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# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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**2012 #13** **April 6, 2012**

**INSIDE:**



## Annual Meeting Attendees Celebrate ABC's 50th Anniversary and Discuss Change

In addition to the usual plenary sessions and the Scientific, Medical, and Technical (SMT) Forum, nearly 200 attendees at this year's America's Blood Centers Annual Meeting enjoyed a special 50th Anniversary Celebration in Scottsdale, Ariz. last week. The evening social events often highlighted ABC's and its members' past accomplishments, while the sessions reminded attendees just how much healthcare and blood banking have changed over the years, focusing on how blood centers can position themselves for continued success.

The Annual Meeting kicked off on Saturday, March 24, with a mini-concert and putting green competition to benefit the Foundation for America's Blood Centers (FABC) (see page 6). Sessions got underway on Sunday morning, beginning with an ABC Members meeting where members approved the slate of officers and Board of Directors' nominees chosen by the ABC Nominating Committee in January (see *ABC Newsletter*, 2/3/12). David Green, CEO of Mississippi Valley Regional Blood Center, will serve as president-elect, and Susan Rossmann, MD, chief medical officer at Gulf Coast Regional Blood Center, will serve as vice president.

Following Sunday's SMT sessions, guests enjoyed a memorable 1960s-themed evening at the "CCBC Supper Club '62" dinner, hosted by Blood Systems, which announced during dinner a $50,000 donation to the FABC. On Monday, attendees heard presentations on the evolving healthcare environment during the "Navigating Through the Paradigm Shift" program. The meeting concluded with the *Awards of Excellence* & 50th Anniversary Reception and Banquet, which lived up to all of its expectations.

**Working Together.** Kim Parker, executive vice president of the California Employers Association (CEA), highlighted the importance of collaborating and sharing data and best practices among blood centers during her presentation at the ABC Members meeting. With years of trade association experience, Ms. Parker related her experience working with members of the CEA to how ABC's member centers can work together to produce positive results for the entire blood banking community. "You need to get rid of that mentality that you're giving away secrets [by sharing information] … Sharing data allows sharing of best practices to solve issues more quickly," said Ms. Parker.

She noted that influencing regulatory changes is easier with a large number of

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## OUR SPACE

ABC CEO Jim MacPherson

### Regulatory Flexibility

In the past, I have mentioned efforts to "harmonize" the way regulators approve the devices we use to collect and process blood and test donors in order to speed access to these devices at lower costs. Such an approach is already successfully done for drugs under the International Commission on Harmonisation (ICH).

There is growing interest on the part of regulators in North America and Europe to head in that direction and you likely will hear more about it in the future. However, recently I heard a US regulator give an opposing view. He expressed the position that international harmonization stymied regulatory flexibility and innovation. The more I have thought about that, the more alarmed I have become. Do we really want our regulators to be "innovative" at the expense of speeding access to product improvements for patients?

The whole point of regulation is to protect the public from unsafe and ineffective drugs, food, devices, etc. FDA and many other regulators do a great job in that regard. But regulations *per se* inhibit flexibility and innovation in the marketplace. Increasingly, getting market approval for high-tech devices or drugs cost in the tens of millions of dollars, primarily to conduct safety and efficacy trials.

The whole point of harmonization is to encourage innovation by making the approval processes more predictable across literally hundreds of regulatory agencies around the world. Do we really want individual regulators to get creative with new requirements that other regulators don't feel are necessary? Aren't the barriers to market entry high enough?

We want and need flexibility among our regulators, but not to use such flexibility to oppose speeding access to safety improvements across the many borders our suppliers must deal with. Heaven forbid!

Jmacpherson@americasblood.org *Visit Jim on Facebook: www.facebook.com/JimMacPhersonABC.*

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

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blood centers behind the advocacy initiatives. "Just like two heads are better than one, 70 blood centers are better than one," said Ms. Parker. "When you're sharing data from the Data Warehouse with amazing information from a large number of members, people will be more inclined to accept that information. The numbers matter." She also spoke about the vitality of passion, engagement, excellent customer service, and communication in driving the success of organizations with members, such as ABC.

**Regulatory and Medical Change.** Several sessions during the SMT Forum discussed impending changes in blood regulation and developments in transfusion medicine. Jed Gorlin, MD, MBA, medical director and vice president of Medical and Quality Affairs at Memorial Blood Centers, began the presentations with an overview of recent discussions surrounding donor hemoglobin eligibility standards and maintaining adequate iron stores.

Dr. Gorlin first summarized the November 2011 FDA and Health and Human Services (HHS) workshop focusing on changing donor eligibly criteria for minimum hemoglobin levels and interdonation intervals to maintain donor iron stores (see *ABC Newsletter*, 11/18/11). Some major points hit were: hemoglobin is often a poor indicator of iron deficiency; changing the hemoglobin requirements or the interdonation period would have substantial effects on blood availability; and donors have gender and race-specific risk for iron deficiency. He also summarized the progress of the AABB Interorganizational Committee, with some next steps being to monitor outcomes of various studies on improving donor iron management and to develop informational materials on donor iron depletion. Dr. Gorlin emphasized that "the message from FDA is that the status quo isn't ok," and that the blood banking community must be prepared to implement some changes to better maintain iron stores.

Dan Waxman, MD, ABC president and executive vice president and chief medical officer of Indiana Blood Center, discussed one such solution to maintaining iron stores: iron supplementation. He summarized a program at his center which targeted menstruating female blood donors, a disproportionately at-risk population for low iron stores and deferral for low hemoglobin. Providing these females with iron tablets allowed them to successfully complete donations at higher levels than the average donor. Future directions include measuring ferritin levels and expanding the program to other donors.

Other presentations focused on donor health screening (see *ABC Newsletter*, 12/2/11), research concerning outcomes of transfusion red blood cells stored for longer versus shorter periods of time, and additive solutions in platelets. Dr. Gorlin took the stage once again to discuss an obstetric hemorrhage event planning and pre-training program developed by HealthEast Care System in St. Paul, Minn., and Memorial Blood Centers through a grant from the FABC. The program is an in-depth computerized training course designed to aid hospitals served by blood centers. It was made available on flash drives and distributed at the meeting; it will be posted on the ABC website.

**A Night From the '60s.** On Sunday evening, Blood Systems hosted a night to be remembered at the Westin Kierland, complete with cocktails, dancing, dinner, and 1960s-themed musical entertainment. From costumes worn by some Blood Systems employees to Elvis Presley and Marilyn Monroe impersonators, the '60s theme was all around. During dinner, Blood Systems President and CEO Dan Connor gave a warm welcome to ABC and its members and announced that Blood Systems is donating $50,000 to the FABC.

**Navigating Through the Paradigm Shift.** On Monday, attendees learned how the economy, healthcare reform, and other changes in the current healthcare environment will trickle down and affect blood

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50th Annual Meeting (continued from page 3)

centers. Laurie Liles, president and CEO of the Arizona Hospital and Healthcare Association, began the presentations with a talk focusing on the delayed impact that the recession had on hospitals and how hospitals are preparing to handle the Affordable Care Act. She noted that as hospitals take on increasing financial burdens, they will be looking to partners, such as blood centers, to help drive down costs. Martha M. Kendrick and Eric Rasmussen of Patton Boggs LLP then provided a legislative update and tips to blood centers on engaging their legislators.

