AABB Conference Brings Bacterial Contamination of Platelets to Forefront, Explores Secondary Bacterial Screening Tests

Transfusion medicine experts recognize bacterial contamination of platelets as one of the most important infectious risks associated with transfusion therapy. Although the clinical implications for patients are not well understood, studies have estimated that about 1 in 3,000 to 1 in 5,000 apheresis platelet doses may actually be contaminated with bacteria despite testing negative with early culture screening.

Various blood banking and transfusion medicine professionals converged on Tuesday in Bethesda, Md., for a one-day public conference held by AABB to discuss the benefits, potential costs, and efficacy of secondary bacterial screening of platelets. Discussions primarily focused on tests deployed at the point of issue in transfusion services. Perspectives were offered from hospital physicians, blood bankers, researchers, and device manufacturers. Representatives from America’s Blood Centers and several other organizations including the American Red Cross attended, and various leaders from ABC member centers made presentations.

Bacterial contamination of platelets can cause sepsis, shock, and in some cases, death, although in other cases, the transfusion recipient is largely unaffected. As Jay Epstein, MD, director of the Food and Drug Administration’s Office of Blood Research and Review, pointed out in his introduction, the risk of bacterial contamination of platelets has decreased since 2003 when AABB implemented standard 5.1.5.1, requiring blood centers to “limit and detect” bacteria in platelets. Diverting the initial 15 to 30 mL of platelets collected and better preparation of donors’ arms has greatly improved safety, noted Dr. Epstein. However, some bacterially contaminated platelets may not be detected by culture, and the true risk of sepsis caused by platelet transfusion is unknown due to under-recognition and under-reporting.

“A residual risk of bacterial contamination still exists on the day of transfusion and is associated with septic reaction or fatality,” said Dr. Epstein. “FDA is hopeful that discussing this issue will help to clarify the technical and logistical issues with implementing point-of-issue testing of platelets ... FDA regards this meeting as an opportunity for robust dialogue to determine whether such testing should become routine as a safety standard.”

Richard Benjamin, MD, PhD, chief medical officer of the American Red Cross (ARC) – Biomedical Services, presented ARC data confirming that interventions

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As we know, aging baby boomers will create more vacancies in executive positions than easily can be filled by the next, smaller generation. For certain such talent is out there, but it gets harder to find, making good succession planning a must for boards and staff leadership. To some degree, the deluge of retirements is being delayed by executives working longer than ever. Far be it from me to say the older generation needs to move out of the way for more modern ideas and innovations, but what I see from the younger replacements is encouraging; they will remake our industry for the better.

With Bill Coenen retiring as America’s Blood Centers’ chief operations officer earlier this year, Executive Vice President Celso Bianco to be replaced by Lou Katz in September, and my impending retirement in August 2015, succession planning has been an active preoccupation within ABC. Bill is, fortunately, hanging around as our volunteer chief financial officer, a position he held for several years before joining the staff in 2006. We reassigned his other responsibilities and added more executive support.

The search for Celso’s replacement was extremely gratifying. If I had to name 10 top global docs in bloodbanking today, five of them applied, including Lou, of course.

ABC also spent more than a year exploring a “process” for replacing me. In the end, the ABC Board endorsed an approach that is gaining favor in the private sector. About 18 months before my planned leave date, the Board will hire an executive transition/change consultant. The consultant will create an inventory of the CEO’s and other executive staffs’ skill sets, as well as determine a CEO skill set needed for future challenges. The consultant then would look at senior staff, board members, past executive leadership, and others close to ABC to determine if there were any obvious CEO candidates to target. If so, the Board quietly could choose to interview and hire one of them, or it could conduct a regular search. I personally have seen such an approach carried out very successfully in replacing longtime CEOs among some major healthcare organizations in Washington, D.C.

While participating in discussions of my own replacement made me queasy at first, I now feel reassured knowing that ABC will not lose a heartbeat as the transitions continue.

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Visit Jim on Facebook: www.facebook.com/JimMacPhersonABC

P.S. 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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to reduce bacterial contamination of platelets have improved the safety of these products. For example, the rate of septic reactions to the number of platelet components issued by ARC centers fell from 1:40,000 during March 2003 to December 2003, to 1:107,000 during January 2007 to January 2011, according to passive ARC hemovigilance data. Although interventions to minimize contamination and maximize culture sensitivity may help to further reduce the risk of bacterial contamination and sepsis, Dr. Benjamin suggested that point-of-issue testing and pathogen inactivation should be considered.

Steven Kleinman, MD, senior medical adviser of AABB, compiled data from a large number of previous studies about bacterial contamination of platelets, such as the PASSPORT study, to estimate the residual risk of bacterial contamination of apheresis platelets tested by early culture. He estimated that the risk of transfusing a contaminated unit missed by culture is about 1:1,500, and since the average patient receiving platelets is exposed to six apheresis units, the per patient exposure to a contaminated unit may be 1:250. (The risk of a septic reaction appears substantially less than this.)

Louis Rossiter, PhD, a health economist from The College of William & Mary, Williamsburg, Va., described the current reimbursement milieu in hospitals. He cautioned that decisions about resource consumption needed to be made with the understanding that there are serious funding constraints and that explicit and transparent priority setting was appropriate.

Michael R. Jacobs, MD, PhD reviewed a multicenter study of the Verax Pan Genera Detection (PGD) point-of-release test used on apheresis platelets that had been tested by early culture and were released as “negative-to-date.” The study, published in Transfusion in September 2011, found that about 1 in 3,000 platelet units released as negative by culture was shown to be contaminated using the PGD test within 24 hours of issue. FDA approved the PGD test for use in whole blood derived platelets in 2007 and for apheresis platelets in 2011. Dr. Jacobs said that some future developments of PGD will include a simplified test procedure, improved sensitivity, improved range of bacteria species detected, and reduced false positive rates.

Mindy Goldman, MD, executive medical director of Canadian Blood Services, shared the Canadian and German experience with the Verax PGD test. Of greatest interest were data that suggest that the PGD test misses important gram negative organisms at levels significantly higher than indicated in the package insert approved by FDA.

During a question-and-answer session with the morning panel, ABC Executive Vice President Celso Bianco, MD, asked whether the blood community should aim to determine whether platelet components were sterile or to reduce the incidence of clinically significant events caused by contaminated platelets. “I think they’re one and the same,” responded Dr. Benjamin. “Because a bacterially contaminated unit may not affect one patient but may cause a serious reaction in another.” Dr. Kleinman seconded that sentiment adding, “If we are aiming for zero risk of clinically significant reactions, we don’t know which units will cause a reaction, so we would have to aim to reduce all bacterial contamination. The question becomes how low is low enough and how much will it cost to reach that point? If we want to drive clinical events as low as possible, then we need to do something more ... It seems to me that we should move toward pathogen reduction.”

Peter Tomasulo, MD, executive vice president of the ABC member Blood Systems, Inc. took the podium to discuss improvements that his organization made and continues to make to decrease the risk of releasing bacterially contaminated platelets to the hospitals it serves, such as constant proportion sampling.

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Conference On Bacterial Contamination of Platelets (continued from page 3)

He emphasized that many interventions can and should be made at the blood center rather than at the hospital before transfusion, to improve the safety of platelets. He also suggested that manufacturers should be exploring ways to remove bacteria from platelet components. “We should be designing the manufacture of a high quality, safe product in the blood center, rather than to test it later on and throw out bad units. We should be trying to reduce risk before getting the blood out,” he concluded.

A panel of speakers described the transfusion service perspective on point-of-issue testing. Mark Yazer, MD, associate professor at the University of Pittsburgh and medical director of the Institute for Transfusion Medicine’s Centralized Transfusion Service in Pittsburgh, presented data about Verax PGD testing performed in both Pittsburgh and at Puget Sound Blood Center in Seattle, Wash. The two transfusion services screened 70,561 non-leukoreduced whole blood platelet pools in seven months and found seven confirmed positive (bacterially contaminated) results using the PGD test. Larry Dumont, MBA, PhD, from Dartmouth discussed use of the PGD test in a smaller 355-bed hospital setting, which did not result in finding any confirmed positive bacterially contaminated units out of 3,505 units screened and discontinued its use.

