viewed [here](#). (Source: ASFA e-mail update, 10/21/15)



**REGULATORY NEWS** (continued from page 8)

The Department of Health and Human Services (HHS) published a [final rule in the Federal Register](#) titled “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications.” This rule finalizes a new edition of certification criteria (the 2015 Edition health IT criteria) and a new 2015 Edition Base EHR definition. It also modifies the Office of the National Coordinator for Health IT (ONC) Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings. The 2015 Edition establishes the capabilities and specifics that related standards and implementation specifications that certified EHR Technology would need to include. These requirements are meant to ensure that, at a minimum, such standards support the achievement of meaningful use by eligible professionals, and critical access hospitals, under the Medicare and Medicaid EHR Incentive Programs. (Source: Federal Register, 10/16/15) ♦

**THE WORD IN WASHINGTON**

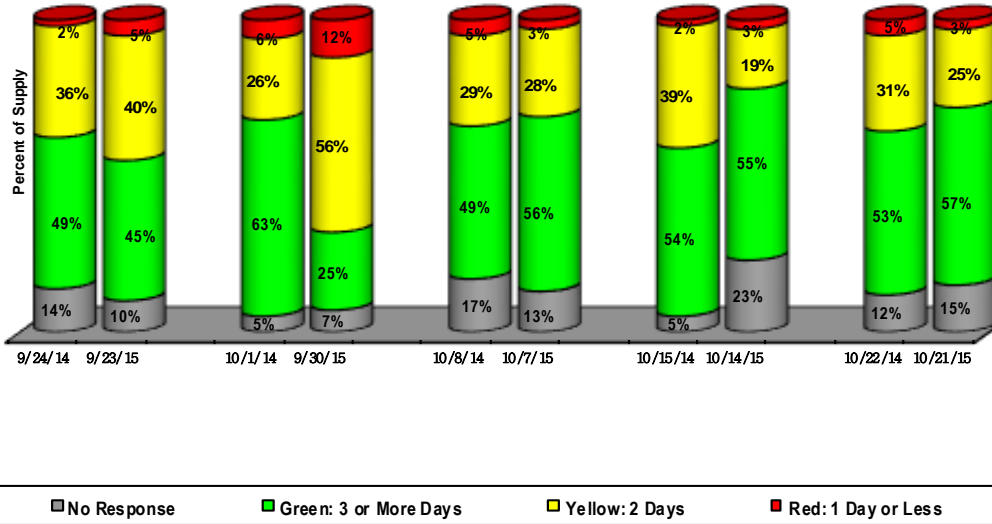
**The US House and Senate are back in session the week of Oct. 19.** With Treasury Secretary Jack Lew having told Congress that Uncle Sam will reach its statutory debt limit on Nov. 3, legislators are pressed to agree on a plan to raise the federal government’s debt ceiling beyond its current \$17 trillion level in order to pay obligations previously ordered by Congress – or risk default. The Treasury secretary’s letter to Congress can be viewed [here](#). Meanwhile, leadership elections to succeed resigning House Speaker John Boehner (R-OH) are slowing progress toward reaching a 2016 appropriations agreement by the Dec. 11 deadline when the current “continuing resolution” funding expires. If you visited with your legislators or their staffs while they were at home, let us know how your visits went by contacting Betty Klinck at [bklinck@americasblood.org](mailto:bklinck@americasblood.org).

**America’s Blood Centers recently posted several new resources available in the [Advocacy section of the Member Website](#).** Learn about the [outcomes](#) of ABC’s advocacy initiative to oppose the cuts to Medicare reimbursement for blood products in the outpatient setting proposed by the Centers for Medicare & Medicaid Services, as well as other important topics in the news that may be of interest to your blood center.

**Presidential candidates from both sides of the aisle have upcoming debates scheduled.** A third Republican debate is scheduled for Oct. 28 in Boulder, Colo., and the second Democratic debate is scheduled for Nov. 14 in Des Moines, Iowa. America’s Blood Centers encourages ABC members to engage with their presidential campaign of their choice, particularly in the early caucus and primary states of Iowa, New Hampshire, South Carolina, and Nevada, plus the “Super Tuesday” states of Alabama, Alaska, Arkansas, Colorado (caucus), Georgia, Massachusetts, Minnesota (caucus), North Carolina, Oklahoma, Tennessee, Texas, Vermont and Virginia. ABC will not support or endorse presidential candidates. A full list of the debates schedule can be found [here](#). (Source: The Washington Post, 10/13/15)

**While the switch to the ICD-10 coding system took place Oct. 1, Congress is monitoring the transition and so are many hospital administrators and others in the healthcare industry.** If your blood center or hospital customers encounter any issues with ICD-10 transition related to blood and blood products, please e-mail [bklinck@americasblood.org](mailto:bklinck@americasblood.org). At this point, America’s Blood Centers is remaining neutral on HR 3018 legislation meant to ease the transition to ICD-10, unless ABC member centers report being negatively affected in some way. ♦

