



# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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December 12, 2014

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**FDA Issues Draft Guidance on Testing Platelets for Bacterial Contamination**

The Food and Drug Administration issued a long-awaited [draft guidance](#) on Monday that provides blood centers and transfusion services with guidelines for testing platelets for bacterial contamination – recognized in the US as one of the most important infectious risks associated with transfusion. The draft guidance would standardize some aspects of early bacterial culture methods at blood centers and provides a route to extend the platelet storage time from five days to six or seven days.

Studies have estimated that about in 1 in 3,000 to 5,000 apheresis platelet doses may be contaminated with bacteria despite testing negative via early culture screening. Over the last several years, AABB has issued standards requiring that blood centers implement measures to mitigate the risk of bacterial contamination of platelets.

While these measures have improved the safety of platelet transfusions, questions have arisen regarding optimal culture methods. Furthermore, transfusion services have been slow to implement secondary point-of-issue screening largely related to cost and cost-effectiveness concerns. FDA’s draft guidance, “[Bacterial Detection Testing by Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion](#),” seeks to address these issues to further improve platelet safety. When it’s finalized, this guidance will supersede the recommendation in section VII.A.2 regarding bacterial contamination testing in the document titled “Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods” from December 2007.

FDA provides guidance to blood collection establishments and transfusion services for initial (primary testing) for bacterial contamination of platelets, mandating no major changes aside from standardization of the volume of product to culture, the time of inoculation, and the time of release following culture. To maximize the sensitivity of the culture, FDA recommends the following for apheresis and pre-pooled platelets derived from whole blood:

- Test platelets using a FDA-cleared culture-based bacterial detection device no sooner than 24 hours after collection;
- Use the maximal sample volume permitted by the device’s instructions for use and inoculation of the sample into at least an aerobic culture medium; and

(continued on page 3)



## OUR SPACE

Jodi Zand, Manager, Events & Fundraising, ABC

### 'Tis The Season

As the holidays approach, many begin to ponder which charitable organizations they would like to support. We hope that you consider the Foundation for America's Blood Centers (FABC) in your charitable gift planning this year! 2014 has been an exciting year for both ABC and the FABC.

One of our biggest new projects is the development of the ABC Professional Institute (API). Set to launch this spring as part of the new ABC members' website, the API promises to be a cutting edge educational resource that will benefit all blood banking professionals at ABC's member centers and in the industry. We offer a variety of [sponsorship levels](#) to give everyone the chance to be a part of the API!

The blood banking industry lost a dear friend this year with the passing of Jerry Haarmann, former president and CEO of GSABC. Jerry was a dedicated leader in the blood banking industry for over 20 years. A group of his former colleagues came together to memorialize Jerry by creating the Jerry Haarmann Memorial Campaign. We seek to raise \$25,000 in honor of Jerry to support a blood banking certificate program named after him, which will be offered through the API. You can contribute to the Jerry Haarmann Memorial Fund [here](#).

We are also planning a few fun events to benefit the FABC, taking place at our ABC Annual Meeting this March in Washington, D.C. On Sunday, March 22 you can hit the [Top of the Town](#) for "A Monumental Af-fair" to catch the best views of Washington while mingling and dining with colleagues. You'll experience breathtaking views and a hysterical performance by [The Capitol Steps](#), a political satire comedy group. For the true Washington experience, I suggest upgrading to the VIP ticket for a moonlit luxury limo tour of the DC Monuments after the event, complete with strawberries and champagne.

Last but not least, we are hosting the first ever ABC's Got Talent show on Monday, March 23! There are many ways to get involved – you even have time to enter your talent before the Dec. 31 deadline! Stay tuned to the *ABC Newsletter* in early January when you'll be able to vote on the contestants' videos *and* support the FABC through a minimum suggested donation of \$10 per vote!

So, as you finish your shopping (through our [Amazon Smile](#) account of course!) and start thinking about your year-end donations, please consider contributing to the FABC in one of the many ways listed above. Your contributions will help us continue supporting the life-saving mission of community blood centers, and to make the season a little brighter for patients in need of blood and their families.

[jzand@americasblood.org](mailto:jzand@americasblood.org) ♦

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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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FDA Platelet Draft Guidance (continued from page 1)

- If the instructions for use on the bacterial detection device specify a minimal incubation period, release the products consistent with the instructions. Otherwise, release products with negative results no earlier than 24 hours after culture inoculation.

The recommendations are the same for primary testing of whole blood derived (WBD) platelets at blood centers, except that the guidance specifies the inoculation of cultures no sooner than 24 hours after collection of the youngest unit in a pool using the largest volume permitted by an FDA-cleared culture-based bacterial detection device. Transfusion services intending to transfuse single units of WBD platelets should either test the units as described above and/or use a rapid bacterial detection device cleared to detect the presence of bacteria no sooner than 72 hours after collection; the product should be used within four hours of a negative rapid test.

FDA recommends that transfusion services take measures to minimize transfusion of platelets on days four and five of their shelf life, based on the observation that septic reactions occur mainly on these two days.

The agency provides additional considerations for subsequent retesting (secondary testing) prior to transfusion that would detect bacteria missed on the early culture-based test and offer a route to extend platelet shelf-life. However, it is important to note that to qualify for extended dating, the platelets must be tested with an assay approved as a “safety measure” (as opposed to a quality control claim) and stored in containers approved for extended storage – of which the latter are not currently available. Among currently available rapid bacterial assays, only the Verax Platelet PGD test is FDA-cleared as a “safety measure” (for leukoreduced apheresis platelets within 24 hours prior to transfusion).