Katharine A. Downes, MD, associate director of the Blood Bank/Transfusion service at the University Hospitals Case Medical Center in Cleveland, Ohio, shared her institution’s experience with the PGD test. After performing the PGD test on platelets in a research setting from September 2009 to December 2011 and in the transfusion service setting from December 2010 to December 2011, the hospital, one of the sites in the multicenter study that Dr. Jacobs described, decided to stop using the test for operational and fiscal reasons. Andrew Heaton, MD, discussed PGD testing at the North Shore University Hospital (NSUH), which was also part of the PGD study. The hospital found no confirmed positive results using the PGD test. While Dr. Heaton believes that the study shows feasibility of the test, it provided no evidence to support point-of-issue screening of all platelets. After a four-month review, the hospital decided to use the PGD test only in patients with a reaction to platelet transfusion.

After hearing the transfusion service perspective on point-of-issue screening, the audience listened to a preliminary cost analysis of implementing such a test from Louis Katz, MD, executive vice president of Medical Affairs at Mississippi Valley Regional Blood Center. Dr. Katz presented a model from a subgroup of the AABB Bacterial Contamination Task Force that estimated that testing all apheresis platelets distributed in the US would have direct costs of more than $70 million and $117,439 per true positive identified, using data from the Jacobs study. Assuming the worst case, that all true positives result in adverse outcomes such as sepsis, the group estimated that this test could lead to about $7 million in savings due to sepsis care avoided over one year. In an era of severe resource constraints in hospitals, when a decision to use resources in one area might require fewer resources in another, Dr. Katz advocated that policy decisions in this area need to be made in the broad context of competing patient safety goals in a way that would maximize patient benefit. Examples of competing priorities included hospital infection control and blood management.

The conference then allowed pre-registered speakers to participate in a period of open discussion. Andrew Levin, CEO and scientific director of Immunetics, spoke about the BacTx Rapid Test, which FDA recently approved for detecting bacterial contamination in leukocyte-reduced whole-blood derived platelet units (see ABC Newsletter, 6/15/12).

AABB President Darrell J. Triulzi, MD, concluded the conference with some closing remarks. “Our goal was to hear from blood centers, hospitals, doctors, nurses, and patients, all of whose views are valid and

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important. I think our goal of listening and hearing relevant information in the field was well accomplished. At this point, it is time to go back, digest this information, and decide what, if any, regulatory or policy changes are needed. It is clear that today’s meeting has brought this issue to the forefront.”

American Red Cross Partners with ABC in Seeking Clarity on Medical Device Tax

The American Red Cross (ARC) last week sent the Internal Revenue Service a letter supporting comments that America’s Blood Centers (ABC) filed with the agency in May seeking to clarify which items purchased by blood centers should be subject to a 2.3 percent medical device excise tax that takes effect in 2013.

The July 9 letter, signed by J. Chris Hrouda, executive vice president of Biomedical Services at ARC, was submitted in response to a Notice of Proposed Rulemaking (NPRM) issued by Treasury and the Internal Revenue Service earlier this year on implementation of the excise tax. ABC’s comments in part question whether many of the items sold to blood centers are or should be considered taxable medical devices.

The ARC, the nation’s largest blood collecting organization, asks Treasury/IRS “to take these requests [submitted by ABC] under serious consideration.”

- Specify that all products licensed by the Center for Biologics Evaluation and Research (CBER) are not to be treated as medical devices. As licensed biologics are not defined as medical devices, this clarification will help reduce the risk of an excise tax being imposed on the manufacturers of biologics.

- Exclude combination products and kits when a majority of the cost is attributable to products not considered medical devices or impose a tax only on the portion that is by definition a medical device. This not only ensures that nonmedical devices are excluded from the tax, but it also prevents double taxation – taxed as a single entity and again taxed when combined.

- Clarify that certain medical devices used by the blood industry are not taxable as they are not “intended for humans.” Devices used to manufacture blood products more closely resemble products used to produce and manufacture drugs and biologics, not medical devices related to patient care.

The tax was enacted as part of the Patient Protection and Affordable Care Act (ACA), the constitutionality of which was upheld last month by the US Supreme Court. The tax is levied on the manufacturers, producers, or importers of medical devices and is expected to bring in an estimated $29 billion in revenue over 10 years. The revenue is intended to help offset the costs of expanding Medicaid under the ACA by up to 30 million more beneficiaries. While blood centers are not being taxed directly, there is little doubt, given the history of other excise taxes, that they and other medical device consumers eventually will bear the financial brunt of the tax.

The IRS NPRM seeks comments that will, among other things, further clarify which products and categories of products should or should not be taxed as medical devices. The agency is expected to publish final comments sometime in the fourth quarter of 2012.

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ARC Partners With ABC On Medical Device Tax (continued from page 5)

ABC believes that few, if any, blood center supplies or devices fall under the strict definition of medical device. Blood center supplies are used in a non-medical setting for the manufacture of blood products. The manufacturing umbrella includes the collection, processing, testing, labeling and distribution of blood products, which are then used in a medical setting. The devices themselves are not intended for humans to diagnose or treat diseases, which are among the criteria for determining if an item is a taxable medical device.

With the assistance of Group Services for America’s Blood Centers, ABC has estimated that the tax could add $2 to the cost of each blood collection. One type of item licensed by CBER that ABC and ARC argue should not be taxed are the reagents that blood centers regularly purchase for use in tandem with blood testing assays to detect infectious diseases. The annual cost of reagents to independent blood centers is approximately $385 million annually, or as much as $770 million annually if ARC (and hospital-based blood collectors) purchases are included. That works out to an added cost to the blood industry of about $36 million per year, if companies passed along the cost of the tax directly to blood centers.

On June 22, ABC representatives met with officials from the ARC at its headquarters in Washington, D.C. Present from the ARC were Neal Denton, senior vice president of Government Relations and Strategic Partnerships; Craig B. Mendelsohn, MD, vice president and deputy general counsel; David C. Damon, executive director of Finance; and Dawn P. Latham, senior policy advisor of Congressional Relations. Pending approval from ARC leadership, ARC and ABC officials at the meeting tentatively agreed to work together to minimize the impact of the tax on blood centers.

“We thank the Red Cross for its gracious consideration of our position and for sending this letter in support of our comments,” said Jim MacPherson, CEO of ABC. “This is a great milestone for the blood community. By partnering with ABC on this initiative, the Red Cross shows that two groups of people who often act as competitors can still work together for the common good of patients and blood centers everywhere. We offer our gratitude and willingness to continue this partnership so that blood centers are treated fairly in the eyes of the law.”

ABC comments to the IRS can be accessed on its website at http://members.americasblood.org/go.cfm?do=FileCenter.Get&fid=3705

– Robert Kapler, rkapler@americasblood.org

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**Breaking News: Bonfils Blood Center Responds to Colorado Shooting**

A gunman wearing a mask set off an unknown gas and fired into a crowded movie theater in suburban Denver, Colo., at the midnight opening of the Batman movie on Thursday evening, killing 12 people and injuring at least 50 others, reported the Associated Press. At present time for the ABC Newsletter, Blood Centers of America (BCA) had been in touch with ABC member Bonfils Blood Center, which worked diligently throughout the night to meet the immediate needs of hospitals treating the shooting victims. At present time, Bonfils Blood Center has been able to meet these needs. BCA will continue to assess the situation and will correspond with ABC members if assistance is needed.
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Central Jersey Blood Center Appoints Pascal George New CEO

Central Jersey Blood Center, headquartered in Shrewsbury, N.J., welcomed Pascal George, MBA, to its staff on July 16 as the center’s new CEO. Mr. George comes to the center with an extensive background in healthcare administration, finance, and management, and brings with him more than 20 years of experience in all blood banking operations. Mr. George replaces Michael Clark who resigned from this position in January.

