



# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: [www.americasblood.org](http://www.americasblood.org)

2013 #37

October 11, 2013

**INSIDE:**

- Our Space: The Government May be Shutdown, but we Still Need You .....2
- Studies Offer New Insights for Preventing Transfusion-Transmitted CMV .....4
- ABC Webinar to Explore E-Learning Authoring Tools .....6
- Sponsorship Opportunities for 2014 ABC, FABC Meetings Now Available6
- ABC Webinar to Discuss Bacterial Detection .....6
- RESEARCH IN BRIEF ....7
- Blue Platelet Special: The S-Word .....8
- BRIEFLY NOTED .....9
- REGULATORY NEWS....9
- GLOBAL NEWS .....10
- INFECTIOUS DISEASE UPDATES .....10
- STOPLIGHT®: Status of America's Blood Centers' Blood Supply12
- MEMBER NEWS.....12
- PEOPLE .....13
- MEETINGS .....15
- POSITIONS AVAILABLE .....15

**Please Note:** The *ABC Newsletter* will not be published next week, Oct. 18, because ABC staff will be attending the AABB Annual Meeting in Denver, Colo. The next issue will be published on Oct. 25.

**Survey: Most Americans Oppose Federal Agency Making Cost-Effectiveness Evaluations for Medical Treatments**

As numerous federal agencies and healthcare providers attempt to stifle rising healthcare spending, many countries have turned to cost-effectiveness research (CER) to evaluate whether certain medical treatments or tests should be implemented. However, CER is often a point of political controversy in the US and the results of a recent survey suggest that Americans will not be throwing their support behind a government agency focused on health-related CER assessments any time soon.

Agencies in the UK, Italy, Germany, and Australia conduct CER to judge the clinical benefits and costs of new treatments relative to the current standards of care and set explicit thresholds to justify paying for new treatments. A group of researchers, led by Michael D. Botta, PhD, of the Harvard School of Medicine, conducted a nationwide public survey to determine public opinion in the US on government use of CER and on specific decisions driven by CER using real-world scenarios. Their results were published online Oct. 7 in *JAMA Internal Medicine* (previously the *Archives of Internal Medicine*).

The authors surveyed 1,017 adults ages 18 and older, measuring their support for a government CER agency and support for each of the four CER-driven decision scenarios. They found that most of the overall study population – 56 percent – opposed a government CER agency. Democrats and Independents were about evenly split, while a significantly smaller percentage of Republicans said they would support such an agency (27 percent). Younger respondents, ages 18 to 29, were significantly more likely to support an agency than respondents 63 years and older. Respondents did not support CER-driven decision making within any of the four specific healthcare scenarios. Partisan affiliations did not appear to drive public opinion regarding the scenarios.

“This study should offer a warning to the research community that, despite the cost-saving potential of CER, it is likely to engender widespread opposition when put into practice in the US – particularly if decisions are widely known by the public,” concluded the authors. “Growing healthcare spending will require smarter choices on the part of healthcare payers and consumers. This research suggests

(continued on page 3)



## OUR SPACE

FABC Director of Fund Development Jodi Zand

### The Government May be Shutdown, but we Still Need You

As the partial government shutdown closes in on the end of its second week, and the world nervously turns its attention to the possible default of the US Treasury, there is a rather somber attitude in Washington D.C. and all over the country. Many are experiencing the “trickle-down effect” of the shutdown. It really hit me when I visited the Starbucks by the ABC office at 8 a.m. the other day. Normally, this particular branch tends to have a line out the door of caffeine junkies getting their fix, especially during the morning, but I was the only customer in the whole café that morning. The baristas confirmed it has been like that all week.

Although I’m pretty sure Starbucks will survive a few weeks or more of the furlough, in times of economic uncertainty, the most vulnerable are often the ones hit the hardest. Patients, who need blood for a variety of reasons, either once or on a regular basis, such as those with bleeding disorders, do not get a furlough. Parents with children who have hemophilia do not get furloughed from the constant worry that their kids playing in a soccer game or schoolyard playground could be one fall or injury away from a devastating consequence. Blood centers do not get furloughed from ensuring a safe and adequate supply is available for all who need it, even though a lack of people working often leads to a lack of people donating blood. And our industry most definitely cannot shut down the quest to continue to find new innovations and procedures to keep up with the ever-changing ebb and flow of demand for blood and specialized blood products.

Times like this certainly take the “fun” out of fundraising. Charitable donations often come to a grinding halt during a recession. However, The Foundation for America’s Blood Centers remains more committed than ever to ensuring that we continue to award grants that enable our member blood centers to continue leading the way to new heights in transfusion medicine.

This is why we need your support more than ever. As most of you know by now, our partner this year for our annual gala is the World Federation of Hemophilia USA. The commitment and passion I have seen from the folks at WFH USA to their constituents is paralleled only by the commitment and passion our blood centers have for serving all patients who need blood. But we cannot continue this mission without your help. I encourage all of you who are able, to attend or sponsor this event on Nov. 14 at the Biltmore Hotel in Phoenix, Ariz. I know times are tough, and the future is uncertain, but we cannot afford to shut down on the patients and their families who count on both ABC Members and the WFH USA. Not when they need us the most.

For details about attending or sponsoring the annual gala, please visit [www.annualgala.com](http://www.annualgala.com) or contact Jodi Zand at [jzand@americasblood.org](mailto:jzand@americasblood.org).

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

The ABC Newsletter (ISSN #1092-0412) is published 46 times a year by America’s Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2013 by America’s Blood Centers. Reproduction of the ABC Newsletter is forbidden unless permission is granted by the publisher. (ABC members need not obtain prior permission if proper credit is given.)

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

#### America’s Blood Centers

President: Dave Green

Interim Chief Executive Officer: William M. Coenen

ABC Publications Editor: Betty Klinck

Business Manager: Leslie Norwood

**Annual Subscription Rate: \$390**

Send subscription queries to

[mnorwood@americasblood.org](mailto:mnorwood@americasblood.org).

America’s Blood Centers

725 15th St. NW, Suite 700, Washington, DC 20005

Phone: (202) 393-5725

Send news tips to [newsletter@americasblood.org](mailto:newsletter@americasblood.org).

Cost-Effectiveness Research (continued from page 1)

that the public will not support the federal government making those decisions for them.”

While these results are discouraging, they do not come as a surprise, said Brian Custer, PhD, MPH, an associate investigator at Blood Systems Research Institute (BSRI), who often conducts CER related to blood safety interventions.

“I think that many in the general public have nowhere near the subject matter expertise necessary to be comfortable with the questions CER studies seek to answer. The primary premise of CER is that budgets are limited and so tough decisions have to be made because we cannot afford to implement all possible interventions.” While most Americans are acutely aware of tight budgets, “the connection does not exist between the presence of limited budgets and an understanding of how CER can contribute to decision-making that seeks to achieve the greatest health benefit with available resources.”