FDA’s secondary testing recommendations state that platelets still in the transfusion service’s inventory on day four or five of storage may be tested in the transfusion service or shipped to a cooperating blood center for secondary rapid or culture-based testing. Re-issued platelets can be relabeled for six or seven day storage, if a culture-based secondary test is performed and a storage container approved for extended storage is used. FDA offers maximum flexibility, noting that there is no requirement to perform any secondary testing, rapid or culture-based (i.e., no changes are being required in the transfusion service).

The agency provides recommendations to licensed blood centers for submitting biologics license applications (BLA) supplements to include bacterial testing of platelets. FDA seeks to assist blood centers in determining which reporting mechanism is appropriate for a change to approved-BLAs, as it applies to the bacterial testing of platelet products and the manufacture of platelets with a six or seven-day expiration date.

America’s Blood Centers’ staff is in the process of reviewing the details and will compile comments from member blood centers to submit an official response to FDA. ABC members who wish to provide input may contact ABC Chief Medical Officer Louis Katz, MD, at [lkatz@americasblood.org](mailto:lkatz@americasblood.org). ♦

### **We Welcome Your Letters**

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at [newsletter@americasblood.org](mailto:newsletter@americasblood.org) or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

## ABC 2013-2014 Financial Ratio Survey Illustrates Industry Trends, Challenges

America's Blood Centers recently shared the results of its 2013-2014 Financial Ratio Survey – completed by 67 of ABC's member blood centers, representing nearly all (99 percent) of member blood collections. The annual survey provides participating ABC member blood centers with interesting facts and ratios that allow them to anonymously benchmark themselves against other blood centers around the country.

“The fact that a majority of our members participated in this survey shows that they feel it's an important survey,” said ABC Chief Financial Officer Bill Coenen. “While this is all public data that could be gained going through blood centers' annual reports and IRS forms, that would be a laborious process and would not be as current. This exchange of data is the one place where all of this financial information comes together.”

Donyah Perine, director of Financial Services at LifeShare Community Blood Services, headquartered in Elyria, Ohio, said her center has been participating in the ABC Financial Ratio Survey for many years and uses the information to show their board of directors where LifeShare stands comparatively against other centers in the country. They also use it to find areas for improvement. She noted that the survey is a good starting point for sharing of best practices among blood centers.

Among this year's notable findings, the survey results showed that despite the many challenges facing blood centers and increasing cost pressures on centers, gross revenues increased 6.2 percent from \$3.88 billion in 2012-2013, to \$4.12 billion in 2013-2014.

“I can see that blood centers are getting serious about reducing costs to maintain margins,” said Walter Ott, chief financial officer of Carter BloodCare, headquartered in Bedford, Texas, whose blood center has been participating in ABC's Financial Ratio Survey for about 10 years. He noted that the survey results highlight that while blood centers are seeing decreasing revenue from core services – the provision of blood products – they are seeing increasing overall revenue from diversified services, such as reference consultation and clinical apheresis.

The results also illustrate that ABC member blood centers contribute significantly to the local workforce – contributing \$1.63 billion to their local labor force in salaries and benefits this year. “We are not only a large contributor to the local economy in that regard, but we are also a very important contributor to the local healthcare industry,” said Mr. Ott.

Another positive indicator for blood centers reflected in this year's survey was the continuing of a trend in long-term debt to total assets, showing that members are depending less on debt to finance their operations.

In terms of challenges facing ABC member blood centers, the survey results show a continuing trend of blood center margins that are lower than those of hospitals. “Regardless of margins of the hospitals, we have to look for ways to reduce cost and to be more efficient and strategic in order to remain a healthy business capable of providing our valuable service to the community,” said Mr. Ott.

Ms. Perine encourages all ABC member blood centers to complete this survey in future years and to take advantage of the reported results. “It's a very easy survey to complete, and while I know some people are hesitant about sharing information, it is very secure and is reported anonymously. It's something that we really utilize a lot in our center and I feel all blood centers should be using it,” she said. 💧



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## INSIDE ABC

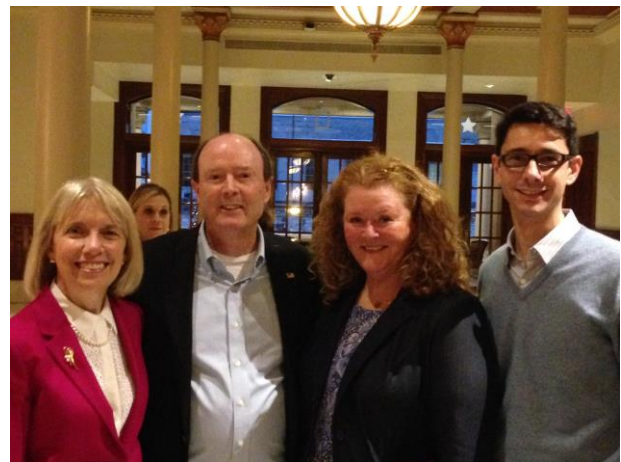
*The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified. ♦*

### **Deadline Extended to Submit Nominations for ABC Awards of Excellence**

America's Blood Centers has extended the deadline to **Dec. 19** to submit nominations for the 18<sup>th</sup> Annual Awards of Excellence. This program provides ABC members with the opportunity to offer national recognition to local individuals, civic groups, media, and corporations for their commitment to community blood programs.