The keynote speaker, Ian Morrison, PhD, an author, consultant and futurist, provided a realistic view of the future of the healthcare industry in the US based on various trends, the effects of healthcare reform on Medicaid, and the creation of healthcare exchanges. Dr. Morrison began with a discussion of some key environmental drivers for change in the healthcare system such as state and federal budgets being under pressure, healthcare reform creating increased demands on care delivery, mandated coverage expansion under the Patient Protection and Affordable Care Act (PPACA), doctors and hospitals coming together, and all stakeholders seeing payment tied to quality.

Dr. Morrison also discussed how hospitals will navigate the shift from a volume-based healthcare system to a value-based system. He emphasized that among the myriad of changes caused by a poor economy and the prospect of expanded coverage under PPACA, hospitals are forming alliances such as large healthcare systems and are focusing on substantively improving patient care. He concluded saying that blood centers should partner with their customers (hospitals) to help solve their problems by providing care "better, faster, and cheaper."

Former Congressman John Shaddeg discussed just how vital it is for blood centers to form relationships with their representatives in Congress as the world of healthcare evolves. He recommended that blood centers have a federal lobbyist and build friendships with legislators that may come in handy down the road. After an afternoon filled with presentations about change, attendees heard a panel discussion called "Adapting to Change – Seizing Opportunities," in which representatives from three blood centers presented different approaches to dealing with change.

**Adapting to Change.** Roy Roper, president and CEO, of Blood Bank of Delmarva, described some difficulties that Blood Bank of Delmarva was having when he came on board two years ago. He discussed changes made in five key areas: customer growth, human capital, organizational culture, operational efficiency, and re-engaging the community. By the end of this transformational period, the blood bank saw $2.2 million in revenue growth and formed a clear strategy for the future. He emphasized communication, investing in the right employees for the job, and creating a positive culture. "Change can be challenging, but it's our perspective on change that helps frame the way you approach it," said Mr. Roper.

Bobby Grigsby, executive vice president of Strategic Alliances for Carter BloodCare, spoke on how forming partnerships and alliances will help blood centers to remain relevant and successful. Carter BloodCare, for example, is a founding member of The Alliance for Community Transfusion Services, a partnership between seven ABC members. He noted that this alliance allows the blood centers to remain independent, while enjoying the economic benefits of a large centralized blood center. Jacquelyn Fredrick, CEO at BloodCenter of Wisconsin, explained how the center's focus on improving patient care and providing lower healthcare costs has helped BloodCenter of Wisconsin remain successful and provide a wider range of services to the hospitals it serves.

***Awards of Excellence*.** Following the day's insightful discussions, guests headed to the *Awards of*

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50th Annual Meeting (continued from page 4)

*Excellence* and 50th Anniversary Reception and Banquet, featuring a special photographic timeline and video commemorating the last 50 years in blood banking. ABC Annual Meeting regulars have come to anticipate the awards ceremony each year, as it provides ABC with the opportunity to recognize those individuals and organizations who go above and beyond in supporting the blood banking community (see *ABC Newsletter*, 2/3/12 for award recipient details). The evening was filled with laughter, applause, and even some tears.

Guests shared a misty-eyed moment as Larry Frederick Award winner, Judy Socha, described how her son's fight with leukemia has motivated her to hold more than 217 blood drives since 1971. Later in the evening, guests were on their feet applauding as Celso Bianco, MD, ABC's executive vice president, received the Thomas F. Zuck Lifetime Achievement Award. The audience roared with laughter as past FABC President Lauren Larsen, always a jokester, took the stage to receive a surprise award for her work in raising awareness and funding for blood donation. Ms. Larsen recently resigned for medical reasons but promised to remain supportive of the FABC, ABC, and its members. (See page 7 for *Awards of Excellence* photos).

ABC would like to thank all of the speakers, sponsors, and member blood centers that made ABC's 50th Annual Meeting a success.

America's Blood Centers would like to thank the following organizations for making our 50th Annual Meeting and Celebration a success!

The 50th Annual Meeting was hosted and supported by

Blood Systems

ABC would like to give a special thanks to Blood Systems for its generous $50,000 donation to the Foundation for America's Blood Centers.

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## Annual Meeting Guests Treated to Concert and FABC Putting Green Competition

America's Blood Centers' Annual Meeting featured a unique opening event this year in celebration of ABC's 50th anniversary. Guests were treated to a special mini-concert by pop songstress Jenni Alpert and a putting green competition that raised more than $3,000 to benefit the Foundation for America's Blood Centers (FABC) on Saturday, March 24.

Pop songstress Jenni Alpert performs at ABC's 50th Annual Meeting at the Scottsdale Plaza Resort in Scottsdale, Ariz.

As part of ABC's three-day 50th anniversary celebration, guests enjoyed a cocktail reception and swayed to Ms. Alpert's soothing musical melodies in an outdoor courtyard at the Scottsdale Plaza Resort. Between songs, Ms. Alpert spoke to the audience about her "Blood Driven" tour last summer when she covered 5,000 miles of the West Coast performing and speaking at blood drives, blood centers, children's hospitals, and local venues to raise awareness about blood donation.

ABC President Dan Waxman, MD, stops for a photo with Ms. Alpert after her performance.

Ms. Alpert's songs touched on themes of love and individuality, and she emphasized to the crowd that blood and blood donation connects people. She offered her talent to all of ABC's blood centers, saying that she is excited about the prospect of making trips to centers around the country to raise awareness for blood donation through performance. After Ms. Alpert's performance, attendees headed over to the putting green where some donated to the FABC for a chance to compete in the competition.

More than thirty representatives of various ABC members and other attendees showed their generosity and golfing skills by participating in the FABC's putting green challenge. Participants could advance onto the next hole after making a successful putt, and the person who made it to the end of the putting green won a special trophy. Dirk Johnson, chief operating officer of BloodSource, took home the grand prize trophy, wrapping up the fun-filled evening.

After winning the putting green challenge, Dirk Johnson (right), of BloodSource, poses with the runner-up, J. Daniel Garrick (left), of Lifeblood.

### 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 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.

## 15th Annual *Awards of Excellence* & 50th Anniversary: A Night in Photographs

Merlyn Sayers (left), M.B., B.Ch., Ph.D, president and CEO of Carter BloodCare, and Louis Katz (second from left), MD, executive vice president of Medical Affairs at Mississippi Valley Regional Blood Center, present Celso Bianco (second from right), MD, executive vice president of ABC, with the Thomas F. Zuck Lifetime Achievement Award. On the right is ABC President Dan Waxman, MD.

Dr. Waxman presents Michelle Stefan, the FABC Board Chair, with the President's Award

Dr. Waxman presents Glen Galindo, accompanied by a past student, with the National Partner of the Year Award, accepted on behalf of the National Cesar E. Chavez Blood Drive Challenge.

Dr. Waxman (left) and Larry Frederick (right) present Judy Socha with the Larry Frederick Award

Al Whitney and Larry Frederick, both ardent blood donation advocates, meet up before the *Awards of Excellence* while enjoying the blood banking timeline.