**STOPLIGHT®: Status of the ABC Blood Supply, 2014 vs. 2015**



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

**MEMBER NEWS**

**South Texas Blood & Tissue Center (STBTC), a subsidiary of BioBridge Global, recently recognized donor Marcos Perez who reached his 90-gallon donation last Friday.** Mr. Perez, a 55-year-old regular platelet donor of San Antonio, Texas, was welcomed with a certificate and cake. Another BioBridge Global subsidiary, the Blood & Tissue Foundation, held another exciting celebration – the Red and White Ball. It is an annual fundraising event for which the proceeds went to purchase equipment for a new stem cell expansion laboratory. (Source: STBTC press release, 10/22/15)



(Photo left) Marco Perez III is recognized by staff members at STBTC as he reaches his 90<sup>th</sup> gallon donation. (Photo right) Blood & Tissue Foundation Chairman's Award winner, Karen Heintz, receives her award at the Red and White Ball alongside her daughter.

**Héma-Québec, the blood provider of Québec, recently gained approval from Health Canada, the Canadian regulatory agency, to extend the shelf-life of platelets to seven days.** Normally, platelets can only be stored for five days prior to transfusion, however new storage and testing practices have

(continued on page 11)

**MEMBER NEWS** (continued from page 10)

emerged to maintain the safety and efficacy of platelets over an extended shelf-life. Héma-Québec submitted an application to Health Canada to obtain approval for seven-day platelets following culture of platelets after a 48-hour waiting period and a 12-hour post-inoculation incubation using a two-bottle system (20 mL of product sampled). The underpinning of Héma-Québec's request is twofold: to reduce the risk of bacterial contamination of platelets and to increase the availability of platelets by extending the shelf-life. With regard to platelet safety, the blood provider felt it necessary to take further steps to mitigate sepsis caused by bacterial contamination of platelets. The residual risk of bacterial platelet contamination causing severe adverse reaction in a patient was about 1 in 100,000 based on Héma-Québec's experience using a single-bottle culture at 24 hours, according to Gilles Delage, MD, Msc, vice president of Medical Affairs at Héma-Québec. Further, one of the three sepsis cases reported by the Québec hemovigilance system following transfusion of a contaminated platelet transfusion was fatal, added Dr. Delage. Evidence, both by modeling and clinical experience, has shown that increasing the delay before culture to 48 hours and doubling the sample volume increases the probability of detecting a contaminated platelet, thus reducing the risk of post-transfusion sepsis, said Dr. Delage. With regard to the extended shelf-life, a prospective randomized clinical trial in Britain shows that six- to seven-day platelets are as effective as younger platelets for the management of patients with hematologic cancer and low platelet counts. Health Canada will require Héma-Québec to report details on all cases of adverse reactions to platelet products due to bacterial contamination (already in place for years at the center). The blood service must also conduct bacterial culture on all platelet products that outdate until it can demonstrate that the rate of positive cultures at outdate has not increased compared with the experience with five-day platelets cultured at outdate (1 in 4,000). The shelf-life for platelets in the US is currently five days, as mandated by the Food and Drug Administration. However, experts have suggested that with the implementation of pathogen reduction and other safety measures, FDA may approve seven-day platelets provided that adequate safety measures are in place. ♦

**PEOPLE**

**Matthew D. Coleman, MD, FASCP**, was recently named medical director of LifeShare Blood Centers based in Shreveport, La. He initially joined the company as associate medical director in 2011. "LifeShare has been very fortunate to have such a bright and knowledgeable physician working with Dr. Levy these past three years. His strong blood center experience, including cellular therapies, makes him well qualified to assume the helm as medical director," said Margaret Wallace, CEO of LifeShare Blood Centers. Dr. Coleman succeeds Gary Levy, MD, who retired from LifeShare on Sept. 30 (see [ABC Newsletter, 9/18/15](#)). Dr. Coleman is a fellow of the American Society for Clinical Pathology and a diplomate of the American Board of Pathology with certification in Clinical Pathology and Blood Banking/Transfusion Medicine. After receiving a Doctor of Medicine from the University of Oklahoma College of Medicine, he completed a residency in anatomic and clinical pathology at the University of Oklahoma Health Sciences Center and a transfusion medicine fellowship at Baystate Medical Center/Tufts University of Medicine in Springfield, Mass. Dr. Coleman's experience in the blood banking industry includes medical director positions with United Blood Services, Inova, and the National Marrow Donor Program. (Source: LifeShare Blood Centers press release, 10/16/15)