**CER in Blood Safety.** Blood bankers in the US often pride themselves on having one of the safest blood supplies in the world. But what about achieving the safest blood supply possible, while best using the available resources? Regulators in the blood community have generally shied away from CER assessments, sometimes mandating expensive blood safety interventions, such as screening tests or donor deferrals, despite the extreme rarity of finding a donor with the given infectious agent or yielding very minimal benefits for transfused patients. Screening for human T-lymphotropic virus (HTLV), Trypanosoma Cruzi (*T. Cruzi*), and syphilis are a few examples of such interventions.

“CER in blood safety is an important component of evidence-based policy making. It has not driven decisions, but it has contributed to better use of resources through, for example, selective testing for *T. Cruzi* and seasonal, triggered, individual donation nucleic acid testing for West Nile virus,” said Dr. Custer.

As blood bankers continue experiencing a decreased demand for blood products and thus operating on limited budgets, CER may become even more vital in helping decide which interventions yield a high enough blood safety benefit to merit their implementation. “I would argue that this is exactly the time we need more, rather than less, CER in blood safety,” said Dr. Custer. “The most value for our money can only be achieved by the use of CER and the blood community needs to be willing to objectively include CER in its decision-making, whether public opinion and regulators are comfortable with its use or not.”

The *JAMA Internal Medicine* article can be previewed or purchased at <http://bit.ly/1hC9uaF>.

**Citation:** Botta MD, *et al.* Cost-effectiveness decision making and US public opinion. 2013 Oct. 7. [Epub ahead of print] ♦

### 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.

## Studies Offer New Insights for Preventing Transfusion-Transmitted CMV

Two studies and an editorial published this month in *Transfusion* suggest approaches to preventing transfusion-transmitted cytomegalovirus (TT-CMV). The findings suggest that blood products from CMV-positive donors who have very recently seroconverted are most likely to contain CMV DNA detected by polymerase chain reaction (PCR) testing, a likely indicator of infectious virus. Study results also support previous findings that leukoreduction does not significantly diminish plasma viral DNA.

Malte Ziemann, MD, and colleagues of the University Hospital of Schleswig-Holstein in Germany, tested whole blood samples from 22,904 donations for antibodies and CMV DNA to help determine the optimal transfusion strategy for at-risk patients. Yasumi Furui, MD, and colleagues of the Japanese Red Cross assessed CMV prevalence with both antibody testing and PCR in the Japanese population by analyzing 2,400 samples of whole blood collected from 12 groups of Japanese blood donors.

Most people infected with CMV remain asymptomatic, but it causes morbidity and mortality in immunocompromised patients. Typically, blood products are either leukoreduced, undergo serologic screening for CMV-specific immunoglobulin G (IgG), or both to reduce TT-CMV risk for at risk patients, however some breakthrough cases of TT-CMV occur despite these interventions.

Ziemann and colleagues performed CMV serology and nucleic acid testing (NAT) on samples from approximately 23,000 whole blood donations. Ten samples were reproducibly positive for DNA and were categorized as donations from either 1) seronegative (window period) donors, 2) newly seropositive donors (IgM positive), or 3) long-term seropositive (remotely infected) donors.

“One of the most significant findings was that plasma CMV DNA was found most often and at highest levels in group 2, the donors who had very recently seroconverted,” write John D. Roback, MD, PHD, and Cassandra D. Josephson, MD, of Emory University School of Medicine, in an accompanying editorial. “Although they did not perform viral cultures, other studies suggest that this time of peak viral DNA is associated with infectious virus in the plasma.”

In contrast, they found that window period (infected but seronegative) donors and those with latent CMV infection (seropositive for IgG only) rarely had detectable plasma CMV DNA, and only at very low levels. “Thus, even seronegative donors in the window period of CMV infection may present a low risk of transmitting CMV,” wrote the editorialists. “Furthermore, the results also support the use of leukoreduced blood from remotely infected donors since their incidence of viremia from CMV reactivation is comparable to, or less than, window period-seronegative donors.” The researchers’ findings offer a novel approach to providing CMV-safe transfusions – providing leukoreduced units from donors who seroconverted at least one year earlier.

In the other CMV study, Furui and colleagues determined changes in seroprevalence and DNA positivity during different decades of life. They measured CMV-specific IgM and IgG in 2,400 samples of whole blood collected from 12 groups of blood donors categorized by sex and age at 10-year intervals from their teens into 60s. They also tested for CMV DNA.

On average, 77 percent of donors in this study were seropositive, including nearly 100 percent of those over age 60. The researchers found CMV DNA most frequently in those older than 60 (including plasma fraction) and, consistent with Ziemann *et al*, also found that the highest CMV DNA prevalence was in donors who were IgM positive (recently infected). Units from donations with CMV DNA in plasma, as

(continued on page 5)

TT-CMV (continued from page 4)

expected, still had detectable CMV DNA after leukoreduction, confirming other study findings that leukoreduction does not significantly diminish plasma viral DNA (or, likely, plasma virus).

“Taken together, the data from these articles improve our understanding of the advantages and drawbacks of various strategies to prevent white blood cell-associated infections,” wrote Drs. Roback and Josephson. They explore several TT-CMV prevention methods, noting that while combining serology and NAT testing with leukoreduction “has the potential to completely eliminate the risk of CMV transmission ... it yields a relatively small donor pool.” They add that a better tradeoff would be combining leukoreduction with NAT. They suggest considering pathogen inactivation as it “may turn out to be logistically simpler and less expensive.”

These TT-CMV risk-reduction strategies do not consider the impact of widespread monitoring of patients at risk for clinically significant CMV infection using sensitive CMV antigen or CMV PCR assays, and providing preemptive treatment in the event of infection, regardless of its source – from person-to-person transmission, transplanted tissue and cells, or transfused blood products. This might be more cost-effective than additional measures aimed solely at transfusion transmission of the virus.

**Citation:** Furui Y, *et al.* Cytomegalovirus (CMV) seroprevalence in Japanese blood donors and high detection frequency of CMV DNA in elderly donors. *Transfusion*. 2013 Oct;53:2190-2197.

Ziemann M, *et al.* The impact of cytomegalovirus DNA on transfusion strategies for at-risk patients. *Transfusion*. 2013 Oct;53:2183-2189.

Roback JD, Josephson CD. New Insights for preventing transfusion-transmitted cytomegalovirus and other white blood cell-associated viral infections. *Transfusion*. 2013 Oct;45:2112-2116. ♦



# SAVE THE DATE

## America's Blood Centers' 52nd Annual Meeting

March 22-25\*, 2014 – Palm Springs, CA  
Omni Rancho Las Palmas Resort & Spa

### 2014 Annual Meeting Schedule

- Saturday, March 22: FABC Links for Life Golf Tournament  
GSABC Member/Vendor Reception  
Hospitality/Networking
- Sunday, March 23: Scientific, Medical and Technical Forum  
ABC Members Meeting  
Reception co-hosted by LifeStream and  
Blood Systems  
Hospitality/Networking
- Monday, March 24: Blood Center Leadership Forum  
ABC 17th Annual Awards of Excellence  
Banquet  
Hospitality/Networking

\*March 25 meetings are by additional invitation only.

“The ABC Annual Meeting offers us the chance to discuss emerging issues in our field, exchange ideas and celebrate the excellent work of the membership throughout the year. The greater the attendance – the greater the value to all involved. Your engagement in ABC matters!”