Dr. Waxman and Blood Bank of Delmarva CEO Roy Roper present Buzz Christensen with the Outstanding Humanitarian Service Award, accepted on behalf of the Salisbury Host Lions Club of Salisbury, Md.

Dr. Waxman (right) and Mike Pratt (left), CEO of Florida's Blood Centers, present Dean Kurtz (center) with the ABC Corporation of the Year Award, accepted on behalf of Daytona International Speedway.

David Perez (left), president and CEO of Terumo BCT, Ms. Stefan (second from left), and Jodi Zand, the FABC's director of Fund Development, (right), present Erin Survant with the Terumo BCT Award, which she accepted on behalf of Coastal Bend Blood Center.

Ms. Zand (left) and Ms. Stefan (right) present Peter Scott, CEO of Alignment Enterprises, with the FABC's 2011 Volunteer of the Year Award


Ms. Stefan (right), of the FABC, presents Lauren Larsen (left), past FABC president, with a surprise award for her dedication to raising awareness for blood donation and helping to ensure a safe and adequate blood supply.

## A Note of Thanks From Carter BloodCare

Carter BloodCare wishes to express our sincere thanks to America's Blood Centers' Disaster Task Force, Wendy Trivosonno, Bill Coenen, the National Blood Exchange, and the following blood centers, for your prompt help with blood and components in the aftermath of the recent damaging tornadoes in North Central Texas: BloodSource; BloodCenter of Wisconsin; Community Blood Center of the Ozarks; Gulf Coast Regional Blood Center; Kentucky Blood Center; LifeShare Community Blood Services; LifeSource; Memorial Blood Centers; Mississippi Valley Regional Blood Center; Puget Sound Blood Center; Rock River Valley Blood Center; United Blood Services; and Virginia Blood Services.

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# INSIDE ABC

## Register for the Human Resources & Member Training/Development Workshop

America's Blood Centers' Human Resources and Member Employee Training & Development Committees have announced their first joint workshop to be held from May 1 to 3, in Sacramento, Calif., at the Sacramento Marriott Rancho Cordova. ABC would like to remind interested attendees to register by April 9, and that sponsorship opportunities are available.

Interested participants may register to attend two or three days of the workshop. Please contact lbeaston@americasblood.org if you have not received your invitation to register. For organizations interested in sponsorship opportunities, there are four sponsorship levels available. Organizations may review the sponsorship package at: http://members.americasblood.org/go.cfm?do=FileCenter.Get&fid=3605, and select a level of partnership that best fits its needs. Please contact Abbey Nunes at anunes@americasblood.org for additional sponsorship questions.

Additional information about the workshop is available for members at: http://members.americasblood.org/go.cfm?do=Page.View&pid=15. ♦

## AABB Publishes Clinical Practice Guideline for RBC Transfusion

More than 15 million units of whole blood and red cells (RBCs) are transfused annually in the US, but there is much variation among physicians in when they decide to transfuse patients. AABB recently published a clinical practice guideline providing recommended transfusion triggers to help facilitate the appropriate use of RBC transfusions when treating stable adults and children.

Members of AABB's Clinical Transfusion Medicine Committee, along with representatives from major stakeholders in transfusion practice developed this guideline. Jeffrey L. Carson, of the Robert Wood Johnson Medical School at the University of Medicine and Dentistry of New Jersey, was the lead author of the guideline. It was published online in the *Annals of Internal Medicine* on March 27.

Blood management and appropriate use of blood and blood products has been a central theme in the transfusion medicine world recently, especially since a June 2011 meeting of the Health and Human Services' Advisory Committee on Blood Safety and Availability. At the meeting, experts emphasized that there is excessive and inappropriate use of blood, and that developing appropriate transfusion triggers and blood management systems is vital to improving patient care.

**Methods.** The guideline authors created these recommendations based upon a systematic review of the literature from 1950 to February 2011 on randomized clinical trials evaluating transfusion thresholds. The authors examined the proportion of patients who received any RBC transfusion and the number of RBC units transfused to describe the effect of restrictive transfusion strategies on RBC use.

Among other requirements, studies included must have assigned transfusion groups on the basis of a clear transfusion trigger or threshold based on the hemoglobin level or hematocrit to be reached before RBC transfusion. To determine the clinical consequences of restrictive transfusion strategies, the authors examined overall mortality, non-fatal myocardial infarction, cardiac events, pulmonary edema, stroke, throembolism, renal failure, infection, hemorrhage, mental confusion, functional recovery, and length of hospital stay.

The researchers used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology to assess importance of each outcome in influencing the decision to administer a transfusion to a patient, and also to rate the quality of the evidence across all outcomes. The guidelines were designed to focus on hemodynamically stable adults and children who are candidates for RBC transfusion, and on hemoglobin concentration thresholds and other clinical variables that might trigger RBC transfusion.

**Trials Included.** After conducting the literature search, 19 trials met the inclusion criteria. Overall, 39 percent fewer patients received transfusions in the restrictive group than in the liberal group. The mean number of RBC units transfused was 1.9 units lower and the mean hemoglobin concentration before transfusion was 1.48 g/dL lower in the restrictive group.

**The Guideline.** AABB made four main recommendations for various patient groups.

- Recommendation 1: AABB recommends adhering to a restrictive transfusion strategy, using a hemoglobin level of 7 to 8 g/dL in hospitalized, stable patients as a transfusion trigger.
- Recommendation 2: AABB suggests adhering to a restrictive strategy in hospitalized patients with preexisting cardiovascular disease and considering transfusion for patients with symptoms of a hemoglobin level of 8 g/dL or less.

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AABB RBC Transfusion Guideline (continued from page 10)

- Recommendation 3: AABB cannot recommend for or against liberal or restrictive transfusion threshold for hospitalized, hemodynamically stable patients with acute coronary syndrome.
- Recommendation 4: AABB suggests that transfusion decisions be influenced by symptoms as well as hemoglobin concentration.

**Discussion.** In describing the evidence supporting Recommendation 1, the authors noted that restrictive transfusion resulted in lower mortality than did liberal transfusion, although that finding was not statistically significant. For most outcomes evaluated, the authors observed no evidence that restrictive transfusion strategy harmed patients. The ability to walk independently or length of hospital stay did not differ between the two groups. They noted that the three largest trials observing transfusion triggers conclusively showed a lack of benefit with liberal transfusion.

"On the basis of data from all the available randomized trials, the panel found little evidence to support a liberal transfusion strategy." They explain that 7 and 8 g/dL were chosen as the appropriate restrictive transfusion thresholds because those indicators were used in the three largest studies included. Despite concern about using restrictive transfusion strategies in cardiovascular disease patients, the panel recommended a restrictive strategy for this group because a large clinical trial (FOCUS) showed a statistically non-significant increase in myocardial infarction in the restrictive transfusion group, but not an increase in mortality.

If the restrictive strategy is implemented widely, exposure of patients to RBC transfusions would decrease by an average of 40 percent, which would have a large effect on blood use and the risks for infectious and non-infectious complications of transfusion. Although the blood supply is very safe now, with extremely low risks of getting an infectious disease from transfusion, decreasing unnecessary transfusions can improve patient care.