The Awards of Excellence reception will be held on Monday, March 23 at the Ritz Carlton, Pentagon City in conjunction with ABC's 53<sup>rd</sup> Annual Meeting in Washington, D.C. Don't miss your chance to recognize the individuals and organizations who are committed to supporting community blood centers and volunteer blood donation! Please visit <http://bit.ly/10uHSCq> for more information and submit your nominations by Dec. 19. ♦

### **ABC Members Visit Austin for Supply Chain Optimization Workshop**



Earlier this week, blood center professionals representing nearly 20 of America's Blood Centers' member blood centers attended the ABC Supply Chain Optimization Workshop at the Driskill Hotel in Austin, Texas. Pictured above (left), audience members listen to a talk by Michael Hasler, PhD, about purchasing decisions and the total cost of ownership. Pictured right (from left to right) are ABC CEO Christine Zambricki, DNAP, CRNA, FAAN; Rhode Island Blood Center CEO Larry Smith; Patricia Killeen, executive director at New York Blood Center; and ABC Chief Operating Officer Matt Granato. See next week's Newsletter for more on the workshop!

### **The Deadline is Approaching to Submit Your ABC's Got Talent Video!**

Got talent or know somebody at your blood center who does? Well, America's Blood Centers is looking for you! The Foundation for America's Blood Centers and ABC are hosting the first-ever ABC's Got Talent Show – a virtual talent show allowing ABC blood center employees, board members, volunteers, donors, and families to showcase their talents and raise money for the FABC. The deadline to submit videos is **Dec. 31**. So hurry up and send us a video of your talent today! If you or a colleague would like to submit a video, contact Jodi Zand at [jzand@americasblood.org](mailto:jzand@americasblood.org).

## Did You Know...?

**'180'** is the number of active lines during an ABC HR Forum Webinar held on Nov. 20, during which ABC blood center professionals tuned in to learn about how to resolve and prevent bullying, gossip, and harassment issues at the workplace.

*America's Blood Centers' staff, board of directors, and committee members are working daily to support the needs of ABC's member blood centers. Whether it is through public, regulatory or legislative advocacy, educational meetings and webinars, or disaster preparedness assistance, ABC strives to support the continued success and development of independent community blood centers and their employees. Every quarter, ABC staff reports on a series of metrics to the board of directors through the ABC Balanced Measures Report. The ABC Newsletter will highlight one metric each week. Be sure to check it out to find out how ABC is working on behalf of your blood center.*

### RESEARCH IN BRIEF

**A study published Nov. 20 in *The New England Journal of Medicine* (NEJM) reports on an experimental gene therapy for hemophilia that is safe and effective in the treatment of hemophilia B.** Hemophilia B is caused by mutations in the gene factor for coagulation factor IX. Treatment generally requires lifelong injections of factor IX as often as three to four times a day. A.C. Nathwani, MD, of the Royal Free Hospital in the UK, along with colleagues at St. Jude Children's Research Hospital in Memphis, and the University College London, have been studying the long-term efficacy and safety of using gene therapy that uses self-complementary adeno-associated virus serotype 8 (AAV8) as a vector to deliver the factor IX gene that hemophilia B patients lack. Previous studies have had some success, however, achieving stable long-term expression of factor IX has been challenging. In the current study, the researchers inserted the human factor IX gene into the novel AAV8 vector in 10 men with hemophilia B. Two men were given a low dose of the vector, two a medium, and six a high dose. Within four months of receiving the modified gene therapy, the patients' blood levels of factor IX activity increased from less than 1 percent of normal to between 1 and 6 percent of normal. Men receiving a higher dose of the vector produced higher levels of the clotting factor. Higher doses led to a substantial decrease in bleeding and required less treatment with factor IX. The improvements lasted for the entire monitoring period, which was as long as four years for some participants. Side effects were mild, with the most common an increase in levels of a liver enzyme. Over the duration of this study alone, the use of the gene therapy treatment led to a reduction of 3 million units in factor IX concentrate used – a cost savings of \$2.5 million based on 2014 prices. The authors suggest that with further research, this treatment could have a large impact in reducing the burden and cost of treatment of hemophilia B patients.

**Citation:** Nathwani AC, *et al.* Long-term safety and efficacy of factor IX gene therapy in hemophilia B. *N Engl J Med.* 2014 Nov 20;371(21):1994-2004.

**The RING study presented on Dec. 6 at the 56<sup>th</sup> American Society of Hematology (ASH) Annual Meeting held in San Francisco, Calif., highlights the difficulty in studying granulocyte transfusion therapy, but suggests it may not be highly effective in treating bacterial or fungal infections. Old**

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

research has suggested that granulocyte transfusion might be useful for treating bacterial and fungal infections in patients with severe neutropenia due to hematopoietic stem cell transplant or aggressive chemotherapy. However, clinical efficacy is not well understood and historical studies used unstimulated donors, raising the question of the importance of currently achievable high granulocyte doses. The [abstract](#), presented by Thomas H. Price, MD, of the University of Washington in Seattle, reported the results of a recently completed randomized clinical controlled study examining the efficacy of high-dose granulocyte transfusion therapy. One hundred and fourteen patients were enrolled with neutropenia and proven, probable, or presumed bacterial or fungal infection. This was less than half the desired enrollment to produce a study able, with 8 percent power, to detect a 20 percent difference between treatment and control groups. They were randomized to receive either standard antimicrobial therapy or standard antimicrobial therapy plus daily granulocyte transfusions from normal donors stimulated with G-CSF (450µg) and dexamethasone (8mg). The primary endpoint was the composite of survival plus a microbial response at 42 days after randomization. Among subjects with sufficient data to determine the primary outcome, success rates were 42 percent in the granulocyte group and 43 percent for the control group in the “intention to treat” analysis, and 49 percent in the granulocyte group and 41 percent in the control group for subjects who adhered to their assigned treatments. The differences in the primary endpoint success rates for granulocyte and control arms were not statistically significantly different for any infection type, whether analyzed by “intention to treat” or “per protocol.” However, the authors note that because of the low accrual, it is possible that a true effect was missed.