Born in France, Mr. George completed his graduate studies in business administration and spent a few years as a human resources manager in France before moving to the US. He obtained a Masters of Business Administration from the University of Pennsylvania’s Wharton School of Business and quickly reached an executive position at the SUNY Health Science Center at Brooklyn, N.Y. He went on to potentiate a financial turn-around as the vice president of operations for Interfaith Medical Center, a distressed community hospital.

Changing industries, Mr. George then led the emerging services division of New York Blood Center (NYBC), later moving on to lead regional operations. He then took over chief operating officer responsibilities to reorganize the operations of Progenitor Cell Therapy, then a start-up cell therapy laboratory. He was brought back to NYBC to plan and implement the coalescing of multiple departments into a new Medical Programs division, and to organize the relocation and modernization of the largest public cord blood bank in the world. Mr. George was later asked to take full operational responsibility for a $300-million business.

Throughout his career, Mr. George developed processes to engage executives to work better together, handle change, and improve business results, said the release. He has demonstrated success in areas such as operations management, business development, Board and government relations, community outreach, and labor relations, according to the press release. Mr. George plans to streamline Central Jersey Blood Center’s operations, reinforce the motivation of staff, and improve the value of the center’s services in the midst of major transformations in blood banking.

“We are most pleased that Mr. George has joined us, based on his experience in the industry, his general business knowledge, and the obvious enthusiasm with which he has taken on the position. We anticipate greater involvement and increased awareness in the community under Mr. George’s leadership,” said Central Jersey Blood Center’s Board Chairman Don J. Summa. (Source: Central Jersey Blood Center press release, 7/16/12)

HCV Infectivity Study in Chimps Offers Insight Into Efficacy of HCV Screening

Researchers recently published results of a study investigating hepatitis C virus (HCV) infectivity in chimpanzees transfused with plasma collected from humans in the nucleic acid test (NAT) window period, before HCV RNA was detectable using Food and Drug Administration-licensed assays. This study offers a better understanding of how effective nucleic acid testing (NAT) for HCV is and how to calculate more accurate residual risk estimates of acquiring HCV through a transfusion.

The study was conducted by Michael P. Busch, MD, PhD, of Blood Systems Research Institute; Khrishna K. Murthy from Texas Biomedical Research Institute; Harvey J. Alter, MD, from the National Institutes

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HCV Infectivity in Chimps (continued from page 7)

of Health and colleagues. The results were published in the June 28 issue of Blood. Among other findings, this study showed that large-volume plasma transfusions can transmit HCV infection before RNA detection by currently licensed donor screening assays, but the interval of infectivity before RNA detection appears to be very brief.

Background. At least 130 million people worldwide have persistent HCV infection, which can cause chronic liver disease, cirrhosis, hepatocellular carcinoma, and extrahepatic diseases. Serologic and NAT screening tests have dramatically reduced the transmission of HCV through blood and blood products, although further minimizing this very low risk remains an important goal for the blood community.

The researchers of the current study describe the interval between HCV infection and the development of high-level viremia. There is an eclipse period, lasting days to several weeks, during which HCV RNA is not detectable in the blood by current assays, although the virus has likely established a foothold in susceptible cells. Occasionally during the eclipse period, “blips” of HCV RNA, representing very low levels of viremia, may occur. The eclipse phase is followed by an exponential increase in HCV RNA, called the “ramp-up” period, during which time RNA levels become readily detectable by qualitative and quantitative NAT testing.

Methods. The researchers sought to determine whether HCV can be transmitted during this eclipse period, as well as the risk that the blips of HCV RNA may pose in transfusion-transmission of HCV by experimentally testing the infectivity of serially collected plasma donations from source plasma donors recently infected with HCV. First, the researchers evaluated infectivity from donations initially assessed as occurring immediately before the onset of the ramp-up phase viremia. Next, they evaluated infectivity of non-viremic and low-level HCV RNA-positive (blip) donations from donors who demonstrated intermittent HCV RNA detection in the eclipse phase of HCV infection.

Serial plasma aliquots (50 mL) obtained from 10 commercial donors who converted from HCV RNA negative to positive were transfused into two chimpanzees to assess infectivity during early HCV infection. The investigators were able to trace the donor sources of infection in the recipient animal because the donors were infected with disparate HCV strains.

Results. Plasma obtained four days before HCV RNA was detected by licensed assays transmitted HCV infection to chimpanzee X355. Additional testing of this infectious PCR-negative plasma generated positive results in two of 23 replicates using a sensitive transcription-mediated (TMA) assay, and was estimated to contain 60 copies/50mL transfused. Plasma units obtained up to eight weeks earlier were not infectious in a second susceptible chimp, even when receiving transfusion of plasma from donors with low-level, intermittent HCV RNA detection.

Chimp X355 developed acute viremia with subsequent seroconversion, but cleared both virus and antibodies in 17 weeks. When re-challenged 38 months later with 6,000 RNA copies/mL from the same donor, X355 was transiently re-infected and again lost all HCV markers.

Conclusions. The authors conclude that while transfusions can transmit HCV infection, during the eclipse period, before RNA detection, the interval of test-negative infectivity is very brief. The data also suggested that the early blips of HCV RNA appear non-infectious and can be ignored when calculating residual transfusion risk. An accompanying editorial in Blood explains that “perhaps during early infection, the ratio of susceptible cells to the number of functional HCV virions is so high that HCV readily

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spreads from cell to cell without much spilling over into the blood; thus, the small amount of HCV RNA observed in the blood at this stage may represent defective, noninfectious particles.”

The researchers also found, as was evident in one of the chimps, that markers of HCV infection can be rapidly lost after exposure to low-dose inocula, suggesting that more HCV infections occur than are currently documented. The editorial authors note that this finding underscores the challenges of HCV vaccine development. “New strategies to test HCV vaccines are urgently needed as ethical restrictions limit the use of chimpanzees in medical research,” they write.

Citation: Busch MP, et al. Infectivity in chimpanzees (Pan troglodytes) of plasma collected before HCV RNA detectability by FDA-licensed assays: implications for transfusion safety and HCV infection outcomes. Blood. 2012 June 28; 119(26): 6326-34.

See You in September

I know that most of us across the country are trying to beat the heat – I know I can’t help but dream about the crisp, cool autumn days to come. Actually, I’m sure many of us would settle for temperatures below 90 degrees for just a few consecutive days … However, what I am really looking forward to this fall is the Unity Gala that we are hosting with the Sickle Cell Disease Association of America (SCDAA) on Sept. 27 in Baltimore!

The gala is shaping up to be lots of fun and an event not to be missed. This will be the 40th gala for the SCDAA, and they have assured us that they know how to throw a party! And in the two events I have been to with America’s Blood Centers and the FABC, we’re not too bad ourselves at putting on a good time.

The Unity Gala is taking place in the beautiful Baltimore Marriott Waterfront Hotel, situated by the Inner Harbor with great views of the Harbor and the city of Baltimore.

There is a reason for Baltimore’s nickname – the Charm City. Home to a bustling waterfront scene, great restaurants, two exciting sports teams, and lots of American History (it is of course, the birthplace of the Star Spangled Banner), Baltimore has a lot to offer – so why not make a weekend out of it? I mean, how many mini-vacations have you had a chance to take where you can experience a wonderful big city with a small-city charm AND help save lives by funding research for a cure for sickle cell disease and keeping a safe and plentiful blood supply?

In all seriousness, if you are remotely connected to blood banking, you need to attend this event. I know we are often inundated with story after story of the many reasons that people need blood each and every day, and every single one of those stories is important. However, I think we in the blood community have all been especially touched by sickle cell disease. Sickle cell patients are born with an abnormality that makes their blood cells misshapen, causing many of them to endure a lifetime, too often a shortened one, of pain, aided only by frequent transfusions.