– Dave Green, MSA  
ABC President

### Registration Fees

ABC Annual Meeting: \$725  
Non-members (non-vendor), contact Lori Beaston at [lbeaston@americasblood.org](mailto:lbeaston@americasblood.org) for invitation and registration fees and information.

Sponsorship opportunities available.  
Contact Abbey Nunes at [anunes@americasblood.org](mailto:anunes@americasblood.org) for details.



Palm Springs International Airport (PSP) is served by most major airlines. Additional nearby airport options include: Los Angeles International Airport (LAX) - 140 miles; Ontario Airport (ONT) - 80 miles; and John Wayne Airport, Orange County (SNA) - 110 miles.



America's Blood Centers®  
It's About *Life*.

## 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. ♦*

### **ABC Webinar to Explore E-Learning Authoring Tools**

America's Blood Centers' Employee Training and Development Committee will hold a two-part webinar series titled "E-Learning Smack Down: Finding a Winner in Authoring Tool Contenders." Part 1 of the series will be held on Oct. 24 at 2:30 p.m. ET.

During the first part of the series, speakers will discuss two available authoring software products in use at their centers and lessons learned in the selection process. In the second part of the series, set for Nov. 14 at 2 p.m. ET, speakers will present e-learning programs created at their blood centers.

ABC members can find information about accessing the webinar in MCN 13-130 at <http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=4539>. More details about Part 2 will be available in the next few weeks.

### **Sponsorship Opportunities for 2014 ABC, FABC Meetings Now Available**

America's Blood Centers and the Foundation for America's Blood Centers (FABC) recently released information about sponsorship opportunities for ABC's 2014 meetings and specialty workshops, as well as FABC events. Sponsoring an ABC or FABC event offers vendors and other organizations the opportunity to network with key decision makers in blood banking and transfusion medicine.

The 2014 sponsorship document provides information about upcoming ABC meetings, specialty workshops, and FABC events with details about the various sponsorship levels available for these events and benefits of each level. This sponsorship opportunity information can be accessed at [www.americasblood.org/get-involved/sponsorship-opportunities.aspx](http://www.americasblood.org/get-involved/sponsorship-opportunities.aspx).

### **ABC Webinar to Discuss Bacterial Detection**

America's Blood Centers' Technical/Lab Director's Committee will hold a webinar titled "Bacterial Detection – the Current State of Affairs" on Nov. 7 at 3 p.m. ET. The webinar will discuss current blood center practices regarding bacterial detection in platelet components, as well as point-of-care testing for bacterial contamination of platelets.

AABB's 27<sup>th</sup> Edition of *Standards for Blood Banks and Transfusion Services*, which went into effect on May 1, 2011, increased the requirement for bacterial detection in platelet components to either be conducted with a method approved by the Food and Drug Administration or one validated to provide equivalent sensitivity. AABB performed a survey last year to assess the impact of this standard. The survey had over an 80 percent response rate from blood centers, providing an excellent snapshot of the industry's approach to complying with the enhanced requirements.

This webinar will review the results of that survey, as well as provide an assessment of the current risks for bacterial contamination in platelet components. The webinar will conclude with a discussion of point-

(continued on page 7)

**INSIDE ABC** (continued from page 6)

of-care testing for platelet detection. Attendees will hear from some of the leaders in the field of bacterial detection in platelet components and will have the opportunity to ask them questions.

More information and webinar login details can be viewed in MCN 13-133 at <http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=4544>. ♦

**RESEARCH IN BRIEF**

This month, *Transfusion* published a special themed issue of the journal titled “Thirty Years of Progress Since the Recognition of Transfusion-Associated AIDS.” This edition marks the first-ever themed issue of *Transfusion*, write Michael Busch, MD, PhD, and Paul M. Ness, MD, in an editorial introducing the issue. “It is appropriate that this first themed issue of *Transfusion* is focused on the enormous impact that transfusion AIDS (HIV) and hepatitis (HBV and HCV) have had on diverse aspects of the blood transfusion community,” they write. This issue includes several commentaries written by regulatory and patient advocacy experts who describe the beginning of the AIDS/blood epidemic and the changes in blood safety that have evolved over the last 30 years. This issue also explores transfusion-transmitted emerging infectious diseases, describing some of the proactive monitoring, evaluation, and response to known and emerging infectious disease threats to the blood supply. This issue is available to subscribers or for purchase at <http://bit.ly/1g02E3j>.

**Citation:** Busch, MP and Ness, PM. First “themed issue” of *Transfusion* on thirty years of progress in blood safety since recognition of transfusion-associated AIDS. *Transfusion*. 2013 Oct;53:2357-2358 ♦



# SAVE THE DATE

America's Blood Centers'  
Medical Device Data Systems  
(MDDS) Workshop  
January 15-16, 2014 –  
Washington, DC

**DoubleTree Washington, DC - Silver Spring**  
**Negotiated hotel room rate: \$139 + tax**

**2014 Workshop Fees**

**Member Registration:** \$375 (early bird); \$425 (regular)

**Non-Member Registration:** \$745

There are four (4) \$800 scholarships available to ABC members to cover the cost of registration fees and help with travel expenses. The application form and details will be made available once registration opens.

Sponsorship opportunities available. Contact Abbey Nunes at [anunes@americasblood.org](mailto:anunes@americasblood.org) for details.

Medical Device Data Systems, or MDDS, are devices intended to transfer, store, convert data from one format to another according to preset specifications, or display medical device data. They function solely as a conduit through which medical device data flows, is stored, or displayed. MDDS are regulated by FDA. In 2011, the FDA issued a final rule reclassifying MDDS to Class I, the lowest of the three regulatory classifications which are based on the level of control necessary to assure the safety and effectiveness of the device. Though issued in 2011, the impact is just beginning to be felt in blood centers, hospitals and other areas where medical devices are used.

This workshop will look at the MDDS requirements from all sides: the FDA, medical device manufacturers, blood centers, hospitals, and industry experts, and will cover the effects of this change on blood centers and other impacted health care institutions as well as provide direction on implementation of the FDA guidance requirements. Participants will learn what an MDDS is, the actual requirements, and how to navigate FDA device inspections and development in a quality systems environment.



There are three convenient airports that service the Washington area – Dulles International Airport, Reagan National Airport and Baltimore/Washington International Airport – which are served by all major US airlines. Please note that the closest airport is National. Hotel is metro accessible.

**BLUE PLATELET SPECIAL****Lauren Ward Larsen**

---

**The S-Word**

Over the years I've come across numerous stories involving organ donation. A friend of mine is on her 17<sup>th</sup> year with the heart of a woman who was thrown from a horse. A man I know is alive and running marathons because the family of a young man who'd been shot saw through their grief to donate his organs. I even met a woman whose kidney donor is still very much alive. The circumstances in which organ donors become organ donors varies, but oddly enough, and despite its higher than average rate of donation, I'd never come across a story that involved organ donation after suicide. Until last week, when the story hit too close to home.