**Citation:** Price TH, *et al.* The RING study: A randomized controlled trial of GCSF-stimulated granulocytes in granulocytopenic patients. Abstract SCI-16. ASH Annual Meeting. 💧

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## BRIEFLY NOTED

The new [Federal Health IT Strategic Plan for 2015 to 2020](#) was published earlier this week, outlining the federal government's health IT priorities. The plan, published by the Office of the National Coordinator (ONC) for Health IT in the Department of Health and Human Services, encompasses the entire federal government, including input from the Defense Department's Military Health System and the Veteran Affairs Department's Veterans Health Administration, among other federal agencies. The plan focuses on five goals – expanding the adoption of health IT, advancing secure and interoperable health information, strengthening healthcare delivery, advancing the health and well-being of individuals and communities, and advancing research, scientific knowledge, and innovation. “During the information age, innovation and technological advancements have been difficult to predict. This plan accounts for how the federal government views our nation's current landscape and articulates our values and priorities in shaping tomorrow's landscape,” Karen DeSalvo, MD, the national coordinator for Health IT, wrote in her opening letter of the plan. While this plan focuses on federal strategies, efforts by healthcare entities and providers, public health entities, payers, technology developers, community-based nonprofits, home-based supports, and academic institutions are also essential to its success, according to ONC. (Source: Federal Health IT Strategic Plan for 2015 to 2020, 12/8/14)

The American Society of Hematology (ASH) recently announced its listing of 10 evidence-based recommendations in an effort to prompt conversations between physicians and patients about the necessity of certain practices in hematology. The listing was developed as part of the “Choosing Wisely” campaign led by the American Board of Internal Medicine (ABIM) Foundation, focused on engaging physicians to encourage the appropriate use of medical procedures and tests to improve patient care and preserve finite resources. The first five items on the ASH Choosing Wisely list were released in 2013 and highlighted later that year in an [article published in Blood](#). The list was recently updated to include five additional commonly used tests, treatments, and procedures in hematology that physicians and patients should question in certain circumstances. These new practices are highlighted in another [Blood article](#) published this month, which further describes the methods used to develop the list and the evidence supporting the recommendations. In its list, ASH makes recommendations for the appropriate use of red blood cell transfusions and plasma and prothrombin complex concentrates, as well as several hematologic tests. The full list can be viewed online at [www.hematology.org/Clinicians/Guidelines-Quality/502.aspx](http://www.hematology.org/Clinicians/Guidelines-Quality/502.aspx). (Source: ASH Choosing Wisely list, 12/4/14) ♦

## REGULATORY NEWS

The Food and Drug Administration recently issued Guidance for Industry titled “[Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture](#).” The guidance is intended to provide manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture (including source plasma) with recommendations to assist in determining which reporting mechanism is appropriate for submission of a change to an approved Biologics License Application (BLA). This guidance finalizes the draft guidance of the same title dated June 2013 and supersedes the guidance titled “Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture,” dated July 2001. (Source: FDA guidance, 12/1/14)

The Food and Drug Administration announced yesterday that it has approved MP Diagnostics HTLV Blot 2.4, the first FDA-licensed supplemental test for Human T-cell Lymphotropic Virus-I/II (HTLV-I/II). The test is intended for use as an additional, more specific test for human serum or

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

plasma specimens that have previously tested positive on an FDA-licensed HTLV-I/II blood donor screening test. The MP Diagnostics HTLV Blot 2.4 is a qualitative enzyme immunoassay test intended to confirm infection with HTLV and to differentiate between HTLV-I and II. “We welcome additional well-characterized, more specific supplemental assays for counseling our donors,” said America’s Blood Centers Chief Medical Officer Louis Katz, MD. “We also recognize that such tests are the first step toward the development and implementation of reentry algorithms that allow us to expunge non-specific results from our donors’ records.” More information about the test can be found at <http://1.usa.gov/1BAU1Gf>. (Source: FDA press release, 12/11/14)

**The International Council for Commonality in Blood Banking Automation (ICCBBA) recently released the new ISBT 128 Product Description Code Database version 6.0.0.** ISBT 128 is the international standard for the identification and labeling of products of human origin. All database updates are listed in the version control sheet. The new database can now be downloaded as a Microsoft access database. ICCBBA will continue providing the original tables (i.e., Attribute, Class, and Product Description) for a period of time to allow software developers to adapt their software to the new tables of the database. The original tables can be found among the new tables. ICCBBA notes that users can be assured that although the structure of the database has changed, the product description codes themselves have not changed. The new database can be downloaded [here](#). The supporting document for the new data base is ST-010 and can be downloaded [here](#). New product description codes for medical products of human origin can be requested via their respective request forms found in the ICCBBA website (with a login). The Standard Terminology document, which provides definitions to all ISBT 128 terminology, has also been updated. The new Standard Terminology version can be accessed on the [ISBT 128 website here](#). (Source: ISBT 128 e-mail, 11/24/14) ♦