The bottom line is – their lives depend on us to keep fighting for a cure and to not only guarantee that blood is available for the inevitable moment when they have a crisis and need a transfusion, but also to continue building our rare donor programs and diversify our donors. Such programs ensure that our blood centers are able to meet the special transfusion needs of these patients to help them live fulfilling healthy lives. Yes, it is a sobering thought and a heavy topic, but we can also have some fun while supporting these worthy causes! We’ll see you in September.

To sponsor the gala, or purchase tickets or tables, please visit www.annualgala.com or contact Jodi Zand at 202.654.2994 or jzand@americasblood.org

Jodi Zand is the Foundation for America’s Blood Centers’ director of Fund Development. You can reach her at jzand@americasblood.org.
Register for the Unity Gala: The Premiere Charity Event For Sickle Cell Disease

Tickets and sponsorship opportunities are now available online for the Unity Gala, hosted by the Sickle Cell Disease Association of America (SCDAA) and the Foundation for America’s Blood Centers (FABC), set to take place in Baltimore, Md.’s lively Inner Harbor on Thursday, Sept. 27. The event will support the life-saving work that the FABC and the SCDAA do to help sickle cell disease patients and their families.

Any individual or organization involved in sickle cell disease, blood donation, or research in these fields is encouraged to attend this event, as it is the premiere annual event to support sickle cell disease. The gala will offer attendees the opportunity to mingle with executives from blood centers, pharmaceutical companies, hospitals, and research institutions related to blood donation and sickle cell disease, making this an ideal venue for vendors and other sponsors looking to reach out to the blood banking and sickle cell communities.

The FABC funds initiatives of America’s Blood Centers’ members that help to improve the availability, quality, and safety of the blood supply. The SCDAA works to advocate for and enhance its membership’s ability to improve the quality of health, life, and services for individuals and families affected by sickle cell disease, while promoting the search for a cure. Because sickle cell disease patients require frequent blood transfusions, the partnership is a natural fit for the two organizations.

Sickle cell disease is hereditary and is caused by an abnormal type of hemoglobin that can make red blood cells assume crescent shapes and become more “sticky.” The misshapen red blood cells then get stuck in small blood vessels and interrupt blood flow, causing organ and tissue damage, pain, stroke, and sometimes death. Frequent blood transfusion is the most common therapy for these patients. And since sickle cell disease primarily affects people of African descent, blood from African American donors is normally the safest and best matched blood for sickle cell patients.

The gala will not only promote programs that recruit minority donors and people with rare blood types to treat patients currently struggling with sickle cell disease, it also celebrates the SCDAA’s 40th year of fighting for a more permanent cure for this disease. For those who want to learn more about sickle cell disease, SCDAA will offer attendees the opportunity to register for and attend the SCDAA 40th Annual Convention, held from Sept. 25 to 29.

More information about the gala is available at [www.annualgala.com](http://www.annualgala.com), and details about sponsorship opportunities can be found at [www.thefabc.org/gala/unitygala_sponsorships.php](http://www.thefabc.org/gala/unitygala_sponsorships.php). To get involved with the gala, contact Jodi Zand at (202) 654-2994 or jzand@americasblood.org or Wyndsi Curtis at (410) 528-1555 or scdaa@sicklecelldisease.org.
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“As a subsidiary of ABC member South Texas Blood and Tissue Center, QualTex Laboratories understands the mission of community blood centers and the challenges facing us in this tough economic environment. For that reason, we are proud to co-host the first ABC Supply Chain Management Workshop with GSABC. We look forward to a very valuable meeting and hope this new workshop joins the roster of ABC specialty workshops to help member blood centers improve the service to their communities.”

- Linda Myers, President/COO, QualTex Laboratories
BRIEFLY NOTED

*Transfusion Medicine Reviews* published online on May 24 a summary of the National Heart, Lung, and Blood Institute’s (NHLBI) Retrovirus Epidemiology Donor Studies’ (REDS) findings, specifically REDS-II results. This summary was authored by the researchers involved in REDS, led by Steven Kleinman, MD. The REDS program was created in 1989 as a response to the emerging HIV/AIDS epidemic. REDS-II, initiated 10 years later, approached infections and non-infectious problems such as transfusion-related acute lung injury that could affect the US and international blood supply. REDS conducted from 1989 to 2001, and the REDS-II, conducted from 2004 to 2012, were NHLBI-funded, multicenter programs focused on improving blood safety and availability in the US, wrote the authors. REDS-II also included international study sites in Brazil and China. The three major research domains of REDS/REDS-II have been infectious disease evaluation, blood donation availability, and blood donor characterization. Both programs have made significant contributions to transfusion medicine research methodology with mathematical modeling, large-scale donor surveys, innovative methods of repository sample storage, and establishing an infrastructure that responded to potential emerging blood safety threats. Blood safety studies have evaluated epidemiologic and/or laboratory aspects of human immunodeficiency virus, human T-lymphotropic virus 1/2, hepatitis C virus, hepatitis B virus, West Nile virus, cytomegalovirus, human herpesvirus 8, parvovirus B19, malaria, Creutzfeldt-Jakob disease, influenza, and *Trypanosoma cruzi* infections. Other analyses have characterized blood donor demographics, motivations to donate, factors influencing donor return, behavioral risk factors, donors’ perception of the blood donation screening process, and aspects of donor deferral. In REDS-II, two large-scale blood donor protocols examined iron deficiency in donors and the prevalence of leukocyte antibodies. This review describes the major study results from more than 150 peer-reviewed articles published by these two REDS programs. In 2011, a new seven-year program, the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III), was launched. REDS-III expands beyond donor-based research to include studies of blood transfusion recipients in the hospital setting and adds a third country, South Africa, to its international program (see *ABC Newsletter*, 8/26/11). The abstract of this summary is available at [www.tmreviews.com/article/S0887-7963(12)00025-9/abstract](http://www.tmreviews.com/article/S0887-7963(12)00025-9/abstract).

**Citation:** Kleinman S, *et al.* *Trasfus. Med Rev.* 2012 May 24. [Epub ahead of print].

The risk of disease transmission through organ and tissue transplantation is difficult to quantify because no standards exist for donor evaluation, including epidemiological screening, and because of the changing characteristics of pathogens and complications related to recipient surveillance, according to a workshop summary published this month in *Emerging Infectious Diseases*. The summary was compiled by Melissa A. Greenwald, MD, of the Food and Drug Administration; Matthew J. Kuehnert, MD, of the Centers for Disease Control and Prevention; and Jay A. Fishman, MD, of Massachusetts General Hospital and Harvard Medical School, both in Boston. The paper summarizes the issues emerging from a May 2010 workshop titled “Emerging Infectious Diseases: Evaluation to Implementation for Transfusion and Transplantation Safety.” The goal of the workshop participants was to develop “a research agenda to characterize the risk for transmission of donor-derived infections and inform the development of guidelines for emerging infectious diseases.” Disease transmission by organs and tissue appears to be rare. Based on limited data, one estimate puts the incidence of recognized infectious disease transmission in organ recipients at approximately one percent. Risks to recipients have been identified primarily through published descriptions of clusters of allograft recipients with infections, such as those caused by lymphocytic choriomeningitis or rabies virus, or events associated with blood products. Donor screening is complicated by “potential organ and tissue donors residing in or migrating between geographic regions where different organisms are endemic,” the authors note. The paper points out that the changing geographic distribution of West Nile virus, chikungunya virus, dengue virus, and babesia have led to “clusters of infections.

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transmitted to organ recipients in regions where the pathogens are not endemic.” Challenges in evaluating donors include the variability in performance between tests and laboratories, an absence of post-transplant active surveillance and reporting, and coordinating and sharing aggregated donor screening and testing data. Immediate clinical needs include optimizing assays and information sharing practices between suppliers and clinical centers. Key research needs include development of reliable baseline data for the number and types of tissue grafts distributed each year, improved seroprevalence data for potential donors, better data on the transmissibility of potential pathogens by type of organ and tissue, and better data on the effect of tissue processing on decreasing or eliminating infectious organisms. The team concludes that “Gaps in systematic identification and characterization of the scope and magnitude of donor-derived infectious disease transmissions through organ and tissue transplantation remain a major hurdle to improvements in assessing risk and in developing more effective donor screening and testing strategies. These gaps can be addressed by a shared, overarching research agenda among the allograft communities.”