**Looking Ahead.** The researchers recommend that future research in this area focus on wider patient populations such as patients with acute coronary syndrome, elderly patients recovering from illness acquired as a result of hospitalization, patients with gastrointestinal bleeding, and transfusion-dependent patients. Also, future trials should explore lower hemoglobin thresholds in intensive care unit patients, write the authors.

"In order to avoid unnecessary transfusions, AABB developed this guideline to provide clinicians with evidence-based recommendations about when it is appropriate to transfuse," said Dr. Carson in an AABB press release. "Optimal patient care should involve administering enough red blood cells to maximize clinical outcomes while avoiding transfusions that expose patients to potential infectious or noninfectious risks and increase medical costs." The guideline is available at: http://bit.ly/HcvWce.

**Citation:** Carson JL, *et al*. Red Blood Cell Transfusion: A Clinical Practice Guideline From the AABB. Ann Intern Med. 2012 March 26. [Epub ahead of print]

## CDC Announces New Funding to Support PEPFAR- Related Safe Blood Activities

The Centers for Disease Control and Prevention has announced a number of new grants that support efforts to strengthen blood collection and transfusion services in a number of countries participating in the President's Emergency Plan for AIDS Relief (PEPFAR) program.

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PEPFAR Grants (continued from page 11)

One grant, a modification of a previous grant notice, supports five grants of up to $15 million each to help maintain a safe blood supply in various unspecified PEPFAR host countries. That grant is open to a range of state, US territory, county, and local governments; nonprofit community-based organizations; for-profit organizations, including small, minority or women-owned businesses; universities and colleges; and native tribal governments.

More information on "Technical Assistance Support for the Strengthening of Blood Transfusion Services in Selected Countries under the President's Emergency Plan for AIDS Relief" is available at: http://www.grants.gov/search/search.do;jsessionid=n9wPP7nPL7Hrct8lpZJyJKfMPYfQc9fjLLM2LWYQ75DVKjvL3DHd!98924490?oppId=158873&mode=VIEW. Please refer to funding opportunity number CDC-RFA-GH12-1255.

Two other grant notices seek applicants who can help ensure two specific countries in Africa are able to strengthen or sustain their safe blood collection activities.

CDC has announced a modification to a previous grants notice that supports Tanzania and Zanzibar. That notice announces a single award of $1.5 million, which is part of a $7.5 million program, to help Tanzania meet its safe blood collection targets.

Tanzania is a country in East Africa composed of 26 regions, including those of the semi-autonomous region of Zanzibar. According to the notice issued March 30, "Tanzania suffers from an acute shortage of blood donors, and the current number of donations is estimated to be only about 20 percent of the World Health Organization's estimated minimum requirements for the country."

There are three organizations that collect blood in Tanzania. The main one is the National Blood Transfusion Service (NBTS). CDC currently provides about 80 percent of the budget for NBTS, with the balance coming from that country's Ministry of Health and Social Welfare. The Tanzanian People's Defense Force also does some blood collecting through a sub-grant through NBTS. In March 2010, the NBTS established a five-year plan with blood collection targets but has so far fallen short of those targets. According to the notice, only the Tanzania Red Cross Society has the infrastructure in place to help NBTS meet its collection goals. Apparently then, the Red Cross Society will be the presumed recipient.

The notice was posted March 23 and the closing date is May 7, 2012. More information is available at: http://www.grants.gov/search/search.do;jsessionid=Km45P7vJzdntKJGnnv1JT1nYTytZ2NZryGNyM2rpKnMbtznlvpTG!98924490?oppId=149253&mode=VIEW. Please refer to opportunity number CDC-RFA-GH12-1235.

CDC also has announced a grant of $250,000, as part of a total program funding level of $650,000, to support blood collection efforts in Mozambique, in southeastern Africa. The grant will support community-based organizations that have been working with the Mozambique Ministry of Health to promote safe blood donation.

In 2011 the health authorities in the country estimated that about 1.7 million Mozambicans were HIV-positive with only about 240,000 receiving anti-viral treatment. According to the 2011 UNAIDS Report, the HIV/AIDS epidemic in Mozambique seems to be leveling off.

The notice was posted March 23 and the closing date is May 14, 2012. More information is available at: http://www.grants.gov/search/search.do;jsessionid=n9wPP7nPL7Hrct8lpZJyJKfMPYfQc9fjLLM2LWYQ75DVKjvL3DHd!98924490?oppId=151653&mode=VIEW . Please use funding opportunity number CDC-RFA-GH12-1255. (Source: Grants.gov, various dates)

## Congratulations on ABC's 50th Anniversary

As America's Blood Centers celebrated its 50th anniversary last week in Scottsdale, Ariz. during the Annual Meeting, various organizations and professionals that have worked with ABC sent their congratulations to ABC CEO Jim MacPherson. ABC also continues to receive tributes to its anniversary from various legislators and government leaders (see *ABC Newsletter*, 3/23/12). Below are some of these congratulatory notes.

(*Editor's Note:* Below is an excerpt from a speech drafted by Gilles Folléa and Jeroen de Wit to be read to ABC members at the Annual Meeting on behalf of the European Blood Alliance as EBA representatives could not attend the meeting.)

Dear ABC colleagues,

Different circumstances ... have impeded … executive member[s] of EBA to attend the celebration of America's Blood Centers' anniversary jubilee in Scottsdale. Despite our physical absence that we sincerely regret, we'd like to be associated to this exceptional event, unique in the life of all participants, in asking Jim to voice this speech on behalf of us.

We'd first like to warmly congratulate you and your predecessors who have actively contributed to a continuously improving transfusion service, while consistently defending and promoting the core values that ABC and EBA firmly share together: voluntary non-remunerated donations, nonprofit, advocacy for a continuously improving quality of blood products and services for the benefit of patients and donors …

[W]e'd like to take the opportunity of this extraordinary Jubilee, to reiterate with solemnity and strength, some important recent accomplishments resulting from our collaboration, and recall some outcomes expected from the future of our collaboration. Networking, with a constant exchange of information and data, is certainly the most important achievement gained from our partnership so far. The appreciated active participation of ABC colleagues in the EBA, now ABO extended, Emerging Infectious Diseases Monitor, to help timely monitor emerging Infectious Diseases, share preventive measures and bring expertise to members and regulators, is part of this networking …

Keeping all these good elements in mind, with many others, and convinced that we'll reinforce our effective partnership in the future, we wish you all and ABC a happy birthday and all the best for your missions and our collaboration at the service of patients and donors …

– Gilles and Jeroen
(View the full speech here: http://members.americasblood.org/go.cfm?do=FileCenter.Get&fid=3645)

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Dear Jim,

On behalf of all my colleagues from the Austrian Red Cross Blood Service and Blood Centers we wish you a joyful celebration of ABC's 50th Anniversary. We are sorry that we were unable to attend.

Congratulations to the strength and serving attitude of your organization developed by people described in your last article in your "Our Space" column.

Thank you so much for your contributions in European Blood Alliance meetings, especially in topics like

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Congrats to ABC (continued from page 13)

competition, which was a very important topic especially for Austria through the last five to six years. All the best for coming years. The challenges for all of us probably will not become less.