**THE WORD IN WASINGTON**

**A new bill introduced in the US House of Representatives would grant existing pharmaceutical products an additional six months of marketing if the product is used to treat or prevent a rare disease or condition.** The bill, the “Orphan Product Extensions Now Accelerating Cures and Treatments Act” (OPEN ACT) 2014, appears to be loosely modeled off a similar plan in place for pediatric products. Under Food and Drug Administration regulations for pediatric drugs, sponsors are eligible to receive an additional six months of exclusivity if they can prove their product is safe and effective in children. Under the OPEN ACT, FDA would be permitted to extend a drug’s exclusivity period by six months if a product – initially not approved as an orphan drug product – is later approved as such. Orphan drugs are those approved to treat rare conditions, defined as those affecting fewer than 200,000 people in the US. If passed into law, this legislation would be of substantial benefit to marketers of rare disease drugs.

**The House Energy and Commerce Committee’s Subcommittee on Health met on Dec. 9 to hold a hearing on healthcare fiscal priorities.** Witnesses included Mark Miller, executive director of the Medicare Payment Advisory Commission (MedPAC), who was asked about MedPAC’s recommendations for redesigning Medicare benefits and for site-neutral payment for certain hospital and physician office services, according to an AHA News Now report, from the American Hospital Association. Committee members also asked MedPAC to look at consolidation in the oncology sector and criticized the commission’s recommended changes to the Graduate Medical Education program. Other topics of discussion

(continued on page 10)

**THE WORD IN WASHINGTON** (continued from page 9)

included the slower rate of growth in Medicare spending under the Affordable Care Act, with members noting that fewer readmissions and hospital-acquired conditions and the use of accountable care organizations are reducing costs. Other witnesses included representatives from the American Action Forum, the Committee for a Responsible Budget, and the Georgetown Public Policy Institute. (Source: AHA News Now, 12/9/14) ♦

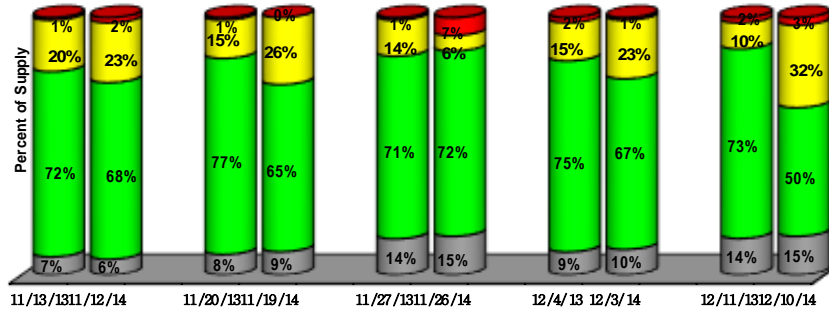
**INFECTIOUS DISEASE UPDATES****MALARIA**

The Centers for Disease Control and Prevention's [Morbidity and Mortality Weekly Report \(MMWR\)](#) published on Dec. 5 the 2012 malaria surveillance report for the US. Malaria surveillance in the US is conducted to identify episodes of local transmission and to guide recommendations for travelers. CDC received 1,687 cases of malaria with onset of symptoms in 2012, including 1,683 cases classified as imported, one laboratory-acquired case, one nosocomial case, and two cryptic cases. There were no cases caused by transfusion-transmission. The total number of cases represents a 12 percent decrease from the 1,925 cases reported in 2011. *Plasmodium falciparum*, *P. vivax*, *P. malariae*, and *P. ovale* malaria species in 58 percent, 17 percent, 3 percent, and 3 percent of cases, respectively. Despite the overall 12 percent decline in the number of cases reported in 2012 compared with 2011, the overall trend in malaria cases has been increasing since 1973. "While progress has been made in reducing the global burden of malaria, the disease remains endemic in many regions, and the use of prevention measures by travelers is still inadequate," concluded CDC. (Source: CDC MMWR, 12/5/14)

**CHIKUNGUNYA VIRUS**

The Centers for Disease Control and Prevention's Dec. 5 [Morbidity and Mortality Weekly Report \(MMWR\)](#) describes the transmission of chikungunya virus in the continental US, particularly in Florida, in 2014. Compared with other states, Florida has seen an especially large number of chikungunya fever cases. From Jan. 1 to Oct. 14, there were 272 imported cases reported in Florida, compared with 1,110 reported in the other 47 contiguous states. Since June 27, there have also been 11 locally acquired (autochthonous) chikungunya cases identified in Florida: two in Miami-Dade, four in Palm Beach, four in St. Lucie, and one in Broward. All of the locally acquired cases were laboratory-confirmed, seven by polymerase chain reaction. Among the imported cases, the most common country of exposure was Haiti, followed by the Dominican Republic. CDC notes that based upon the US experience with dengue virus, awareness of the situation in Florida can help inform surveillance activities and control efforts throughout the US. (Source: CDC MMWR, 12/5/14) ♦

**STOPLIGHT®: Status of the ABC Blood Supply, 2013 vs. 2014**



■ No Response   
 ■ Green: 3 or More Days   
 ■ Yellow: 2 Days   
 ■ Red: 1 Day or Less