REGULATORY NEWS

The Food and Drug Administration has approved the first over-the-counter test for HIV that uses a saliva specimen and provides results directly to the user. The agency’s approval of the OraQuick In-Home HIV Test, manufactured by OraSure Technologies, comes on the heels of a positive recommendation in May by the Blood Products Advisory Committee (BPAC), which voted 17-0 to recommend approval of the OraQuick test, finding that the test is safe and effective and that the benefits outweigh the potential risks (see ABC Newsletter, 5/18/12). About 2.8 million people are expected to use the test annually, an FDA reviewer estimated. FDA projects that the test would result in 45,000 new positive test results and could prevent more than 4,000 HIV transmissions a year. To use the OraQuick test, a person swabs his or her upper and lower gums, then inserts the swab into a vial of test fluid. If the user has HIV, two colored lines appear on the test strip after 20 to 40 minutes. The information booklet in the package states that an OraQuick HIV support center can be contacted 24 hours a day, 7 days a week for counseling on the test results and it offers referrals for medical services. “Knowing your status is an important factor in the effort to prevent the spread of HIV,” said Karen Midthun, MD, director of the FDA’s Center for Biologics Evaluation and Research, in a statement. “The availability of a home-use HIV test kit provides another option for individuals to get tested so that they can seek medical care, if appropriate.” Results of a clinical trial of the OraSure test showed that 106 previously undiagnosed people infected with HIV were identified out of 5,558 individuals who used the product, according to OraSure. The sensitivity of the test is 92.98 percent (95 percent confidence interval, 86.6 to 96.9 percent). The specificity of the test is 99.98 percent (95 percent confidence interval 99.9 to 100 percent). However, in OraSure’s clinical trials, eight individuals out of 5,558 received a false negative result. OraQuick, then, could lead to 3,800 false negative tests in people who wouldn't otherwise be tested, the FDA reviewer said. The test can be expected to deliver one false positive test for every 3,750 true negative results, or approximately 1,100 false positive test results per year. BPAC members didn’t think the potential issues raised by inaccurate results warranted not approving the test. They especially hoped OraQuick will be used by high-risk people who wouldn't otherwise get tested. OraSure said that 41 percent of those who used OraQuick in its clinical trial had never been tested for HIV previously. Of those who learned they were HIV-positive from the OraQuick test, 96 percent said they would likely follow up with a doctor or clinic for treatment options, the company said. (Sources: MedPage Today, 5/16/12; 7/3/12)
REGULATORY NEWS (continued from page 13)

The Food and Drug Administration recently issued a letter approving Baxter Healthcare Corporation’s supplement to its biologics license application for Immune Globulin Infusion (Gammagard Liquid), for maintenance therapy to improve muscle strength and disability in adult patients with multifocal motor neuropathy. The Office of Blood Research and Review of FDA’s Center for Biologics Evaluation and Research issued the letter on June 22. The review of this product was associated with National Clinical Trial number NCT 00666263, said the letter. The letter is available at http://1.usa.gov/LAsWcI. (Source: CBER approval letter, 6/22/12)

GLOBAL NEWS

The Australian Red Cross Blood Service announced in a press release last month that it is relocating part of its Adelaide manufacturing operations to Melbourne. Preparations for the move will take several months, with the majority of the work being completed in October 2012. Blood collection and distribution in South Australia will continue as usual, and there will be no changes to blood supplies for Adelaide patients and hospitals. The blood service has made a significant investment in South Australia in recent years and will be making several changes. It is opening a new $4 million dollar donor center in Regent Arcade in Adelaide this month. Australian Red Cross Blood Service recently opened a new $2 million blood donor center in Marion, Australia. “South Australian blood donors are a vital part of the nation’s blood supply and we are confident that our donors continue to support the blood service,” said Australian Red Cross Blood Service Chief Executive Jennifer Williams. The move will significantly reduce the business cost of processing and testing blood for patient use, said the release. (Source: Australian Red Cross Blood Service press release, 6/28/12)
INFECTIOUS DISEASE UPDATES

BABESIOSIS

The Centers for Disease Control and Prevention published in last week’s Morbidity and Mortality Weekly Report (MMWR) the results of surveillance for babesiosis in 18 states in 2011. Babesiosis is a tick-borne disease spread by the parasite Babesia microti, which infects red blood cells. The disease can cause fever, flu-like symptoms, and hemolytic anemia, although others infected with the parasite remain asymptomatic. In recent years, reports of tick-borne and transfusion-associated cases have increased, however lack of a common case definition has hindered public health authorities from adequately monitoring the disease’s spread. In January 2011, national surveillance for babesiosis began in 19 jurisdictions (18 states and one city) using a standard case definition developed jointly by the CDC and the Council of State and Territorial Epidemiologists. The CDC MMWR summarizes the 2011 surveillance results. State health departments notify CDC of babesiosis cases through the National Notifiable Diseases Surveillance System using the standard case definition, which is combined with data collected by state health departments, as babesiosis has been a notifiable disease in some states for several years. In 2011, CDC was notified of 1,124 cases of babesiosis: 847 were classified as confirmed cases and 277 as probable cases. Supplemental data were provided for 797 (71 percent) of the 1,124 cases. The median age of patients was 62 years; 63 percent were male and 34 percent were female, with 3 percent not reporting sex. Among the 583 cases with data on race/ethnicity, the majority of cases were reported among non-Hispanic whites than people of any other ethnicity. The 1,124 cases occurred in residents of 15 of the 18 states, with 1,092 being reported by the seven Babesia microti-endemic states: Connecticut, Massachusetts, Minnesota, New Jersey, New York, Rhode Island, and Wisconsin. The state in which exposure occurred (as opposed to the state that reported the incident) was available for 202 patients, 192 of whom became infected in their own state of residence. Of the 295 patients for whom data were available, 156 (53 percent) recalled a tick bite in the eight weeks before symptom onset. Ten cases of babesiosis in transfusion recipients were classified by the reporting health departments as transfusion-associated, and two blood donors were reported. Each of the two blood donors was linked to one recipient; linked donors were not reported for eight of the 10 cases. Four other patients received blood transfusions before symptom onset, but whether these cases were transfusion-associated is unknown. One reported case was attributed to congenital transmission. Tick-borne and transfusion-associated cases of babesiosis occur in multiple parts of the US, including outside of areas in known endemicity, writes CDC. “Ongoing national surveillance using the standard case definition will provide a foundation for developing evidence-based prevention and control measures to reduce the burden of babesiosis,” CDC concludes. The full report is available at www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a2.htm. (Source: CDC Morbidity and Mortality Weekly Report, 7/13/12)

ARBOVIRUSES

The Centers for Disease Control and Prevention last week released statistics for US arboviral disease cases in 2011, showing that while West Nile virus (WNV) remained the most prevalent cause of arboviral outbreaks in the nation, La Cross virus (LACV) was the most common cause of arboviral disease among children. The findings were reported in CDC’s July 13 issue of Morbidity and Mortality Weekly Report (MMWR). In 2011, CDC’s ArboNet passive surveillance system received reports of 871 cases of arboviral diseases (among those that require national notification), excluding dengue. Of the total, there were 712 cases of WNV, 130 cases of LACV, 16 cases of Powassan virus (POWV), six cases of St. Louis encephalitis virus (SLEV), four cases of Eastern equine encephalitis virus (EEEV), and three cases of Jamestown Canyon virus (JCV). About 72 percent were classified as neuroinvasive diseases, for a national incidence of 0.20 per 100,000 population. Michigan reported the

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INFECTIOUS DISEASE UPDATES (continued from page 15)