I met Christine when I was 29 and she was a painfully shy and quiet 5-year-old. Her mom, Bonnie, and I both worked at PepsiCo and became fast friends in no time. Through shared meals, Chuck E. Cheese outings, dog walks, and other escapades, I grew to love Bonnie's two kids as much as I loved her. A single mom, Bonnie was concerned about caring for her children should she die prematurely, and when she asked me if I'd be their guardian if something ever happened I agreed without pause.

A year after that conversation, cancer happened. Her children, ages 7 and 9 at the time, watched as she hemorrhaged on the floor of the public library before she lost consciousness. At the hospital, it was discovered that Bonnie had uterine cancer so advanced her body was actually trying to abort her uterus; thus, the massive hemorrhage. Bag after bag of blood was transfused, which helped give my friend 10 more years of life she wouldn't otherwise have had – to create more memories with her kids, to bring them to the threshold of adulthood.

Bonnie's death eight years ago was particularly tough on her daughter, who had become rebellious and had not yet found her path in life. Despite having a monthly allowance from the trust her mom had set up for me to manage, Christine struggled. Over the years, I held my breath with each new direction she took, hoping this would be the one that stuck. With the birth of her daughter two years ago, it seemed she had finally found her footing. She left an unhealthy marriage, took a steady job in a stable company, got promoted, bought a better car – one more suitable for transporting a toddler to and from daycare. And when I went to visit Christine a few months ago, I told her how proud I was of her, how happy I was for her and for the joy she had found in motherhood.

But I missed the signs. I did not see how much she was showing her brave mommy face to the world while battling her demons in private. On Facebook, at work, and in her daily interactions, she kept her struggles a secret from so many of us who knew and loved her. Hours after she made an irrevocable decision in a moment of what must have been excruciating emotional pain, her brother and husband (to whom she was still legally married) were approached about organ donation.

Next week, I'll head to Orange County to lead her memorial service and spread her ashes in the same location at sea where we spread her mother's ashes. In the wake of Christine's death, there is still so much I don't know or understand. I don't know if she regretted her decision the moment she kicked away the stool. I don't know if her two-year-old daughter will remember her 10, even five, years from now. I don't know if her soul lives on, if she'll be with us on that boat, enveloping us in her love as we say our goodbyes.

But this much I do know: several people – “friends we've never met,” as I like to think of them – have been given a second chance at life because two young men made a momentous decision at the deathbed of a young woman I love dearly. Rest in peace, sweet girl.

*Lauren Ward Larsen is the author of “Zuzu's Petals: A True Story of Second Chances,” which shares her story of her path to becoming an international blood donation advocate. More of her stories can be found at <http://laurenlarsenslovelightlaughter.blogspot.com>. She can be reached at [Lauren@LaurenWardLarsen.com](mailto:Lauren@LaurenWardLarsen.com). ♦*

## BRIEFLY NOTED

**Attendees at a congressional briefing in Washington, D.C. on Sept. 4 urged caution over the Food and Drug Administration's new breakthrough designation, warning that patient safety may be overlooked in pursuit of speeding drugs to market.** In 2012, FDA established the "breakthrough therapy" designation, offering a fourth expedited review and approval pathway intended to rapidly bring drugs for serious diseases into the hands of patients who need them, reported *Nature Medicine*. With more than two dozen therapies granted the designation since applications started to roll in a year ago, some researchers are now raising concerns over patient safety. "The breakthrough drugs pathway provides yet another even faster pathway to allow approval of drugs on the basis of very limited data," Aaron Kesselheim, MD, who studies pharmacoeconomics at Brigham and Women's Hospital in Boston, told *Nature Medicine*. "Drugs need to be approved efficiently and rigorously – and I don't think that second half of the equation is being emphasized," he said. Dr. Kesselheim spoke on the implications and consequences of the breakthrough designation at the Sept. 4 congressional briefing, which was sponsored by the Patient, Consumer, and Public Health Coalition, a healthcare advocacy group. A primary concern raised at the briefing was that drugs evaluated under expedited review mechanisms are often approved off the back of surrogate endpoints, which are easier and quicker to collect than clinical endpoints. Surrogate outcomes, which generally involve laboratory tests for particular biomarkers, remain controversial as they do not always capture the true clinical outcomes of interest. Although FDA requires that drug sponsors run phase 4 confirmatory trials after receiving breakthrough designation, the agency is typically met with fierce opposition from drug companies, patients, and doctors if it tries to revoke the drug's approval. Despite these criticisms of the breakthrough designation, FDA's commitment to accelerating approval process seems to have more supporters than detractors – and in fact, many enthusiasts seek ways to further expedite the process. The *Nature Medicine* article can be viewed at [www.nature.com/nm/journal/v19/n10/full/nm1013-1196a.html](http://www.nature.com/nm/journal/v19/n10/full/nm1013-1196a.html).

**Citation:** Jiang K, *et al.* Caution urged over the FDA's new breakthrough designation. *Nat Med.* 2013 Oct 7;19(10):1196. ♦

## REGULATORY NEWS

**The Food and Drug Administration has posted updates regarding limited operations during the government shutdown, and has had to postpone at least one advisory committee meeting.** Since the federal government shutdown last week in the absence of an approved federal spending bill from Congress, several agencies and offices within the Department of Health and Human Services have limited their operations. FDA stated in an update regarding the Center for Biologics Evaluation and Research (CBER) that during the government shutdown, CBER operations will be limited to the following:

- Emergency work involving safety of human life or protection of property;
- Criminal law enforcement work; and
- Activities funded by carryover user fee balances, including user fee balances under the Prescription Drug User Fee Act (PDUFA), and Medical Device User Fee Amendments (MDUFA). Carryover user fee balances will only be spent on activities for which the fees are authorized under the Federal Food, Drug, and Cosmetic Act.

With respect to the medical product user fees, during the lapse period, FDA will not have legal authority to accept user fees assessed for fiscal year 2014, until a fiscal year 2014 appropriation for FDA is enacted. The CBER update can be viewed at <http://1.usa.gov/s1xJw>. FDA will therefore be unable to accept

(continued on page 10)

**REGULATORY NEWS** (continued from page 9)

any regulatory submissions for fiscal year 2014 that require a fee payment and that are submitted during the lapse period. Another FDA update regarding medical products reiterated some of these points, and is available at <http://1.usa.gov/1fVp1GU>. FDA already postponed at least one advisory committee meeting because it is not an activity funded by user-fees; it remains to be seen if others will be postponed or canceled. (Sources: FDA CBER What's New announcement, 10/7/13; FDA Medical Products Activities During Federal Government Shutdown, 10/7/13; FDA meetings announcement, 10/8/13) ♦