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

**MEMBER NEWS**

**The Illinois Coalition of Community Blood Centers (ICCBC) recently held an event with students, faculty, and local elected officials to honor a retired high school teacher, Carol Johnson, who was awarded the Coalition’s 2014 Best High School Blood Drive Coordinator State Award. The ICCBC is a statewide association made up of nonprofit blood centers, all members of America’s Blood Centers, which seek to increase awareness of the importance of volunteer blood donation. Since 1997, Ms. Johnson has been organizing blood drives at Harlem High School in Machesney, Ill., and has been responsible for the collection of more than 2,000 units of blood. “Though there are many honors for blood donors, the volunteers who work behind the scenes organizing the blood drives are often overlooked, which is why the Illinois Coalition of Community Blood Centers launched their Blood Drive Coordinator Recognition Program,” explained Margaret Vaughn, ICCBC’s director of Government Affairs. “Since that time, Governor Pat Quinn has issued proclamations declaring July as Blood Drive Coordinator Month and the ICCBC holds an annual statewide competition in which blood centers from across the state submit nominations in various categories. Rock River Valley Blood Center nominated Carol Johnson in the Best School Blood Drive Coordinator Category.” Machesney Park Mayor Jerry Bolin attended the event to**



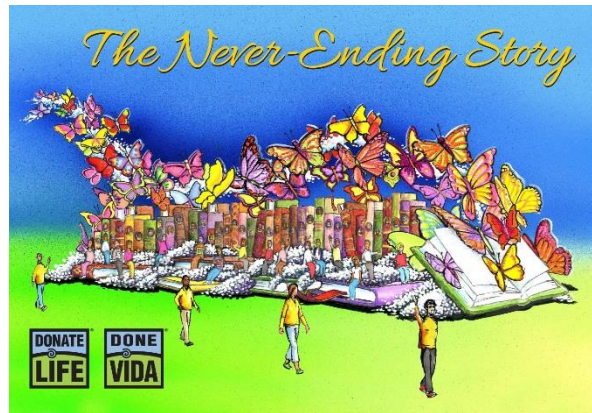
Pictured first row (left to right) Harlem High School (HHS) student KaeyIn Ghinazzi, Carol Johnson, ICCBC Government Affairs Director Margaret Vaughn. In the second row is RRVBC HS Coordinator Melinda Garrington, HHS Principal Terrell Yarbrough, Illinois State Sen. Stadelman (D-Rockford), Machesney Park Mayor Jerry Bolin, and HHS Associate Principal Jeremy Bois.

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## MEMBER NEWS (continued from page 11)

honor Ms. Johnson, who received a congratulatory certificate on behalf of the Illinois Senate from Sen. Steven Stadelman (D-Rockford). She also received a copy of House Resolution 1340 sponsored by Rep. Joe Sosnowski (R-Rockford), which was adopted by the Illinois House of Representatives last week. “Everyone at the Rock River Valley Blood Center (RRVBC) would like to applaud the tireless efforts of Carol Johnson and all of our blood drive coordinators. Mobile blood drives provide a significant amount of the community blood supply. These coordinators do most of the donor recruitment and planning. It is because of people, like Carol, that take time out of their busy schedule, that we have an adequate blood supply. More so, Carol’s efforts to cultivate lifelong donors out of the students helps to ensure that the next generation of donors will be there to step up in the future,” said Jennifer Bowman, RRVBC spokesperson. The ICCBC also recognized the following individuals with awards for their contributions to blood banking: Adam Munds of Tolono, Ill., named the 2014 Most Innovative Blood Drive Coordinator Award, and Pauline Kuebler, RN, named the 2014 Most Dedicated Blood Drive Coordinator;(Source: ICCBC press release, 12/2/14)

**BloodCenter of Wisconsin recently announced that organ donor families across the country are being invited to honor the gift of life by dedicating a rose for the 2015 Donate Life Rose Parade float to be featured in the 2015 Tournament of Roses Parade in Pasadena, Calif. On Jan. 1.** As home to the Wisconsin Donor Network and Wisconsin Tissue Bank, BloodCenter of Wisconsin hosted a rose dedication event and invited the family of Laylah Petersen, a 5-year-old Milwaukee girl who was killed on Nov. 6, 2014. Laylah’s heart valves were donated to give another child a second chance at life. Laylah’s parents, Robert Peterson and Ashley Fogl, dedicated roses in memory of Laylah along with several other family members at BloodCenter of Wisconsin’s headquarters. BloodCenter President and CEO Jackie Fredrick expressed her gratitude to the family. “Our wish for you is peace and comfort and remembrance, all your life,” she said. Jackie also dedicated a rose in honor of all local donor families whose life-saving gifts have helped countless patients. Since 2004, the Donate Life Rose Parade Float has served as a memorial to organ and tissue donors and recipients to inspire the world to save and heal those in need through the gift of life. Ms. Fogl expressed her feelings on the importance of organ donation and her daughter’s final gift in a recent [Fox6 Milwaukee news clip](#). ♦



A rendering of the Donate Life Rose Parade float.