The greatest number of WNV cases (32), followed by New York (28), Illinois (22), and Florida (20). Of the 130 LACV cases reported by 14 states, 89 percent were considered neuroinvasive. Among patients, the median age was 8 years (range: 3 months to 84 years), and 123 patients (95 percent) were aged 18 years or younger. LACV neuroinvasive disease incidence was highest in West Virginia, Ohio and North Carolina. In an editorial note, MMWR points out that EEEV disease is rare but lethal, resulting in three deaths among four patients. The national incidence of WNV neuroinvasive disease was 0.16 per 100,000 population last year, generally consistent with incidence rates during the 2008 to 2010 period, in which a mean of 0.20 was reported. However, the number of LACV neuroinvasive disease cases increased by 73 percent from 2010 to 2011. And more POWV cases were reported in 2011 than in any previous year, and included the first case reported from Pennsylvania. Wisconsin, meanwhile, reported its first EEEV cases since 1984. In addition to the nationally notifiable arboviral diseases, two other arboviral diseases were reported to CDC: two cases of Colorado tick fever and one case of Cache Valley virus disease. (Source: Morbidity and Mortality Weekly Report, 7/13/12)

MEMBER NEWS

BloodCenter of Wisconsin research, featured in the June issue of Nature Medicine, may help protect against radiation toxicity, reported the center in a press release on July 6. The research shows that boosting a certain type of protein in the body’s blood making system may protect otherwise fatal radiation poisoning. This discovery could have a profound impact on the treatment of patients who have undergone radiation therapy or those who’ve sustained radiation injuries from emergency situations, said the release. The findings open the potential for new treatments against radiation toxicity following radiation therapy for cancer treatments, or from a nuclear disaster. The Blood Research Institute study was led by senior investigator Hartmut Weiler, PhD, whose work is supported by the Blood Research Institute Foundation. “We found that this pathway also helps blood stem cells in the bone marrow to recover faster from the injury caused by radiation exposure,” said Dr. Weiler. “We were also able to show that pharmacologic boosting of this pathway with either of two engineered proteins, recombinant soluble thrombomodulin or recombinant activated protein C, can be used in mice to actually prevent death caused by exposure to lethal doses of radiation.” Of particular interest was the finding that activated protein C reduced death over a 30-day period following radiation even when it was given beginning as late as 24 hours after radiation exposure. This finding is important given the challenge of delivering a drug to victims of a mass disaster in a timely manner. The researchers caution that their study involves laboratory research in mice and it remains to be determined how the findings may translate to human treatment. The report in Nature Medicine integrates previously independent lines of research by multiple, collaborating groups. This research was supported in-part by a National Institutes of Health grant awarded to Dr. Weiler, in response to a congressional mandate for discovery and development of radiation countermeasures. The study abstract is available at www.nature.com/nm/journal/v18/n7/full/nm.2813.html. (Source: BCW press release, 7/6/12)

Blood Bank of Alaska (BBA) teamed up with the US Coast Guard to hold a blood drive in honor of Seaman (SN) Shawn Debenport and to pay tribute to all the donors that aided in saving his life, according to a recent news release. SN Debenport suffers from thrombotic thrombocytopenic purpura-hemolytic uremic syndrome, a rare blood disorder. “If it wasn’t for them, he wouldn’t be here,” said Karrie Debenport, the mother of SN Debenport. BBA reached out to the community and mobilized 400 blood

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MEMBER NEWS (continued from page 16)

donors through both phone calls and e-mails to ensure a steady supply of plasma for SN Debenport. “The turnout of donors to help was tremendous,” said BBA’s Director of Operations Roy Allen. “It is during times like this that shows that Alaskans are really special.”

STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

Total ABC Red Cell Inventory

Percent of Regional Inventory at 2 Days Supply or Less, July 18, 2012

Daily Updates are available at: www.AmericasBlood.org

PEOPLE

Betsy Jett has joined The Food and Drug Administration’s Office of Blood Research and Review (OBRR) as the deputy associate director for Regulatory Affairs. She will be involved in the managed review process, while participating in biovigilance and other blood-related, scientific, and regulatory issues, according to FDA. Prior to assuming this role, Betsy served at the National Institutes of Health in the following positions: chief operations officer for the Clinical Center Department of Transfusion Medicine (DTM); senior quality systems officer (DTM); and technical supervisor for the Transfusion Transmitted Diseases Laboratory. (Source: E-mail from OBRR, 7/11/12)

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Kim Parker, president of the National Employers Association of America and executive vice president of the California Employers Association, was recently featured in Comstock’s Business Magazine. In this issue, she provides helpful tips and information for employers regarding human resources and employee relations. Ms. Parker is a nationally recognized speaker who gave a talk at America’s Blood Centers’ 50th Annual Meeting in March on the importance of collaborating and sharing information and best practices within a competitive environment.

Yasuko Erickson, MD, was recently named vice president of medical affairs at Mississippi Valley Regional Blood Center (MVRBC), announced the center in a press release on July 13. A pathologist who serves on the faculty of University of Iowa’s Roy and Lucille Carver College of Medicine, Dr. Erickson will begin her duties at MVRBC in September. Dr. Erickson takes this position as Dr. Katz leaves MVRBC after 30 years of service to assume the role of executive vice president of America’s Blood Centers. Dr. Erickson earned her medical degree at the University of Utah School of Medicine before coming to the University of Iowa Hospitals and Clinics (UIHC) where she completed her residency in pathology and her fellowship in blood banking and transfusion medicine. She has worked closely with Thomas Raife, MD, medical director of UIHC’s DeGowin Blood Center. “Dr. Erickson’s dedication to patient care, medical education, and the well-being of everyone working at UIHC is beyond all expectation,” said Dr. Raife. “She will be sorely missed, but she will thrive wherever she has the opportunity to improve transfusion medicine.” Dr. Erickson will join MVRBC’s medical affairs team, and her responsibilities will include medical affairs policy, donor management, and oversight of the infectious disease testing lab. “I am very excited to have this opportunity,” said Dr. Erickson. “I’m eager to work with new colleagues at MVRBC and to make a positive contribution to the organization.” In welcoming his replacement to MVRBC, Dr. Katz said, “I cannot think of a better person to join the MVRBC medical and scientific program than Dr. Erickson. Unlike me, she has actually trained in the discipline of transfusion medicine. She will bring a personality, interests, and skill sets to the center that can only mean continued improvement in our ability to provide our staff, donors, hospitals, physicians, communities, and, ultimately, our patients with the level of service they expect and deserve.” (Source: MVRBC press release, 7/13/12)

William Block was recently named as Blood Centers of America’s (BCA) new president and CEO, effective as of July 30, the organization announced in a press release on Monday. Mr. Block succeeds Charlie Mosher, who will retire at the end of 2012 after 23 years of leadership at BCA. Mr. Block brings more than 20 years of healthcare related experience to the position, including his most recent leadership roles at Instrumed International, Inc., Schaumburg, Ill., a surgical instrumentation and medical device company. “The membership of BCA is delighted to have Bill join us as our leader for the future,” said BCA Board Chair Jackie Fredrick. “In an era of revolutionary change in healthcare, Bill brings a unique set of expertise, including leading a medical device business, as well as skills related to supply chain and distribution and serving integrated healthcare systems. He will bring an expanded vision to an already highly successful BCA organization, taking us in new directions.” Over the course of his business career, Mr. Block has worked with hospitals to support customer requirements and improving efficiencies. He has also worked closely with group purchasing organizations and has extensive supply chain experience in the medical industry. “I believe that blood centers are facing significant pressure from their hospital customers in how they can help the hospital use blood more efficiently,” said Mr. Block. “I will help the BCA members respond to this pressure with services – and potentially new offerings – to allow the BCA members to continue to grow in a changing market.” As BCA president and CEO, Mr. Block noted that