Kind regards from Vienna,

Dr. Guenther J Wittauer
Austrian Red Cross, Headquarters
Head of Blood Services

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Hi Jim & Celso,

Just a quick note to wish you and ABC a big Mazeltov (i.e. congratulations) on ABC's 50th birthday. It seems like just the other day that it was a mere child.

I wish that I could have been in Scottsdale for the celebrations, but as a part-timer, I don't get to attend as many meetings as before. On the bright side, my golf handicap has improved.

Talking about part time/retirement, I noted that you, Celso, will soon be part of the club. ABC won't seem the same without you, but I know that you will enjoy the freedom to do other things (plus you get to add "emeritus" after your title).

All the best to both of you.

I hope that we will meet soon (e.g. at the AABB meeting … I need the CME's).

Regards,

Norman D. Kalmin, MD
CEO (emeritus) and Medical Director
QualTex Laboratories

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Dear Jim,

I would like to express my deep congratulations, for ABC's 50 Anniversary. Hopefully in tomorrow land, futures generation in Latin American will celebrate too the alliance among blood banks.

Enjoy the celebration; you have worked hard!!

Un abrazo,

Marcela Garcia
Blood Services and Transfusion Safety Consultant

United States of America

# Congressional Record

PROCEEDINGS AND DEBATES OF THE 112th CONGRESS, SECOND SESSION

## House of Representatives

**March 27, 2012**
**Remarks of Representatives Mike Thompson**
**Honoring America's Blood Centers**

Mister Speaker, I rise today in recognition and praise of America's Blood Centers (ABC), North America's most expansive network of non-profit, community-based blood donation centers. The organization will be celebrating its 50th anniversary this year, and this gives us occasion to honor ABC's and independent blood centers' great contributions to our communities over the years.

In particular, I would like to honor the special contributions to patients in my district made by Northern California Community Blood Bank, based in Eureka, California. Northern California Community Blood Bank is a proud and active member of America's Blood Centers, and its administrator, Thomas Schallert, is a past president of the national organization.

Founded in Scottsdale, Arizona in 1962, America's Blood Centers serves more than 150 million patients by providing blood products and services to more than 3,500 hospitals and healthcare facilities. All told, the organization's members provide half of the US blood supply, and a quarter of that used in Canada.

Founded and operating on the core principals of innovation, data integration, education and advocacy, the organization developed the Appropriate Inventory Management system, the only national database of individualized laboratory, patient and donor information. This infrastructure is absolutely critical to the success of America's Blood Centers; upwards of 40,000 pints of blood are needed every day in America.

The organization's service and influence have also helped to make members of the public more aware of the need for donated blood across the country. Through outreach and education programs such as My Blood, Your Blood, America's Blood Centers has promoted regular blood donation among willing participants, ensuring a safe blood supply and improving the response capacity and emergency preparedness of federal and state agencies.

Mister Speaker, it is appropriate at this time that we extend to America's Blood Centers our gratitude and congratulations on their 50th anniversary. The organization's success has been to the benefit of our country and those who live here, and we are deeply indebted for this important work.

**Rep. Mike Thompson**
**First District, California**

## BRIEFLY NOTED

**A federal appellate court last week (3/27/12) rejected a US Department of Justice request that it reconsider its ruling in December that allows peripheral blood stem cell (PBSC) donors to be compensated.** The Obama administration has 90 days to file an appeal with the US Supreme Court. In December, a three-judge panel of the 9th Circuit Court of Appeals in California ruled that PBSC donors could be compensated. They based the decision on a finding that harvesting marrow stem cells from a donor's blood stream is more like giving a blood donation than donating an organ. The panel also found that the PBSC method is not specifically covered by the National Organ Transplant Act, which forbids paying donors of bone marrow, with violations punishable by jail time. In January, the Justice Department asked the full 11-judge panel to reconsider that ruling. According to the Associated Press (3/27/12) and other news organizations, none of the 25 active judges in the 9th Circuit Court supported the request. America's Blood Centers is part of a coalition of eight health organizations that issued a statement supporting the Department of Justice's appeal of the 9th Circuit Court ruling, citing the potential for serious health risks to patients and donors if the ruling stands. ABC continues to support the position of the coalition. A paper that gives the legal and medical reasons for ABC's support for voluntary donation of blood, tissue, stem cells, and organs is posted on the ABC website at:
http://www.americasblood.org/go.cfm?do=Statement.List (Source: The Associated Press, 3/27/12)

## REGULATORY NEWS

**The Food and Drug Administration released a guidance on March 28 titled "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Clarifications."** This draft guidance document was published for comments, which are due by August 15. The guidance provides guidelines for FDA medical device reviewers and the industry to follow when making benefit-risk determinations during the premarket review process for certain medical devices. "FDA believes that the uniform application of the factors listed in this guidance document will improve the predictability, consistency, and transparency of the premarket review process," states the guidance. This guidance applies specifically to premarket approval (PMA) applications or *de novo* classification petitions. The PMA process is the regulatory pathway for regulatory review of high-risk medical devices. When reviewing a device for PMA, FDA reviewers evaluate data to ensure that the probable benefits of the device outweigh the probable risks. FDA states in the guidance that while there is a heavy emphasis on clinical data, non-clinical data can be important to evaluating the safety and effectiveness of the device as well. One interesting element included for reviewers to consider in making risk-benefit determinations is the patient tolerance for risk and the patient perspective on the benefit. The guidance explains that if the risk is identifiable, the patient may be willing to accept a certain amount of risk. Also, the patient's perceived benefit from the treatment, such as improving quality of life, may make them more tolerant of risk. Elements such as the severity of the illness and the availability of other treatments should be taken into account when FDA reviewers are making risk-benefit determinations, says the guidance. The guidance describes in detail the factors to be considered in making a risk benefit determinations within categories of: assessment of the benefits of devices; assessment of the risks of devices; and additional factors in the assessment of the probable benefits and risks of devices. The document also provides examples of benefit-risk determinations, as well as a worksheet for FDA reviewers to complete when making their risk-benefit determinations. FDA hopes that by providing this worksheet, medical device organizations seeking approval will better understand reviewer expectations when submitting a PMA application. The guidance is available at: http://1.usa.gov/qaX7C7 (Source: FDA guidance, 3/28/12)

**REGULATORY NEWS** (continued on page 16)

**REGULATORY NEWS** (continued from page 15)

**The Centers for Disease Control and Prevention has published a correction to its "Guidelines for Safe Work Practices in Human and Animal Medicine Diagnostic Laboratories – Recommendations of a CDC-convened Biosafety Blue Ribbon Panel."** The guidelines were originally published in the CDC's *Morbidity and Mortality Weekly Report* (MMWR) on Jan. 6, and the correction was published on March 30 also in the MMWR (see *ABC Newsletter*, 1/13/12). On page 72, the sixth bullet of paragraph 11.4.1 should read, "Gloves should be worn when spiking or otherwise entering blood bags. The blood banks should have written procedures to decontaminate or discard blood or component containers visibly soiled with potentially infectious materials (i.e., wiping with an alcohol pad or swab) (Buchta C, Blacky A, Leitner GC, et al. Surface disinfection of packed red blood cells with 70% ethanol. Int J Surg 2006;4:118–21)." These guidelines are meant to promote a culture of safety and supplement the previously published Biosafety Microbiological and Biomedical Laboratories, now in its fifth edition. The guidelines can be accessed at: http://1.usa.gov/wxMapz and the correction can be accessed at: http://1.usa.gov/HlZD9R. (Source: CDC MMWR, 3/30/12)