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## COMPANY NEWS

CSL Behring announced on Dec. 1 that the Centers for Medicare and Medicaid Services (CMS) has extended the new technology add-on payment (NTAP) for Kcentra (prothrombin complex concentrate [Human]) through September 2015 for eligible Medicare beneficiaries treated in the in-patient hospital setting. Kcentra, the first and only non-activated 4-factor prothrombin complex concentrate (PCC) approved by the Food and Drug Administration for the urgent reversal of coagulation factor deficiency induced by vitamin K antagonist (e.g., warfarin) therapy in adult patients with acute major bleeding or in need of surgery or an invasive procedure. More information can be found in the [press release](#). (Source: CSL Behring press release, 12/1/14)

Baxter International reported last week that it has submitted an application to the Food and Drug Administration for the approval of a key hemophilia drug. The drug, BAX 855, is an extended-release version of its flagship hemophilia drug Advate, which is sold in many countries. The company's FDA application is based upon evidence from Baxter's late-stage controlled trial, which showcases that BAX 855 offers a safe and effective treatment option for hemophilia A patients, John Orloff, MD, vice president and global head of research and development for Baxter BioScience, told the Chicago Tribune. In August, Baxter met the primary goal of its late-stage clinical trial – to show that the drug reduces bleeding rates in patients who received the drug on a preventive basis vs. on-demand treatment. The company is recruiting patients for a late-stage clinical trial to test the drug in children ages 12 and younger, reported the Chicago Tribune (Source: Chicago Tribune, 12/1/14) ♦

## MEETINGS

Jan. 8-9, 2015 **FDA Public Workshop “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs), Bethesda, Md.**

The Food and Drug Administration will hold a public workshop Jan. 8 to 9 at the Natcher Center at the NIH Campus in Bethesda, Md. The workshop seeks to discuss the agency's proposal for a risk-based framework for addressing the regulatory oversight of a subset of *in vitro* diagnostic devices referred to as laboratory developed tests (LDTs), which are intended for clinical use and designed, manufactured, and used within a single lab. Those interested in attending must register by Dec. 12 and may do so at the [FDA website](#).

March 13 2015 **Center for Patient Safety 9<sup>th</sup> Annual Conference, St. Louis, Mo.**

The Center for Patient Safety will hold its 9<sup>th</sup> Annual Conference on March 13 at the Crowne Plaza Hotel in St. Louis, Mo. Talks will include topics like diagnostic error, reclaiming passion for a life's work in healthcare, keys to improving safety of care in the next decade, and diverse stakeholders in patient's safety. More information and registration details can be found at [www.centerforpatientsafety.org/2015conference](http://www.centerforpatientsafety.org/2015conference). ♦

## 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).

## POSITIONS AVAILABLE

**Laboratory Technologist II.** Duke University Health System, a progressive facility located in the heart of North Carolina, currently has a full-time position available for a Certified Medical Technologist on third shift in Transfusion Service. Applicants must possess a desire to become an integral member of a team providing blood products at a level I trauma center to patients in a safe, efficient manner. Strong interpersonal, written and verbal communication skills as well as the ability to solve problems are a must. Applicants must have a Baccalaureate Degree (preferably from a Clinical Lab Science program) and certification by a nationally recognized agency at the technologist level. Technologists perform complex serological testing using solid phase technology and prepare blood components for a diverse patient population. New grads welcome to apply. Relocation assistance is available. Duke University Health System offers an excellent working environment with a competitive salary and comprehensive benefits package. The Raleigh/Durham/Chapel Hill area offers broad academic, cultural and leisure opportunities. For more information, contact Mary Lee Campbell via e-mail at [mary.campbell@duke.edu](mailto:mary.campbell@duke.edu) or call (919) 668-2236. More information is available at our website at [www.hr.duke.edu](http://www.hr.duke.edu). Duke University is an equal opportunity affirmative action employer.

**Lead Blood Collection Technician/Glen Mills, PA (A job that restores hope & faith).** This is an opportunity to join a 60 year old non-profit organization with a state of the art blood collection center, and a history of investing in their valued employees. We seek a caring professional to join a team of life savers as a Lead Blood Collection Technician for their new facility located in Delaware County, PA. The Lead Blood Collection Technician is the face of the Blood Bank and sets the stage for a positive experience for the donor. Will greet donors and perform eligibility interviews, and monitors progress during the procedure. Will serve as a consultant to the staff, and assist other Blood Collection Technicians with difficult sticks and needle adjustments. Must also monitor for errors and adjust accordingly, and oversee work and donor flow. Candidates must have one of the following: RN (licensed in PA), Medical Laboratory Technician (MLT), A.S. Medical Technology (MT), or ASCP certification with four years of blood bank experience. This position offers first

class benefits including 401K, Tuition Reimbursement, Pension Plan, 100% paid dental and work life balance. For immediate consideration, please submit your resume to: [lifesaver@thebiggroup.com](mailto:lifesaver@thebiggroup.com).

**Supervisor, Blood Collection (Wilmington, DE).** Join a 60 year old non-profit organization whose mission is saving lives one stick at a time. Working out of the Wilmington site, the Supervisor is accountable for management of employees in Blood Bank Donor Services with a new facility located in Glen Mills, PA. This individual is responsible for coaching, mentoring and supporting staff to meet performance standards. He/she is responsible for managing blood collection activities and monitoring technical compliance with SOP's, FDA, and AABB regulations. Additionally he/she manages projects, assists with the development and review of SOP's, oversees the deployment of new technology and procedures. Candidates must have one of the following educational requirements: RN, Medical Laboratory Technician (MLT), B.S. Medical Technology (MT), or an active ASCP certification. Additional requirements include four plus years of blood bank experience and one year in a leadership role. Ideally candidates will have a working knowledge of apheresis techniques, equipment and supplies. This position offers first-class benefits including 401K, Tuition Reimbursement, Pension Plan, and 100 percent paid dental. For immediate consideration please submit your resume to: [lifesaver@thebiggroup.com](mailto:lifesaver@thebiggroup.com).