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his key priorities will be to build upon the success of the BCA cooperative and drive efficiencies with the supplier community through strategic partnering, as well as understanding the capabilities that BCA offers in the cell therapy marketplace and build a business plan to support it. He also plans to explore business development opportunities that will benefit the BCA membership. “We look to Bill to tap into BCA’s culture and relationships and use these to help the membership adjust to and succeed in the changing healthcare landscape we will be facing during the next few years,” said Mr. Mosher. Mr. Block holds a bachelor’s degree in economics from Wake Forest University. He was a US Army ROTC Scholarship recipient and a Distinguished Military Graduate. (Source: BCA press release, 7/16/12)

Robert Van Tuyle, chief financial officer (CFO) of BloodSource, was recently named 2012 CFO of the Year in the nonprofit category by the Sacramento Business Journal. The 2012 CFO of the Year Awards special publication of the magazine was released on July 13, and an awards breakfast was held on that day at the Sheraton Grande Sacramento in California. Mr. Van Tuyle joined BloodSource as CFO in 2010, and, in the article, says that his philosophy changed a bit after becoming part of an organization with the mission of saving lives. He specifically recalls the day that he met an 11-year-old boy with leukemia who was at BloodSource to meet his stem cell donors. “Let’s just say that the philosophy that guides me day in and day out changed a bit that day,” said Mr. Van Tuyle. “The financials are important, but now it’s as a means to fulfill the mission of helping patients and saving lives.” Previously, Mr. Van Tuyle worked for a number of technology and semiconductor companies, raising venture capital, managing investments, and juggling debt. Mr. Van Tuyle goes on to discuss how important it is for blood centers to remain viable, as well as some of the challenges involved in leading the financials of a blood center. The article discusses some of the achievements that Mr. Van Tuyle has led the blood center to accomplish, such as dramatically cutting debt as the center worked to rebound from the economic recession that began hitting blood centers and other healthcare facilities around 2008. Mr. Van Tuyle has also offered his IT skills to BloodSource, said the article. “He has helped us focus on a lot of the IT things we do. A lot of our other CFOs didn’t have that background, through no fault of their own. But it makes a huge difference,” said BloodSource CEO Mike Fuller. Some new initiatives at BloodSource include allowing blood donors to book donation appointments online and to track their own wellness using tests performed on their donated blood. BloodSource is also introducing a rewards program which allows donors to earn points that can be applied in various ways. “At all my organizations, I’ve always had IT report up through me,” Mr. Van Tuyle said. “It is such a large area of investment. Although technically I may not have the breadth and depth of a lot of IT professionals, I do think I can be an advocate.” The full article is available through a subscription at http://bit.ly/OMpSpG. (Source: Sacramento Business Journal, 7/13/12)

Correction: EBA Executive Elections

In last week’s ABC Newsletter (7/13/12), we published a brief article on page 19 about the European Blood Alliance’s (EBA) election for the Executive Board in the “People” section containing a minor error. We mistakenly said that Lynda Hamlyn, chief executive of UK’s NHS Blood and Transplant, was re-elected to the Executive Board. She was actually elected to fill the vacancy of Alex Aquilina, MD, of Malta, an at-large member of the Board who chose not to run for reelection. We apologize for this error and thank the readers who bring such issues to our attention.
POSITIONS AVAILABLE:

Medical Technologist – Reference Laboratory – full-time. Community Blood Services collects blood donations, and also offers cord blood banking and bone marrow registration and donations, serving the community's transfusion medicine needs. For more than 50 years, we have built healthy, lasting relationships not only with our donors but with our team of highly skilled and dedicated employees as well. If you share our passion for helping the residents of our community, then we invite you to consider joining our team! This position is responsible for performing all Reference Laboratory Procedures which requires a thorough understanding of immunohematology and the principles and properties of red cell antigens and antibodies, including problem solving abilities. A reference laboratory technologist will provide consultation to hospital clients and may be involved in training staff. Education/Experience: Bachelor’s Degree (B.S.) from a four-year college or university; BS in medical technology preferred. One to two years related experience and/or training; or equivalent combination of education and experience. Minimum of two years experience in blood bank including skill in antibody identification procedures is mandatory. MT (ASCP) certification, BB or SBB or eligible preferred. Knowledge or experience in flow cytometry preferred. F/T day shift, some weekends and on call. Interested and qualified applicants please click [link] to apply online.

Director of Donor Recruitment. BloodCenter of Wisconsin is seeking a Director of Donor Recruitment who is responsible for oversight of the Donor Recruitment team (Call Center, Donor Recruitment and Marrow Recruitment) and for achieving sales growth in line with business plans. This position is accountable for working closely with the VP of Marketing and the Director, Donor Services to foster a customer focused culture resulting in increased donor/ sponsor loyalty and new growth. Successful candidates will have demonstrated success in developing and implementing strategic and tactical plans to achieve business objectives. The position requires a minimum of 10 years of senior marketing or business development experience with at least five years as a cross functional project management leader. Seven to 10 years of business to business sales AND business to business sales management experience (preferably industry experience) is also required. A bachelor’s degree in a relevant field is required and an advanced business degree (MBA) is preferred. Please apply online at [link] to apply online.

Medical Director. Seeking a Medical Director for our Arizona Region. This position will be based out of our Tucson, AZ facility. The position will primarily be responsible for Arizona but will assist with coverage for Utah, Idaho, Montana, Nevada, Oregon, and Washington. This position will be responsible for medical coverage of the regional blood center, including a reference laboratory and an active Clinical Services program with therapeutic apheresis and peripheral blood stem cell collections. You will coordinate medical communications between the blood services region, the local and national medical community, and ARC National Headquarters; support the goals and objectives of the organization by providing accurate and timely medical and technical consultation in transfusion medicine to all operational areas of the region and as appropriate to its customers; and promote Red Cross products to the regional medical community. Apply online at [link] to apply online.

Chief Medical Officer. Puget Sound Blood Center is seeking a Chief Medical Officer responsible for providing the overall medical direction and support for all PSBC activities. The Chief Medical Officer serves as the medical division policy decision maker. Licensure as a physician and certification in Blood Banking/Transfusion Medicine or in another, relevant specialty with appropriate experience required. Ability to obtain appointment in the University of Washington School of Medicine at the associate or full professor level required. Interested candidates are encouraged to apply for Chief and/or Transfusion Medicine Physicians, as appropriate. Direct letter of application, curriculum vitae, and names of three references to James P. AuBuchon, MD, President & CEO, Puget Sound Blood Center, 921 Terry Avenue, Seattle, WA 98104. Salary will be commensurate with qualifications and experience. Puget Sound Blood Center and University of Washington are proud to be an Affirmative Action / Equal Opportunity Employers. More info at [link]. University of Washington faculty engage in teaching, research, and service. In order to be

POSITIONS (continued on page 21)
eligibility for University sponsorship for an H-1B visa, graduates of non-U.S. medical schools must show successful completion of all three steps of the U.S. Medical Licensing Exam (USMLE), or equivalent as determined by the Secretary of Health and Human Services.

Transfusion Medicine Physicians (2 positions). Transfusion Medicine Physicians at Puget Sound Blood Center, provide direct medical input and patient care as well as medical/administrative coordination in the delivery of specific transfusion medicine programs. The Physician will be designated to collaborate with director(s) of program(s) to ensure the medical appropriateness of services rendered; there would be particular interest in candidates with experience in therapeutic apheresis, blood components collection, patient blood management, and/or general transfusion medicine support. At least five years’ experience preferred. Appointment in the University of Washington School of Medicine available for interested and qualified candidates. Direct letter of application, curriculum vitae, and names of three references to James P. AuBuchon, MD, President & CEO, Puget Sound Blood Center, 921 Terry Avenue, Seattle, WA 98104. Salary will be commensurate with qualifications and experience. Applications accepted until the position is filled. Puget Sound Blood Center and UW are Equal Opportunity Employers. UW faculty engage in teaching, research, and service. In order to be eligible for University sponsorship for an H-1B visa, graduates of non-U.S. medical schools must show successful completion of the U.S. Medical Licensing Exam (USMLE), or equivalent as determined by the Secretary of Health and Human Services.