**The Food and Drug Administration announced in a press release on March 27 the approval of Omontys (peginesatide) to treat anemia in adult dialysis patients who have chronic kidney disease (CKD).** Omontys is a new erythropoiesis-stimulating agent (ESA) that aids in the formation of red blood cells (RBCs). It works by stimulating the bone marrow to produce more RBCs and reduces the need for transfusions in patients with CKD. The drug is administered as a once-monthly injection. Two randomized, active-controlled, open-label, multi-center clinical trials demonstrated the safety and efficacy of Omontys in patients with CKD who were on dialysis. The trials randomly selected a total of 1,608 patients with hemoglobin levels initially stabilized by ESA to receive either Omontys once monthly or to continue their current ESA (epoetin) treatment, said the release. Results showed Omontys was as safe and effective as epoetin in maintaining hemoglobin levels within the studies' pre-specified range of 10 to 12 grams per deciliter. The most common side-effects observed in 10 percent or more of dialysis patients treated with Omontys were diarrhea, vomiting, high blood pressure, and joint, back, leg or arm pain. Omontys should not be used in CKD patients who are not receiving dialysis or in patients with cancer-related anemia, according to the FDA label. It should also not be used as a substitute for RBC transfusions in patients who require immediate correction of anemia. The press release is available at: http://1.usa.gov/HeSqFs. (Source: FDA press release, 3/27/12)

**The Food and Drug Administration announced in a March 27 press release that it has approved the Avioq HTLV-I/II Microelisa System, a test designed to screen blood donors for antibodies to human T-lymphotropic virus (HTLV) I and II.** The test was created in partnership by Ortho Clinical Diagnostics and Avioq, Inc. Since 2008, there has been only one FDA-licensed donor screening test available for detecting antibodies. Adding this test will provide greater flexibility for blood establishments and help to ensure the safety of the blood supply, said Karen Midthun, MD, director of FDA's Center for Biologics Evaluation and Research. HTLV-I, first identified in 1980, is known as the etiologic agent for adult T-cell leukemia and myelopathy/tropical spastic paraparesis, an inflammatory disease of the central nervous system. HTLV-II is a closely related virus to HTLV-I and is associated with neurological disorders. Both HTLV-I and HTLV-II can be transmitted through transfusion, reuse of syringes, and by breast feeding from infected mothers. Screening of all blood donors in the US for evidence of HTLV infections is required. The Avioq HTLV-I/II Microelisa System is now the only test available that can be used to screen for antibodies to both HTLV-I and HTLV-II. This new test is approved for use in screening donated blood for HTLV antibodies and for testing serum and plasma specimens to screen potential organ donors obtained while the donor's heart is still bleeding, said the release. The test is not

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**REGULATORY NEWS** (continued from page 16)

intended to be used to screen cord blood specimens or cadaveric blood specimens. An Ortho Clinical Diagnostics press release explained that the Avioq HTLV-I/II System assay is compatible with the Ortho Summit System platform. The FDA press release is available at: http://1.usa.gov/GXJRP4. (Source: FDA press release, 3/27/12; Ortho Clinical Diagnostics press release, 3/27/12)

**The Centers for Disease Control and Prevention has updated its recommendation for antimalarial prophylaxis for travelers who stay overnight in Great Exuma, Bahamas, according to the CDC website.** This recommendation comes after CDC identified a *Plasmodium falciparum* malaria case in a US traveler to the island. The traveler visited Great Exuma, Bahamas, between February and March 2012 and reported no other recent travel outside of the US. Because P. falciparum can result in severe life-threatening illness without prompt treatment, CDC has taken the step to recommend antimalarial prophylaxis. CDC's current recommendation for antimalarial medication is for travelers who may stay overnight in Great Exuma, Bahamas, only. Any of these four drugs can be prescribed: atovaquone/proguanil (Malarone), chloroquine, doxycycline, or mefloquine. Travelers to other islands presently do not need to take an antimalarial drug. According to AABB's Standards for Blood Banks and Transfusion Services, 27th Edition, blood donors should be deferred for 12 months following travel to Great Exuma. Based on the likelihood that transmission first occurred in February, and to allow for the possibility that transmission could have occurred prior to the first detected case, deferral should be implemented for travel as of Jan. 1 2012. This recommendation is expected to be temporary, said CDC. The CDC update can be viewed at: www.cdc.gov/malaria/new_info/2012/malariabahamas.html. (Source: CDC website update, 3/30/12; AABB Weekly Report News Flash, 4/4/12)

**The Food and Drug Administration has recently published a list of frequently asked questions about minimally manipulated, unrelated cord blood products for clinical use on its website.** FDA has issued two guidance documents on minimally manipulated, unrelated cord blood. One guidance is intended to assist manufacturers of cord blood in obtaining biologics licenses, and the other is intended to assist potential sponsors in the submission of Investigational New Drug (IND) applications for the use of unlicensed cord blood for a particular patient. FDA has received questions from manufacturers, health care professionals, and others about these guidances, and the agency seeks to respond to these concerns through the FAQs. The FAQs are meant to help clarify FDA's guidance documents and IND requirements "for minimally manipulated, unrelated allogeneic placental/umbilical hematopoietic progenitor cells-cord (HPC-C) for hematopoietic and immunologic reconstitution in patients with disorders affect the hematopoietic system that are inherited, acquired, or resulted from myeloablative treatment," said the FDA website. The FAQs can be accessed at:
www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Industry/ucm297329.htm. (Source: FDA FAQs, 3/26/12)

**The US government released a new policy on March 29 that will require federal agencies to systemically review the potential risks associated with federally funded studies involving 15 "high consequence" pathogens and toxins, reported *Science*Insider, a news blog on the journal *Science's* website.** The reviews are designed to reduce the risks associated with "dual use research of concern" (DURC) that could be used for good or evil, reported *Science*Insider. The new DURC policy will expand the current reviews already conducted by two major biomedical research funding agencies, the National Institutes of Health and the Centers for Disease Control and Prevention. Both agencies already review intramural studies proposed by staff scientists for dual-use potential, and now they will extend those reviews to extramural projects conducted by scientists at universities and other institutions. The new rules would also apply to any other federal agency funding unclassified biological research, such as the US Department of Agriculture and the Department of Defense. The new policy requires agencies to review

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**REGULATORY NEWS** (continued from page 17)

both proposed projects and those already funded. If a review identified DURC potential, the funding agency, the institution, and the lead scientist are supposed to develop a "risk mitigation plan," reported *Science*Insider. It could include efforts to modify how the research is conducted, move it to a more secure lab, or communicate it to the public and other scientists responsibly. For especially problematic studies, agencies will determine whether to "request voluntary redaction of the research publications or communications," or to classify the findings. The policy requires agencies to report to the White House within 60 days on how many proposed or ongoing studies involve the 15 targeted agents, and within 90 days on how many DURC projects their reviews have identified. The 15 targeted agents are: avian influenza virus; *Bacillus anthracis;* Botulinum neurotoxin; *Bukholderia mallei; Burkholderia pseudomalle*, Ebola virus; Foot-and-mouth disease virus; *Francisella tularenis*, Marburg virus; reconstructed 1918 influenza virus; rinderpest virus; toxin-producing strains of *Clostridium botulinum;* variola major virus; variola minor virus; and *Yersinia pestis*. The new policy is available at: http://bit.ly/GWmcjF. (Source: *Science*Insider, 2/29/12) ♦