**GLOBAL NEWS**

**GlaxoSmithKline (GSK), a British drug maker, announced on Oct. 8 that it will seek marketing approval in Europe for the first-ever malaria vaccine next year, reported Reuters.** The vaccine, called the RTS,S vaccine, was found after 18 months of follow-up to have almost halved the number of malaria cases in young children in the trial, and to have reduced by around a quarter the number of malaria cases in infants. “Based on these data, GSK intends to submit, in 2014, a regulatory application to the European Medicines Agency (EMA),” GSK said in a statement. The company added that the World Health Organization has indicated it may recommend use of the RTS,S vaccine from as early as 2015 if EMA drug regulators back its license application. While the RTS,S vaccine was successful in early phase trials, excitement over this vaccine was dampened last year when results from a final-stage trial with 6,537 babies aged six to 12 weeks showed the shot only provided modest protection, reducing malaria infection by only 30 percent compared to the control vaccine (see *ABC Newsletter*, 11/16/12). Previously published data from earlier parts of the trial showed the vaccine’s efficacy to be 65 percent in babies analyzed six months after vaccination, and only around 50 percent in five to 17-month-olds. Further data released earlier this year found the RTS,S vaccine’s efficacy wanes over time, with the shot protecting only 16.8 percent of children over four years. Despite these drawbacks, David Kaslow, vice president of product development at PATH, a non-profit organization focused on improving Global Health, told Reuters that RTS,S would serve as a useful tool alongside other malaria control measures as mosquito nets, insecticides, and anti-malarial drugs. (Source: Reuters, 10/8/13) ♦

**INFECTIOUS DISEASE UPDATES****HEPATITIS C VIRUS**

Research from the Centers for Disease Control and Prevention presented at the ID Week 2013 conference in San Francisco last week reported the first case of hepatitis C virus (HCV) transmission from an organ donor with negative screening by standard pre-transplant nucleic acid testing (NAT) and anti-HCV serology. It takes 7 to 10 weeks to be able to detect HCV antibodies, and three to seven days after infection to detect HCV RNA, but this may vary by test sensitivity and hemodilution of the specimen. On March 9, 2012, two organ recipients were reported to CDC with newly diagnosed HCV infections identified by routine post-transplantation NAT screening. In December 2011, both had received organs – heart and kidney – from one donor, an active injection drug user who had undetectable HCV by polymerase chain reaction (PCR) testing. Genotyping of HCV in the recipients identified genotype 2b HCV, a relatively unusual strain in the US (less than 5 percent of strains). Although archived serum from the donor was negative by PCR on repeat testing, splenocytes from the day of the transplant were positive for HCV RNA, also genotype 2b. This suggests the donor had a very recent HCV infection, and that there is a

(continued on page 11)

**INFECTIOUS DISEASE UPDATES** (continued from page 10)

molecular relationship between the HCV in the donor and the recipients, which shared the uncommon genotype. “These findings highlight the importance of communicating transmission risk to recipients, despite the most sensitive available donor screening. Donor-derived transmission of HCV and standardized recipient follow-up testing should be considered in recipients of organs procured from donors with behavioral risks for blood-borne pathogens,” concluded the abstract authors. The abstract can be viewed at <http://bit.ly/1acI5YY>.

**Citation:** Suryaprasad A, *et al.* Transmission of hepatitis C virus from an organ donor with undetectable viremia by nucleic acid testing. ID Week 2013. 4 Oct. 2013.

**HIV**

**Another HIV vaccine candidate failed to protect against the virus infection as reported in *The New England Journal of Medicine*.** The multicenter, placebo-controlled US clinical trial of the DNA prime-recombinant adenovirus type 5 boost (DNA/rA5) vaccine regimen was halted by its data safety monitoring board because interim results gave little hope that the drug could work. Researchers randomized 2,504 men and transgender women who have sex with men to receive the vaccine or placebo. HIV-1 acquisition from week 28 through month 24, viral load set-point, and safety were assessed. The number of infections was similar whether participants got the vaccine or placebo. The vaccine also had no effect on “viral set-point,” the level of virus in the blood stream after infection and before antiretroviral treatment. The set-point is a marker for the aggressiveness of the infection – a higher set-point is associated with faster progression to AIDS in the absence of treatment. The study “gave a definitive, albeit disappointing, result,” wrote the authors. On the other hand, “we’ve learned a tremendous amount” from each trial of an HIV vaccine candidate, Col. Jerome Kim, MD, acting director for the US Military HIV Research Program in Silver Spring, Md., told *MedPage Today*. He added that despite the “multiple disappointments,” the many trials have really only tested four separate vaccine concepts and each has increased scientific understanding of how HIV and the host immune system interact. Other HIV vaccine researchers are investigating the use of adenoviral vectors and different combinations of HIV proteins and genes, said Col. Kim. Basic research is also focusing on conserved regions of the highly variable HIV genome and finding broadly neutralizing antibodies. (Source: MedPage Today, 10/7/13)

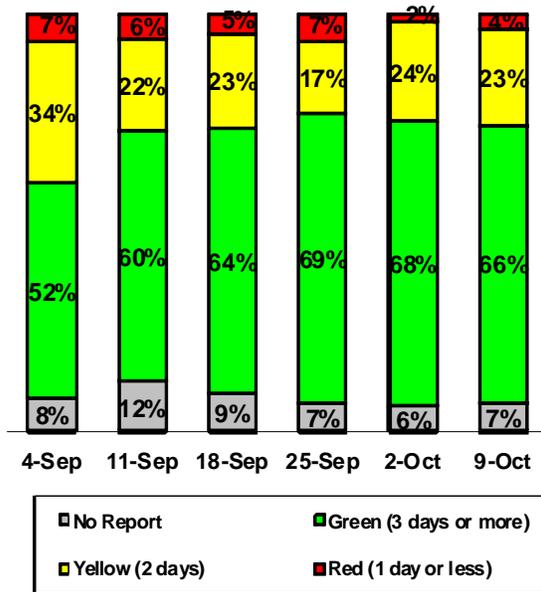
**Citation:** Hammer SM, *et al.* Efficacy trial of DNA/rAd5 HIV-1 Preventive Vaccine. N Engl J Med. 2013 Oct. 7. [Epub ahead of print] ♦

**We Welcome Your Articles**

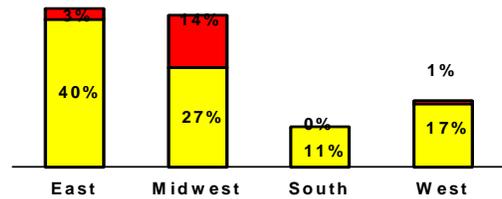
We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer’s name and title will be included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

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

**Total ABC Red Cell Inventory**



**Percent of Regional Inventory at 2 Days Supply or Less, October 9, 2013**



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

Daily Updates are available at:  
[www.AmericasBlood.org](http://www.AmericasBlood.org)

**MEMBER NEWS**

**BioBridge Global has established an investigational study agreement with ExThera Medical to serve as a testing site for a new Seraph Microbind blood safety technology.** BioBridge Global (BBG), is the non-profit holding company that oversees and supports South Texas Blood & Tissue Center, QualTex Laboratories, GenCure, and The Blood and Tissue Center Foundation. The new filter device will be tested for its ability to remove bacteria and viruses from blood and blood products using ExThera’s broad-spectrum biomimetic sorption hemoperfusion technology, according to a press release from BBG and ExThera Medical.