**PEOPLE** (continued on page 12)

**PEOPLE** (continued from page 11)

**Anne Eder, MD, PhD**, is stepping down as the vice president of National Medical Affairs at the American Red Cross, but will continue in a more narrowly defined role in the Biomedical Headquarters Medical Office to support the hemovigilance program and continuing medical education, announced Mary O'Neill, MD, interim chief medical officer. On Nov. 30, she will join the Department of Transfusion Medicine at the Clinical Center, National Institutes of Health (NIH) in Bethesda, Md. as the chief of the Blood Services Section. Dr. Eder joined American Red Cross Biomedical Headquarters (BHQ) in 2004, and has served as the medical director of the Red Cross' hemovigilance program, which has contributed to improving safety for both blood donors and transfusion recipients. Dr. Eder has also served as the BHQ medical support for system regulatory issues, providing medical oversight for regulated procedures and processes. She has become well known in the field for her support of other Biomedical Services functions. "We congratulate Dr. Eder on joining NIH in this prestigious position and wish her every success. We are also very pleased that she will remain with the Red Cross to continue her work with the successful Continuing Medical Education program and critical hemovigilance program which supports the Food and Drug Administration /AABB in advancing donor and recipient safety issues," said Dr. O'Neill. (Source: e-mail update Red Cross, 10/22/15) ♦

**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 Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: [lnorwood@americasblood.org](mailto:lnorwood@americasblood.org).

**EQUIPMENT AVAILABLE:**

**Best Offer.** PK7300 microplate blood donor typing system, Two (2) Pluggo decappers, Two (2) Immucor micro-plate washers for manual Capture assays, Two (2) Immucor microplate incubators for manual Capture assays. For additional details or to make an offer contact Joseph Hulina at [jhulina@cbccts.org](mailto:jhulina@cbccts.org).

**POSITIONS AVAILABLE**

**Director of Technical Services.** Blood Bank of Hawaii, a medium-size blood center (50,000 RBC distribution annually), is seeking a strong leader to oversee all technical operations in the component manufacturing, quality control, and immunohematology reference laboratories and the 16-member team. Headquartered in Honolulu, we are the sole provider of blood to the state's hospitals. If you are a CLS and/or SBB with at least five years' technical and management experience in a blood bank setting, come join a dynamic, cohesive team that is effecting positive change. We offer a competitive salary and excellent benefits. Apply online now at <http://www.bbh.org/about-bbh/employment.html>.

**Director of Hospital Services and Facilities.** The Director of Hospital Services and Facilities is responsible for ensuring alignment of teams with organizational

goals and compliance with regulatory guidelines. This position is accountable for ensuring a dedicated focus on the distribution of quality products in a timely manner while providing the highest level of customer service. This position will participate as a member of the blood bank's senior management team in planning, program formulation and decision making with particular reference to the role, functions and technical support of distribution of blood products and facilities maintenance. This position will be responsible for fostering and enhancing customer hospital relations. The Director of Hospital Services and Facilities will coordinate Blood Bank of Alaska's (BBA) Emergency Planning. This position is full-time exempt. BBA offers competitive

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**POSITIONS** (continued from page 12)

wages and an exceptional benefits plan. We offer medical, dental, vision, life and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, a health and wellness program, and a 401(k) program are also available. BBA is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply online at [www.bloodbankofalaska.org](http://www.bloodbankofalaska.org).

**Director of Laboratory Services.** The Blood Bank of Alaska (BBA) is looking for a Director of Laboratory Services. The Director of Laboratory Services is responsible for functions ensuring alignment with organization goals and compliance pertaining to regulatory guidelines within the laboratory environment. This position will participate as a member of the blood bank's management team in planning, program formulation and decision making with particular reference to the role, functions, and technical support of the blood collection and processing operations throughout BBA. This position will be responsible for compliance in regards to laboratory services. Position will serve on the executive group meetings. This position is full-time exempt. BBA offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, a health and wellness program, and a 401(k) program are also available. BBA is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply online at [www.bloodbankofalaska.org](http://www.bloodbankofalaska.org).

**Quality Assurance Specialist.** Community Blood Center, Inc., a provider of high quality blood products and services located in Appleton, Wis. is seeking a Quality Assurance Specialist to join our team. In this role, you will ensure compliance with regulatory, accreditation, certification and customer requirements. A bachelor's degree with experience working in a blood center, biologics, pharmaceutical or medical industry manufacturing environment with base familiarity of quality assurance practices, training, and federal regulatory practices is preferred. If you are detail-oriented with excellent organizational, oral and written skill and enjoy problem solving, consider this opportunity. For further information and to apply online please visit [www.communityblood.org](http://www.communityblood.org). Community Blood Center,