Chief Quality Assurance & Regulatory Affairs Officer. Puget Sound Blood Center is seeking a Chief Quality Assurance & Regulatory Affairs Officer to join our executive team, reporting to the CEO and responsible for the Quality System governing the collection and distribution of blood and tissue products, laboratory testing services and occupational health. Areas of expertise would include regulatory requirements, quality control mechanisms, records management, document control, and implementing organization wide quality initiatives. Requirements: Bachelor’s degree with 10 years of progressive experience managing QA functions and regulatory compliance in blood banking, healthcare, or pharmaceutical field. A master’s degree is preferred. In-depth knowledge of current GMP for Biologics, Devices and Drugs; experience interacting with the FDA, administering the HIPAA Privacy Rule and minimum five years’ experience directing a team with diverse roles. Proven success in project management, excellent communication skills must be demonstrated. Send application materials to HumanResources@psbc.org or fax to (866) 286-8495. More information at www.psbc.org.

Phlebotomy Instructor. Kentucky Blood Center, located in Lexington, Ky., is seeking a dynamic professional to teach new Blood Collections staff according to KBC Standard Operating Procedures and current FDA and AABB standards. The Phlebotomy Instructor will assess, design, and provide continuing education for current employees; write lesson plans; coordinate and document training and retraining; and work with management to ensure training needs are met. Requires an advanced degree (MT, CLS, or RN preferred) and phlebotomy experience; classroom teaching experience with knowledge of adult learning principles; strong written and verbal communication, organizational, and time management skills; a do-what-it-takes work ethic; and a team player attitude. Competitive salary, comprehensive benefits including health/dental/life, LTD, paid sick/vacations/holidays, EAP, 403(b) retirement savings plan, and pension plan. For more information or to apply online, please visit www.kybloodcenter.org/. Drug-free and EOE/AAP

Regional Director. LifeSouth Community Blood Centers is seeking an enthusiastic and results-oriented professional to join our team as a Regional Director in Mobile, AL. This position directly supervises the Regional Manager and Donor Services Manager and is responsible for: Overseeing the daily operations of the region to ensure that the daily and long-range commitments of the blood bank are met. Overseeing blood collection, donor recruitment, component production, blood labeling, and blood distribution for all branches in the region. Other responsibilities include: Ensuring the region meets established recruitment goals. Reviewing monthly and quarterly QC reports for each hub. Establishing and maintaining positive relationships with local hospitals. Ensuring that the region operates within its budget. Bachelor’s degree required. Minimum of four years of relevant management experience required. Strong verbal and communication skills required and ability to prepare concise and informative reports. Knowledge of modern principles and practices of administration and organization, including general budgeting, accounting, and personnel techniques and management principles and practices. This is a full-time position. Salary range $60,000 - $64,000. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Please click on the link to apply: https://home.eease.adp.com/recruit/?id=1648091.

Donor Services Manager. LifeSouth Community Blood Centers is seeking a confident and task-focused professional for the Donor Services Manager position in Mobile, AL. This position is responsible for managing the collection operation for whole blood and automated mobile operations to ensure the achievement of annual goals in the most efficient and cost-effective manner. Other responsibilities include: Monitor regional
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projections and planning to ensure that the collection goals for the region are met or exceeded. Motivate and educate Donor Services staff members, including establishing and maintaining a positive team morale and fostering operational cooperation within the district and region. Planning, organizing, managing, and directing all aspects of whole blood, apheresis, and automated collection operations (fixed site or mobile) to ensure appropriate staffing and a smooth, efficient process. BA or BS in related field or equivalent combination of education and experience required; nursing qualification strongly preferred. Minimum of three years of supervisory or management experience required. Operational flexibility is required to meet sudden and unpredictable needs. This is a full-time position. Salary range $45,000 - $50,000. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Please click on the link to apply: https://home.eease.adp.com/recruit/?id=1650821.

Medical Technologist or Medical Laboratory Technician. Performs ABO/CMV testing, all general lab procedures including work in components, blood inventory and the blood releasing section of the Laboratory. Must possess an understanding and working comprehension of the scientific, technical, and procedural aspects of laboratory testing, general comprehension of immunologic and genetic factors that affect health and disease. Must have a practical understanding of quality control and be able to perform simple instrument maintenance. Must be able to report test results, quote ranges and specimen requirements. All tests and procedures are performed with the highest standard of professional performance and in accordance with established standards of ethic and medical technology. Has an appreciation of the roles of paramedical and other health related fields, keeping the benefit of the donor, patient, physician and community in mind. Please visit our website at www.bbb.org for more information. Relocation costs are not included.

Lab Technician #568 and #575/Laboratory Technician #569 and #576. Inland Northwest Blood Center, located in the beautiful Pacific Northwest, is seeking two full-time Laboratory Technicians or Laboratory Technologists to join our committed team of professionals in performing serologic investigations and routine/emergency immunohematology. Experience in laboratory work/blood banking desirable; ability to lift up to 25 pounds frequently/up to 50 pounds occasionally; and Laboratory Technician: *MLT(ASCP) or equivalent training and licensure; Laboratory Technologist: Bachelor of Science degree and certification as *MT(ASCP) or equivalent; Current students of an accredited program who will obtain licensure within six months may also apply. Positions #568 & #569 are scheduled evenings (3:00 – 11:30 pm). Complete position descriptions available upon request.

Medical Technologist – Immunohematology. The Community Blood Center (Kansas City) provides blood for the majority of the hospitals in the region and is home to one of 56 AABB certified Immunohematology Reference Labs worldwide. The staff provides consultation to area hospitals, resolution of complex serological problems, and supplies antigen-negative blood or other special units for transfusion recipients. The lab performs a variety of serologic procedures, and molecular phenotyping. Our career ladder allows individuals to continue to grow in their knowledge base and contribution to our lab. The Community Blood Center employs seven SBB’s who teach and mentor our new employees. Requirements: BS degree in medical technology or related field, registered MT(ASCP), CLS, or BB(ASCP); SBB preferred. Education assistance and tuition reimbursement is available to obtain SBB certification. Two to five years laboratory experience; blood bank experience preferred. Skills and Knowledge: advanced problem-solving, good oral and written communication, detail oriented, excellent customer service and time management. Hours during training are 8:30-5:00 Monday-Friday with periodic weekends and will take approximately six months. After the training is complete, the hours will change to meet business needs and will involve some weekends. Applicants must apply online at www.savealifenow.org. EOE M/F/D/V

Chief Operating Officer. Blood Centers of the Pacific located in San Francisco is seeking a highly skilled and experienced Chief Operating Officer to head our Operations department consisting of Donor Collections, Donor Recruitment, Hospital Services, and Technical Operations. Will manage the day-to-day activities of the blood centers and be responsible for the development of a structured planning process to coordinate and ensure our products are produced in a quality fashion to meet customer needs. Will oversee an effective management team to meet organization goals and manage the preparation of departmental budgets and financial aspects of blood center operations. Requires relevant four-year degree and five years experience as a senior manager responsible for personnel management and general operations oversight in blood banking or biomedical/pharmaceutical manufacturing. Equivalencies may be considered. Submit resume to BCP Human Resources – Job Code: COO fax (415) 749-6620 or email: resumes@bloodcenters.org EOE/AA

Manager Donor Recruitment. Indiana Blood Center located in Indianapolis, Ind., seeks an experienced pro-

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fessional with three or more years of successful people management in a sales environment with proven sales accomplishments. The manager provides direct support and supervision to the representatives in the field and at fixed sites and manages the daily operations of all field and Donor Center donor recruitment. This person is responsible for establishing individual recruitment collection goals for his/her team members and assures that these goals are obtained in assigned regional territories.

The manager is also responsible for all fixed site and field recruitment activities including planning and follow-up of mobile blood drives. Requirements: bachelor’s degree in marketing, sales, or a related field required. Valid driver’s license, acceptable driving record and reliable transportation required. Must be proficient in all Microsoft Office products. Please apply online at www.indianablood.org.