“The blood supply is as safe as we can possibly make it using today’s testing technology. Taking part in a study that can provide additional layers of safety to the blood supply is advantageous for our business,” said Linda Myers, CEO of BioBridge Global. “Our core business has been collecting and testing blood and stem cells and we are very pleased to be working with ExThera Medical. This collaboration is a welcome fit as we continue to obtain partners for clinical research on a global basis.” ExThera’s Seraph Microbind Affinity Blood Filter has “received scientific and clinical support for its potential to remove a wide range of bacteria, other pathogens, toxins, and pro-inflammatory cytokines directly from a patient’s blood in a procedure that resembles dialysis,” said the press release. More information can be found in the release at <http://bit.ly/162Xtpx>. (Source: BioBridge Global and ExThera press release, 9/27/13)

## MEMBER NEWS (continued from page 12)

**Shepard Community Blood Center, in Augusta, Ga., is the independent blood center to implement OTIS Blood Bank 8.0, an incident management software that promotes quality improvement.** OTIS, developed by Nouvation, is short for occurrence tracking information system, which is a comprehensive incident-management system first piloted at a “Top 50” hospital in Southern California and developed with strong input from blood bankers, including Sue Mosuch, RN, quality assurance specialist, at Shepard Community Blood Center. Ms. Mosuch said that when she first heard about OTIS in 2008, the blood center was looking for a better way to manage and resolve deviations. “Our paperbound process wasn’t sufficient to please the inspectors. We looked at several vendors – big companies with big complex systems, multiple modules, and multiple user license fees. We ultimately chose OTIS. This ... system impressed us with its ability to enable multiple layers of users to quickly and easily report, track, and trend deviations. It also required only one software license for all our users.” The center purchased and implemented OTIS 7 in 2009, and is now upgrading to the OTIS 8 system. She added that OTIS has improved compliance, allowing blood center staff to quickly turn around Food and Drug Administration biological deviation reports and help resolve deviations. Also, OTIS 7 virtually eliminated the center’s need for paper, and with 8.0, the center’s conversion to paperless is complete. More information can be found in the press release at <http://bit.ly/17ulk0T>. OTIS 8 will be on display at the AABB Annual Meeting Expo Hall at booth #1252 from Oct. 11 to 15 in Denver, Colo. (Source: Nouvation press release, 9/27/13)



**Puget Sound Blood Center, based in Seattle, Wash., recently signed a contract to provide blood for Eastern Maine Medical Center (EMMC) in Bangor, Maine, previously served by the American Red Cross.** Irwin Gross, MD, medical director of EMMC’s Patient Blood Management Program, told local news source, *The Bangor Daily News*, that the decision to contract with Puget Sound Blood Center was based on three key factors – blood freshness, cost savings, and the organization’s ability to work closely with transfusion physicians and patients. He added that the annual cost for blood will be reduced significantly. Puget Sound Blood Center will also work with the hospital to reduce unnecessary transfusions, said Dr. Gross. Puget Sound Blood Center serves more than 77 hospitals in the Pacific Northwest and also shares resources and expertise with hospitals nationally, according to its director of communications, David Larsen. He added that the center prides itself on transfusion expertise, care for hemophiliacs, and the ability to recover stem cells from umbilical cords of newborns. (Source: The Bangor Daily News, 10/7/13) 💧



## PEOPLE

**Dan Waxman, MD, Donald Berglund, MHA, FACHE, and Mary Beth Bassett, MT(ASCP),** have been elected for three of AABB 2013-2014 at-large director positions, announced AABB last week. Dr. Waxman is the executive vice president and chief medical officer of Indiana Blood Center, as well as the immediate-past president of America’s Blood Centers. Dr. Waxman, elected to at-large director position-5, is also a clinical professor of pathology and director of the Transfusion Medicine Fellowship Program at Indiana University Medical Center. Prior to joining Indiana Blood Center, Dr. Waxman held positions at the Community Blood Center of Greater Kansas City and Carter BloodCare in Dallas, Texas. He has been an active AABB member for 28 years and presented more than 40 abstracts at past AABB

(continued on page 14)

## PEOPLE (continued from page 13)

meetings. Mr. Berglund, elected to at-large director position-1, currently leads Memorial Blood Centers in St. Paul, Minn., and is the CEO of Innovative Blood Resources. Mr. Berglund has worked in non-profit healthcare organizations for 26 years, joining Memorial Blood Centers in 2004. He previously served as executive vice president and chief operating officer of Norton Healthcare, Inc., a non-profit system of hospitals, ambulatory care centers, and physician practices based in Louisville, Ky. Mr. Berglund has also served on a variety of boards of directors, including those of ABC, the National Chronic Care Consortium, the Behavioral Healthcare Providers, Red Cross of Louisville, PreferredOne Health Plan, Fairview Clinics, Minnesota Hospital Association, and Minnesota's Medical Alley. He has been an AABB member since 2006 and participates in the National Blood Foundation Leadership Forum.



Donald Berglund, MHA,  
FACHE

Ms. Bassett, elected to at-large director position-7, has served as executive vice president and chief quality officer at Blood Systems, Inc., in Scottsdale, Ariz. since 1996. Before assuming this position, she served as CEO of the national testing laboratory at the American Red Cross in St. Louis. Prior to that, she served as director of the HLA/transplant laboratory and as the director of quality assurance and compliance officer at the American Red Cross Missouri-Illinois Blood Services Region. Ms. Bassett has served on numerous AABB committees and served from 2008 to 2012 on the AABB board of directors. Currently, Ms. Bassett chairs the annual Food and Drug Administration and Current Issues in Blood Banking Pharma conference. She also assisted in developing the first "Improving Manufacturing Practices and Quality" training program for ABC members. She is a national and international speaker in the area of quality and has received several awards. The results of this election will be formally announced on Oct. 15 at the 2013 Annual Business Meeting in Denver, Colo., where elections for the other directors and officers will take place. (Source: AABB Weekly Report, 10/4/13)



Dan Waxman, MD

Ms. Bassett, elected to at-large director position-7, has served as executive vice president and chief quality officer at Blood Systems, Inc., in Scottsdale, Ariz. since 1996. Before assuming this position, she served as CEO of the national testing laboratory at the American Red Cross in St. Louis. Prior to that, she served as director of the HLA/transplant laboratory and as the



Mary Beth Bassett,  
MT(ASCP)

**Training Officer Sgt. Keith Wagner** of Oakwood, Ill., was recently awarded the 2013 Best School Blood Drive Coordinator Award on behalf of the Illinois Coalition of Community Blood Centers (ICCBC), a statewide association of non-profit blood centers, all members of America's Blood Centers. Sgt. Wagner is a training officer at the ChalleNGe Academy in Lincoln, Ill., a military-style boot camp run by the Illinois National Guard for 16- to-18-year-olds to earn their GEDs. He was presented with the award in conjunction with the academy's semi-annual fall blood drive. The ICCBC established the "Blood Drive Coordinator Program" to honor the volunteers who work behind the scenes organizing blood drives and often go unrecognized, explained Margaret



Pictured left to right: Carrie Johnston (Community Blood Services of Illinois); Shirley Wagner; Sgt. Keith Wagner; Margaret Vaughn (ICCBC); and State Rep. Chad Hayes (C-Catlin)

(continued on page 15)