**Marketing and Communications Manager.** We are seeking a highly motivated, independent leader with well-developed skills in marketing and media activities, public relations, event planning and customer service strategic planning. If you are a goal driven, results oriented leader with excellent time management skills, this position may be for you. Successful candidates will possess: Ability to develop a strong networking base in California and Nevada to assist with awareness, outreach, and collaboration. Ability to serve as spokesperson for the District. Ability to create and manage a vision for the customer service component of a non-profit blood center. Exceptional skills in determining marketing needs and analyzing opportunities.

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**POSITIONS** (continued from page 14)

Bachelor's degree or equivalent combination of education and experience required. Must have three years related experience, two years supervisory experience, and a valid driver license with an acceptable driving record. Blood bank or other non-profit experience helpful. Position based out of Ventura, CA. Please mail a resume to: United Blood Services, Human Resources Department, 4119 Broad Street, Suite 100, San Luis Obispo, CA 93401. United Blood Services is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, or protected veteran status.

**Key Account Manager.** The Blood & Tissue Center of Central Texas, located in Austin, is hiring a Key Account Manager to identify, solicit, and successfully source donor sponsor groups with an employee/member base exceeding 250 and have the ability to support the BTC Blood Program. This charismatic professional must understand the value of prospecting and have an aptitude for building strong rapport with high-level business partners. Qualified candidates must have a bachelor's degree in Sales or Marketing with five to seven years of experience in corporate sales and account development or seven to 10 years of relevant work experience in lieu of a degree. Prefer some experience in the blood center environment. Strong oral and written communication skills that effectively reach all levels of personnel and business contacts needed. Must be a highly motivated self-starter with excellent organizational skills, strong interpersonal skills, and have the ability to develop and persuasively deliver presentations. Must be at least 21 years old, hold a valid driver's license, provide a copy of an acceptable driving record, and show proof of liability insurance. Applicants may send cover letter, resume, and salary requirements to [resumes@tcms.com](mailto:resumes@tcms.com). Please include position title in subject line.

**SBB Community Education Coordinator (Pomona, CA).** Are you a Medical Technologist looking to get out of the lab and need a new challenge? In this position you will plan and coordinate the Blood Transfusion Medicine/Science education programs, monitor the schedules, resources and content of the education programs. Provides support to the instructional staff in the didactic and practical phases of the SBB program, coordinate schedules of Transfusion Medicine Fellows, visiting physicians and technologists. Functions as the liaison between the State of California Department of Health Services and the American Red Cross Southern California Region for purpose of maintaining accreditation as a provider of continuing education for California Clinical Laboratory Scientists. Qualifications: MT (ASCP) or equivalent; preferably SBB, five years' experience in a hospital or blood center. California State Clinical Laboratory Scientist (or eligible). We offer

excellent benefits including health/dental/vision insurance, 401(k) and 403(B) and more. To apply visit: [www.americanredcross.apply2jobs.com](http://www.americanredcross.apply2jobs.com), position number BIO49750. EOE M/F/D/V

**Customer Relations Specialist.** Indiana Blood Center is currently seeking a Customer Relations Specialist. Under the direction of the Director, Production, the Customer Relations Specialist is responsible for assessing, recommending, and implementing plans to achieve exceptional customer relations in Blood Services in order to retain current customer base. Works with Blood Services leadership and with peers at affiliate centers to develop plans to generate growth. Is responsible for current customer relationship management and frontline pursuit of new customer prospects. Builds relationships with customers and captures VOC (voice of customer). Supports customer product and inventory needs at the point of hospital blood banks. A bachelor's degree from an accredited college or university in Clinical Laboratory Science or related field; Medical Technologist or Medical Laboratory Scientist (ASCP—American Society for Clinical Pathology) certification required. Minimum of three to five years' job related experience in blood banking/transfusion services; minimum of two years' experience in Customer Service or Customer Account management preferably in association with a blood center; experience with Customer Relationship Management tools, customer surveys and metrics for continuous validation of value delivered to customer is preferred. Valid driver's license required with acceptable driving record that meets IBC's established guidelines. Indiana Blood Center is an Equal Opportunity Employer. Please apply online at [www.indianablood.org](http://www.indianablood.org).

**Director of Donor Marketing (CTTM).** *Be a part of a dynamic and forward thinking affiliation of blood centers in this changing healthcare environment!* This key position is responsible for donor recruitment and donor event management and database marketing. We will rely on you to manage a cross-functional coordinated effort to develop and implement strategy to maximize collections across CTTM. Position is accountable for executing successful campaigns, initiatives and promotions, and understanding and differentiating between activities to increase collections. This role is key in branding and messaging to foster a customer-focused culture resulting in increased donor/sponsor loyalty and new growth through tactical efforts targeted to collection strategies. We will rely on you to evaluate donor marketing programs across CTTM, determine effectiveness of campaigns, and leveraging programs. The ideal candidate will have a bachelor's degree and a minimum of five years' experience in marketing or business development with at least five years as a cross functional project management leader. A minimum of five years

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**POSTIONS** (continued from page 15)

business to business sales experience required. Blood-Center offers a competitive salary, commission plan, and benefits package. Apply online at [www.bcw.edu](http://www.bcw.edu). Equal Opportunity Employer of Minorities, Females, Protected Veterans, and Individuals with Disabilities. ♦