## GLOBAL NEWS

**Blood donors in England and North Wales who have traveled to countries where West Nile Virus (WNV) is prevalent will begin being screened for WNV by May 1, reported the *Wiltshire Times*, a UK newspaper, on March 28.** Previously, blood banks in England and North Wales used donor questionnaires to defer people who had returned from a WNV endemic area for 28 days. The adoption of WNV screening means that donors returning from these areas will be allowed to donate, leading to a decrease in deferrals. "Ensuring the safety and sufficiency of the blood supply is a priority. Testing for WNV ensures the risk of infection is removed, while helping to keep blood stocks more stable over the summer months," Lorna Williamson, MD, Medical and Research director for the UK's National Health Service Blood and Transplant, told the *Wiltshire Times*. Tests will be carried out on donations during the risk period, May 1 to November 30, when less than four weeks have passed since the donor's return from an area where WNV is endemic. The *Wiltshire Times* article is available at: http://bit.ly/HiKfhs. (Source: *Wiltshire Times*, 4/5/12)

**DG Health and Consumers (SANCO), a department of the European Commission and the regulatory agency of the European Union, recently released a document entitled "Guidelines on a Medical Devices Vigilance System."** The guidelines are designed for manufacturers of medical devices and other stakeholders involved, and they outline the process for reporting adverse events related to medical devices. The guidelines update current regulations on medical device reporting, addressing the introduction of European medical device database EUDAMED. The entire guideline can be viewed at: http://ec.europa.eu/health/medical-devices/files/meddev/2_12_1_ol_en.pdf. (Source: DG SANCO guideline, 3/27/12) ♦

## INFECTIOUS DISEASE UPDATES

### DENGUE VIRUS

A group of researchers from Purdue University have identified enzymes and biochemical compounds called lipids that are targeted and altered during infection by the dengue virus, reported Medical News Today. The findings, published on March 22 in the open access journal *PLoS Pathogens*, may indicate a

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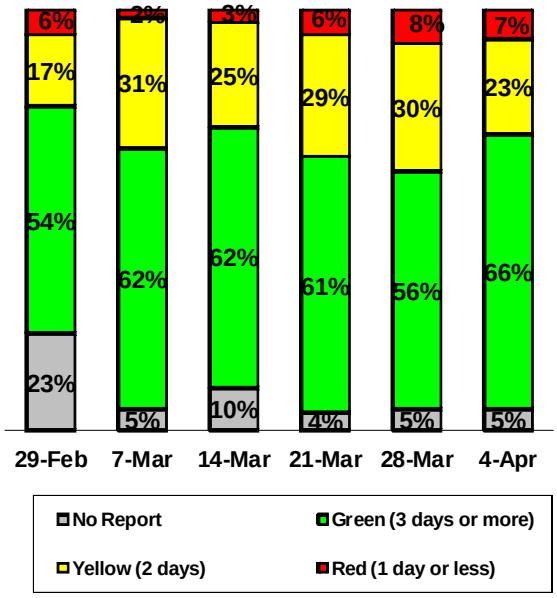
**INFECTIOUS DISEASE UPDATES** (continued from page 18)

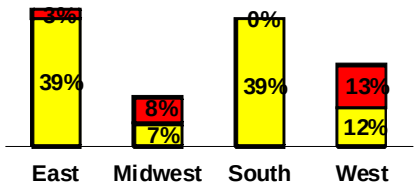
potential new approach to control the virus. The team's findings also indicate that drugs used to treat other lipid-related conditions, such as high cholesterol, might prevent the virus from replicating and could be used as a potential new treatment. The team discovered how infected mosquito cells alter certain lipids in membranes and in biochemical sensors that warn cells of invading viruses, reported Medical News Today. "The virus reorganizes the internal architecture of the cell to support its own needs. Many details are unknown. This is our first attempt to understand how the virus alters lipids as part of the infection process. Part of what we looked at in this work was how the virus changes the cell, and the next step will be to figure out why," Rushika Perera, a research scientist at Purdue University, told Medical News Today. The team gained new insight into how the virus changes lipids in membranes surrounding organelles, including the mitochondria and endoplasmic reticulum. Mitochondria are the cell's power generators while the endoplasmic reticulum is responsible for the production of proteins and lipids, reported Medical News Today. "Findings also show that important host enzymes are used by the virus and may be targets for future antiviral drugs. It turns out the pills you take to control your cholesterol might have some capability to control dengue," Richard J. Kuhn, a professor and head of Purdue University's Department of Biological Sciences, told Medical News Today. The study can be viewed at: http://bit.ly/H5g0HQ. (Source: Medical News Today, 3/22/12)

## STOPLIGHT: Status of America's Blood Centers' Blood Supply

**Total ABC Red Cell Inventory**




**Percent of Regional Inventory at 2 Days Supply or Less, April 4, 2012**




**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

## GRANT OPPORTUNITIES

**The Centers for Disease Control and Prevention has issued a notice of a state grant opportunity to expand the work of the Registry and Surveillance for Hemoglobinopathies (RuSH) project to address "Blood Disorders and Blood Safety," which is designated as the new Health People 2020 topic.** Up to three awards of up to $250,000 are available with no cost sharing or matching requirement. Eligibility is limited to a "state [or territory] agency, its bona fide agent or its equivalent, as designated by the Governor, Health Office, or other state executive as the official applicant for this program," says the grant notice. It was posted on March 30 with a closing date for applications of May 30. Refer to opportunity number CDC-RFA-DD12-1206. The demonstration project will address: surveillance, health promotion, prevention awareness, and laboratory capacity building. Hemoglobinopathies refers to a group of blood disorders and diseases that affect red blood cells, including such inherited disorders as sickle cell disease (SCD) and thalassemia. The Registry and Surveillance System for Hemoglobinopathies (RuSH) is designed to collect information to learn about the number of people living with SCD and thalassemia so to better understand how these disorders affect their health. RuSH is being coordinated by CDC in collaboration with the National Institutes of Health and seven pilot states – California, Florida, Georgia, North Carolina, New York, Michigan and Pennsylvania. The immediate goals of the RuSH pilot project are to determine how many people have SCD or thalassemia; develop plans for a national surveillance system to help understand the health status and practices of people living with SCD and thalassemia; and develop health education materials to increase knowledge and awareness of SCD and thalassemia among members of the general public. More information about the demonstration grant project can be found at: http://www.grants.gov/search/search.do;jsessionid=hvWnP7XWv2wTGpYvGqTr28hry1FJ1pTqnGrdsgPpP8hFPHdJ7W2T!-757993493?oppId=160333&mode=VIEW. More information on the RuSH project can be found at: http://www.cdc.gov/ncbddd/hemoglobinopathies/documents/RuSHfactsheet2010.pdf