Inc. is an Equal Opportunity Employer M/F/Disability/Veteran

**Director of Donor Services.** The Rhode Island Blood Center is currently seeking a Director of Donor Services to manage blood collection activities and collections staff as well as provide leadership to achieve the collection goals of the Community Blood Program. Establish staffing and resources requirements for the safe and efficient collection of blood from donors. Demonstrate knowledge of applicable regulations and incorporate changes into operations. Develop and maintain the department's standard operating procedures. Ensure compliance with all Quality Management Plans and all standards related to the quality program. Prepare the department's annual operating budget. Monitor and adjust budget as necessary. Responsible for hiring, training and performance evaluations. Requirements: BS/BA in science, nursing, or business required. Three to five years of progressively responsible management experience, preferably in a healthcare setting. Demonstrated ability to manage both supervisor and staff level positions required. Apply online at [www.ribc.org](http://www.ribc.org). Join the team that gives the gift of life! We are an Equal Opportunity Employer. 💧

**Sr. Immunohematology Product Marketing Manager (Benicia, CA).** Bio-Rad's Immunohematology department has an amazing opportunity for a Product Marketing Manager. If you are a marketer with a knack for distilling complex topics down to easy-to-understand assets for the benefit of the customer target and sales force personnel, then we want to hear from you. This Product Marketing Manager will be involved in one of the biggest growth opportunities in the company to date. You will be responsible for the day-to-day marketing support of the immunohematology product lines to both the US selling organization and the manufacturing division. Qualifications: BA/BS degree in life science, business or related discipline. MBA and ASCP(SBB) preferred. Three to five years full-time product marketing experience, industry familiarity, including roles supporting a business-to-business sales team. Strong computer skills; SFDC, Marketo and SAP experience a plus. Proven experience working with various internal teams across an organization and excel at weaving external observations and market trends into the marketing strategy. Ability to handle shifting priorities in a constantly changing organization and marketplace. Excellent written and verbal communication skills. Analyze information across the buyer journey and identify opportunities in the marketing and sales processes to improve the time-to-close. Apply: <http://www.bio-rad.com/en-us/corporate/careers>. Job: D15-R-053.



## 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 Norwood by e-mail ([lnorwood@americasblood.org](mailto:lnorwood@americasblood.org)) or by fax to (202) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)

### 2015

Oct. 24. **1st Annual Sickle Cell Disease Symposium: A Comprehensive Approach to Managing Sickle Cell Disease, Concord, NC.** Contact: Amanda Rogers; e-mail: [Amanda.Rogers@carolinahealthcare.org](mailto:Amanda.Rogers@carolinahealthcare.org); phone: (704) 512-6038.

Oct. 24-27. **AABB Annual Meeting, Anaheim, Calif.** Contact: AABB Meetings Department, Phone: (301)215-6482; Email: [ProfessionalDevelopment@aabb.org](mailto:ProfessionalDevelopment@aabb.org). More information can be found [here](#).

Nov. 18. **FDA Joint Meeting of Cellular, Tissue, and Gene Therapies Advisory Committee & Oncologic**

**Drug Advisory Committee, Silver Spring, Md.** More information can be found [here](#). Contact: Jane Kim, [janie.kim@fda.hhs.gov](mailto:janie.kim@fda.hhs.gov)

Nov. 30. **IPFA Public Workshop: Access to Plasma Products, Cape Town, South Africa.** More information can be found [here](#). Contact: [info@ipfa.nl](mailto:info@ipfa.nl).

Dec. 1-2. **IPFA Workshop on Improving Access to Plasma and Plasma Products in the Southern Africa Region, Stellenbosch (Cape Town), South Africa.** Contact: e-mail: [info@ipfa.nl](mailto:info@ipfa.nl). More information available [here](#).

Dec. 6-9. **2015 National HIV Prevention Conference (NHPC), Atlanta, Ga.** More information and registration details can be found [here](#).

### 2016

Feb. 13-14. **SBB Last Chance Review by Webinar.** Sponsored by Gulf Coast Regional Blood Center in Houston, this intensive, two-day annual blood banking review is designed to benefit individuals preparing to take the ASCP SBB/BB Board of Certification examination, physicians preparing for the Board examination in Blood Banking, as well as individuals seeking a refresher course in blood banking. This program provides 13 P.A.C.E., California and Florida continuing education hours. Included in the registration are handouts with

case studies and practice questions. Details and registration at <http://www.giveblood.org/education/sbb-last-chance-review-via-webinar/>. Contact Clare Wong at (713) 791-6201, [cwong@giveblood.org](mailto:cwong@giveblood.org).

March 8-9. **IPFA Asia Pacific 2016 Workshop on Plasma Quality and Supply, Taipei, Taiwan.** More information is available at [www.ipfa.nl](http://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](mailto: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. 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](mailto:meetings@americasblood.org).

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

July 24-28. **WFH World Congress, Orlando, Fla.** Contact: [jbungardt@wfh.org](mailto:jbungardt@wfh.org). More information available [here](#).

Aug. 2-4. **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](mailto: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](mailto:meetings@americasblood.org) ♣