**PEOPLE** (continued from page 14)

Vaughn, ICCBC government affairs director. Since the program was established, Gov. Pat Quinn of Illinois has issued proclamations declaring July as Blood Drive Coordinator Month. The ICCBC also holds an annual statewide competition in the summer in which blood centers from across the state submit nominations in various categories. Community Blood Services of Illinois nominated Sgt. Wagner in the "Best School Blood Drive Category." Sgt. Wagner has organized blood drives on behalf of Lincoln's Chal-leNGe over the past 15 years that have led to the collection of more than 3,000 pints of blood, which saved potentially more than 10,000 lives. State Rep. Chad Hays (R-Catlin) was present at the award ceremony to recognize Sgt. Wagner and introduced House Resolution 570 in honor of Sgt. Wagner's accomplishments. Sgt. Wagner also received a Senate Congratulatory Certificate on behalf of Illinois State Sen. Mike Frerichs (D-Champaign). (Source: ICCBC press release, 9/16/13) ♦

**MEETINGS**

Oct. 31- **5<sup>th</sup> International Meeting on Emerging Diseases and Surveillance, Vienna, Austria.**  
Nov. 3, 2014

The International Society for Infectious Diseases (ISID) and ProMED will hold the 5<sup>th</sup> International Meeting on Emerging Diseases and Surveillance (IMED) 2014 from Oct. 31 to Nov. 3, 2014 in Vienna, Austria. This meeting will explore emerging disease threats, the factors that lead to their emergence, and detecting/responding to such threats. Some session topics include methods and models of disease surveillance detection and reporting, emerging zoonoses and animal health threats; biosecurity and agents of bioterrorism and biological warfare, vector-borne diseases, and many others. More information can be found at <http://imed.isid.org>.

Contact: [info@isid.org](mailto:info@isid.org) ♦

**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. 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:**

**Account Manager, Charlottesville, Va. (Virginia Blood Services).** The Account Manager works to support the region sales team in the identification and development of new accounts at designated target organizations within an assigned territory. Their objective is to solicit corporations, schools, and religious organizations to host mobile blood drives at their locations. The Account Manager is responsible for maintaining as well as growing their existing accounts by building strong customer relationships and working closely with them to increase unit collections at each blood drive. The Account Manager is actively involved in the creation of successful recruitment programs/strategies that will lead to success in the achievement of territory col-

lection goals. Bachelor's degree, five years of relevant experience, and two years of experience in making sales presentations to various group sizes required. Three years of sales experience is also required, but outside sales preferred. VBS is an equal opportunity and affirmative action employer. Applicants may review this

(continued on page 16)

**POSITIONS** (continued from page 15)

opportunity and apply at:  
<http://vbs.balancetrak.com/lists/220/default.aspx>.

**Director, Community Donor Center (CDC), Pittsburgh, Pa. (Central Blood Bank/The Institute for Transfusion Medicine).** This position is responsible for management and direction of employees who may be assigned to multiple collection sites to ensure that they comply with the core corporate goals of Central Blood Bank. Directs the supervision of staff to adhere to Standard Operating Procedures, FDA and AABB regulations. Promotes Six Sigma philosophy and implements control plans to achieve sustainable results. Integrates Donor First principles into all aspects of Donor Services operations. Monitors performance in productivity, proficiency and customer service; and, takes action for improvement. Responsible for technical aspects of automated and apheresis collections. Serves as an on-call resource for technical questions and operational issues. Bachelor's degree required. Advanced degree and RN Licensure preferred. 10 years of relevant experience, six years of supervisory experience, five years of management experience in related field and three years of whole blood and automated management experience required. We offer a competitive salary and benefit package that includes Medical/Dental/Vision, Short/Long Term Disability, Employee/Dependent Life Insurance, Flex Spending Options, 403(b) Retirement Savings (with company match), Tuition Reimbursement, Vacation/Sick Personal Days, and six Paid Holidays. Applicants may review this opportunity and apply at: <http://bit.ly/GPv4gO>. EOE/AA

**Director of Operations/Manufacturing and Hospital Services.** Kentucky Blood Center (KBC), located in Lexington, KY is seeking a resourceful, self-motivated individual to oversee Technical Services processing from receipt of units through distribution including inventory management. The successful candidate will ensure excellent customer service is provided to all KBC blood component customers; ensure Quality System Essentials are implemented, audited, and in compliance within Technical Services; develop and monitor department budgets; and will ensure acceptable validation and implementation of new or revised processes, equipment, computer programs and SOPs. Must have bachelors degree, MT(ASCP) or CLS, or experience deemed equivalent. Three years of management experience in an organization regulated by good manufacturing practices, FDA, AABB or equivalent. Two or more years experience in a blood center managing blood components distribution, inventory, and customer relations preferred. Must have excellent leadership, problem solving and communication skills. 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](http://www.kybloodcenter.org). Drug-free and EOE/AAP.

**Transfusion Services Manager.** Recognized as a leader in transfusion medicine, Puget Sound Blood Center is seeking a highly motivated laboratory Manager to play a crucial role in the development, integration, and day-to-day management of three new Transfusion Service Laboratories based at Seattle area Swedish hospitals opening in late 2013 and 2014. Requirements include: Bachelor's degree in CLS/MT, Master's degree preferred. Must meet CLIA requirements for General Supervisor for Transfusion Service. MLS (ASCP) or equivalent certification required; SBB (ASCP) preferred. Five years' supervisory or equivalent leadership experience required; five years' experience with progressively increasing responsibilities in a CAP/Joint Commission accredited clinical lab preferred. Demonstrated experience managing people and departments; business background and customer service experience desirable. Interested candidates should send his/her resume and cover letter to [HumanResources@psbc.org](mailto:HumanResources@psbc.org). More information on our website: [www.psbcc.org](http://www.psbcc.org). Please indicate job number 7089 on all correspondence. EEO/AA

**Assistant Manager, Consultation and Reference.** Gulf Coast Regional Blood Center is currently seeking an Assistant Manager for our Consultation and Reference lab. Reporting to the Consultation and Reference Manager, this position is responsible for overseeing operations and assisting with management of the Consultation and Reference Laboratory. This includes supervision of staff, maintenance of all policies, procedures and quality control practices and the maintenance of effective customer and inter-and intradepartmental relations. This position requires a degree as Medical Laboratory Scientist (or Medical Technologist); from an accredited four-year college or university plus five years of demonstrably successful management experience in a blood bank, hospital blood bank or allied health laboratory. The successful candidate must have strong leadership and workflow process acumen. Gulf Coast Regional Blood Center is a non-profit 501(c)(3) organization and is accredited, licensed and inspected by the Food and Drug Administration (FDA), AABB as well as local and state authorities. The Blood Center is a proud member of AABB, America's Blood Centers, Blood Centers of America, South Central Association of Blood Banks, and the Texas Medical Center. Please visit our website for more information about our organization and to apply online: [www.giveblood.org](http://www.giveblood.org). Lori Pireu – Recruiter – P-(262) 289-2056 – [lpireu@giveblood.org](mailto:lpireu@giveblood.org).

**Medical Technologist.** Sheppard Community Blood Center has been the local blood provider in Augusta, Ga. for more than 35 years serving 21 local hospitals

(continued on page 17)

**POSITIONS** (continued from page 16)

and the Joseph M. Still Burn Center. Medical Technologist Success Snapshot: 1. Utilizing recent medical technologist laboratory experience (ASCP/AMT or SBB preferred) will perform donor testing using automated/manual methods according to AABB and FDA guidelines. 2. Performs quality control and preventative maintenance functions in order to ensure purity, potency and safety of blood products. 3. Effectively assists team members in a lab environment promoting positive customer service to achieve internal harmony and repeat business. 4. Evaluates work carefully – minimizing errors to reduce potential product waste. 5. Participates in training opportunities ensuring lab team is ready for compliance review visits. Complete MANDATORY application, resume and cover letter. Cover letter should outline experience as it relates to the Medical Technologist Success Snapshots listed above. Application/details on how to apply can be found at: [www.shepeardblood.org](http://www.shepeardblood.org). EOE

**Director of Quality and Regulatory Affairs.** The Stanford Blood Center is seeking a Director of Quality and Regulatory Affairs. Under the general direction of the Administrator and Medical Director of Clinical Services, the Director of Quality and Regulatory Affairs manages the blood center Quality and Regulatory Affairs department, which ensures that, by employing cGMP, blood center is in compliance with all federal, state and local laws and regulations regarding blood collection and testing facilities and all health and safety policies and procedures. Oversees Quality and Regulatory Affairs processes at the Blood Center. Leads development of strategic goals for Quality and Regulatory Affairs department to support overall Blood Center goals. Directly supervises a staff of three Quality Specialists. Four-year college degree required and a minimum of two years working in a supervisory-based Quality and/or Regulatory Affairs position or in a blood center. Familiarity with cGMP concepts and controls, attention to detail, and strong collaboration and influencing skills are required. One or more of the following are preferred: Medical Technology certification, Registered Nurse, Specialist in Blood Banking (SBB) certification, CQA certification, Quality Management tools (FMEA, root cause analysis, etc), or Quality manufacturing tools (Lean Manufacturing, Six Sigma, etc.). To apply, search for Job #60894 at: <http://stanfordcareers.stanford.edu/job-search>.

**Director of Quality Assurance.** Central California Blood Center in Fresno, CA is recruiting for Director of QA. Successful candidate will be Medical Technologist, CLS preferred, with five years' experience in blood banking and/or operations in regulated industry. Responsible for review of regulatory/guidance documents for application. Hosts external auditors/inspectors as needed; performs internal audits; assists with management of licenses and certificates; reviews error reports and corrective actions. Fosters strong process control

through appropriate SOP review and participation in validation activities as needed. Excellent working knowledge of industry regulatory and accreditation standards required; previous experience in auditing and/or technical writing preferred and excellent organizational/ interpersonal communication skills. Minimum of five years of progressive leadership experience in quality management field required. Minimum five years progressive experience in Quality Systems preferred. CCBC offers a competitive salary and benefit package for this position that is a vital member of our Senior Management Team. To apply please fax resume to (559) 224-1310, or post [www.donateblood.org](http://www.donateblood.org) or mail to Central California Blood Center, 4343 W. Herndon Ave, Fresno, CA 93722. EOE

**Reference Lead Technologist.** Community Blood Services, located in Montvale, NJ, is looking for a full time lead reference technologist. 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 lead reference laboratory technologist will provide consultation to hospital clients and may be involved in training staff. Education/Experience: bachelor's degree (BS) from a four-year college or university; BS in medical technology. Three plus 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. Interested and qualified applicants, please contact HR. Email your resume to: <https://home.eease.com/recruit/?id=5040551>. EOE

**Medical Director.** Blood Systems is seeking a Medical Director with expertise in Clinical Transfusion Medicine to join its Medical Affairs team. This position participates in directing, planning, strategizing, and coordinating medical activities in assigned areas of responsibility. Successful candidate will participate in the provision and development of medical policies and strategies. Responsibilities include clinical consultation to hospitals and clinicians in assigned region(s), patient blood management, CLIA laboratory director oversight, and medical direction to manufacturing and clinical services. Medical Director will participate in internal and external continuing medical and/or technical education programs. Knowledge/Experience: MD or DO required. Experience: Fellowship training in blood banking/transfusion medicine or three years experience in the field of Transfusion medicine required. Experience at a blood center which collects, tests, and

(continued on page 18)

**POSITIONS** (continued from page 17)

distributes blood products for transfusion preferred. Licenses/Certifications: Currently licensed (or acquires license within six months) in the state of work required. Board certification in Clinical Pathology, Internal Medicine or Pediatrics, and/or board eligibility in Transfusion Medicine required. Blood Bank/Transfusion Medicine certification within three years of employment required. For consideration, please email your resume by **10/18/13** to [jobs@bloodsystems.org](mailto:jobs@bloodsystems.org). ATTN: HR/2013/115. Please visit our website at [www.bloodsystems.org](http://www.bloodsystems.org). Pre-employment background check and drug screen is required. EOE M/F/D/V

**Donor Relations Consultant (DRC).** Mississippi Valley Regional Blood Center (MVRBC) has an exciting opportunity in our Maryville, Ill. facility for a Donor Relations Consultant (DRC) to develop strong relationships with St. Clair County and Madison County community organizations for hosting mobile blood drives. The ideal candidate will have strong communication and organizational skills, a demonstrated ability to obtain measurable goals, solid customer service experience, previous business to business experience, and the ambition to motivate others. This position requires an individual, who is confident in public speaking, media relations experience is a plus. This is a full time position working Monday through Friday with occasional evenings and weekends. A bachelor's degree, or equivalent combination of experience and education, is required to be considered; preferred studies include business, communications, or marketing. Interested candidates may visit <http://bit.ly/Q4V4mV> to apply.

**Medical Lab Technicians/Technologists. Medical Lab Technicians/Technologists Team Lead (Omaha, NE).** Join our team! LifeServe Blood Center is seeking part-time Medical Laboratory Technologists/Technicians and a full-time Medical Laboratory

Technologist/Technician Team Lead. These positions will perform blood bank reference testing and manage blood and blood product inventories to meet the needs of our hospital customers. Candidates will perform blood bank reference testing including crossmatches, antibody identification, antigen screens, etc. Candidates will also perform needed quality control, equipment maintenance, and calibration as required. MT, MLT or equivalent certification is required. Applications should be submitted online at: [www.lifeservebloodcenter.org](http://www.lifeservebloodcenter.org).

**Manager of Medical Advocacy.** Michigan Blood is looking for a dynamic person to join its Medical Services team. This position will lead the statewide risk management program to ensure a safe, healthy and injury free environment for donors, staff, volunteers and visitors. This role is responsible for management of adverse donor events, creating and maintaining standard operating procedures (SOPs) and an exposure control plan, leading investigations of incidents with injury at all Michigan Blood locations, regulation compliance, risk management education, and developing and maintaining relationships with donors and health care professionals. The ideal candidate will demonstrate remarkable service, engaging presentations, and professional communication (written and verbal) skills. A bachelor's degree in a medical or health-related field required with a minimum of three to five years management experience. Prior risk management experience desirable. We offer a competitive salary and an exceptional benefit plan. If you want to be part of a growing organization and make a life-saving difference, please apply via our website: [www.miblood.org](http://www.miblood.org). EOE ♡