**A recently issued federal funding opportunity notice encourages grant (R01) applications for collaborative systems biology research projects to advance understanding of "normal physiology and perturbations associated with heart, lung, blood, and sleep diseases and disorders."** The notice was issued on March 23 by the National Heart, Lung, and Blood Institute of the National Institutes of Health. A wide range of state, county, and local agencies and nonprofits, as well as for-profit small businesses, are eligible to apply. The closing date for applications is Jan. 13, 2015. Please use funding opportunity number PAR-12-138. No award ceiling or estimated total program funding limit is specified in the notice. However, "Multi-disciplinary expertise across experimental and computational domains is required…" The funding opportunity notice, "NHLBI Systems Biology Collaborations," is available at: http://www.grants.gov/search/search.do;jsessionid=2TT7P7gTJTdQcL4cTFHsnxy0tpCRrHkjCJy1nxMhGdqhzT5nyngT!-757993493?oppId=158054&mode=VIEW ♦

## MEMBER NEWS

**South Texas Blood & Tissue Center's (STBTC) Board of Directors announced in a press release on April 2 that it has created a new holding company that will oversee its two operating units, STBTC and QualTex Laboratories, and its supporting foundation.** The board also announced that it has appointed Dennis K. Fallen as CEO of the holding company, which will encompass STBTC's full range of tissue services and QualTex Laboratories' blood and plasma testing. The new organization that Mr. Fallen will lead is yet to be named. STBTC is asking the IRS to approve the new holding company as a nonprofit 501(c)(3) organization before it will become fully operational. Mary Beth Fisk will remain president and chief operating officer (COO) of STBTC and executive director of the Blood & Tissue Center

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**MEMBER NEWS** (continued from page 20)

Foundation, while Linda Kay Myers serves as president and COO of QualTex, said the release. "The board believes Dennis Fallen's leadership experience with several premier biomedical organizations will provide the seasoned broad-based management and planning expertise that our expanding organization needs to move boldly in to the future," said STBTC Board of Directors Chairman Dennis Stahl. Mr. Fallen has served as vice president and general manager of Fisher Bioservices since 2007, and assumed his role with STBTC on April 2. He has also worked at Baxter Healthcare and the American Red Cross and is retired from the US Navy, where he was a healthcare administrator in the Medical Service Corps. "The South Texas Blood & Tissue Center and QualTex Laboratories are widely respected throughout the healthcare world," Mr. Fallen said in the release. "They have spent years earning a reputation for extremely high quality, meticulous attention to detail, and always thinking of patient needs first. They are also developing exciting new plans for the future, and I am thrilled to have this opportunity to help lead these great organizations." (Source: STBTC press release, 4/2/12)

**Community Blood Center of the Carolinas (CBCC) recently recognized its top blood drive donors and sponsors from 2011, CBCC announced in a press release on March 26.** More than 200 people joined in at the celebration at CBCC's annual awards banquet at The Palmer Building. CBCC gave several awards to individual donors and to blood drive sponsors and community partners. Robert White of Piedmont Medical Center received the award for Advocate of the Year; Rick Hendrick received the President's Award; Steve Lentz and Debra Williams received the Platelet Donors of the Year Award, The Santos Family, Claudia Douglass, Joe Richmond, and Joe and Amy Clipston received special recognition; and Jon Wilson of FOX News Rising, the Charlotte Checkers, and Microsoft Corporation received the Vision Awards. Hendrick Motorsports received the Corporate Sponsor of the Year Award; Red Ventures received the Small Business of the Year Award; Central Piedmont Community College received the College of the Year Award; West Stanly High School received the High School of the Year Award; Elevation Church received the Religious Organization of the Year and the New Sponsor of the Year Awards; Siskey YMCA received the Community Group of the Year Award; Floyd D. Johnson Technology Center received the Largest Blood Drive of the Year Award; and Carolinas Medical Center-Union received the Committee of the Year Award. "We deeply appreciate our blood donors and sponsors, all of whom are incredibly generous and strongly committed to the patients of our community," said CBCC CEO and President Martin Grable. "This event was a poignant reminder of the power of what community can do when we join together. Honoring these individuals and community partners was the least we could to do show our appreciation for their unwavering dedication to helping save local lives." (Source CBCC press release, 3/26/12)

## PEOPLE

**James Berger, MS MT (ASCP) SBB,** has been appointed as the senior advisor for Blood Policy in the Office of the Assistant Secretary for Health (OASH), wrote Robert O. Valdiserri, MD, MPH, the deputy assistant secretary for health in the Office of HIV/AIDS and Infectious Disease Policy, in a letter to colleagues. Mr. Berger has been serving as the interim senior advisory for Blood Policy since September when Jerry Holmberg, PhD, stepped down from the position. The letter from Dr. Valdiserri notes that the Office of Blood Safety and Availability has recently been moved into the Office of HIV/AIDS and Infectious Disease Policy. Mr. Berger joined the Department of Health and Human Services in January 2011

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**PEOPLE** (continued from page 21)

as the associate public health advisor for Blood, Organ, and Tissue Safety Policy. His previous work experience was with the Department of Veterans Affairs as the National Enforcement Officer for laboratory quality and as the Department of Defense's functional manager for identifying and standardizing the blood bank software requirements that were used in the military for both peacetime and contingency operations. He has also worked with the American Red Cross as a senior manufacturing engineer, developing and testing new products, equipment, and processes. During his military career, Mr. Berger was the chief of the Air Force Blood Program, Medical Readiness Division. In that position he was responsible for developing policies and procedures to issue rapid expansion, mobilization, and deployment of medical resources to support Air Force Contingency Operations worldwide. Jim has earned his master's degree in applied biology, immunohematology, and guidance counseling. During his Air Force Service, Mr. Berger was selected to attend the Immunohematology Fellowship at Walter Reed Army Medical Center where he received his MT (ASCP) SBB certification. (Source: NHLBI letter, 435/12)

**Charlie Mosher** will be retiring as president and CEO of Blood Centers of America (BCA) at the end of 2012 after 23 years leading the organization, BCA announced in a press release on April 3. During Mr. Mosher's tenure as BCA's president, BCA has grown from eight blood center members to 38. Additionally, Canadian Blood Services and the Hemophilia Alliance GPO are also affiliated with BCA. BCA has grown from a simple group purchasing organization, expanding to provide programs in operation improvement through benchmarking, networking, and targeted education activities. Under Mr. Mosher's leadership, the organization has also created a biological business that includes a blood exchange, a plasma and derivatives program and sourcing clinical and manufacturing grade materials. "I've thoroughly enjoyed every single day that I've worked for BCA. The BCA staff, member blood centers, their staff and the individuals we deal with through all of our contracts and programs in the industry have been the source of great inspiration for me to do my best to lead BCA." Mr. Mosher said in the release. "Although there is no perfect time for making a decision like this, I think this is the right time for me to step aside and let a new CEO write BCA's next chapter." (Source: BCA press release, 4/3/12)

**Gary H. Gibbons, MD,** has been appointed the new director of the National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI), announced an NIH press release on Thursday. Dr. Gibbons is the founder and current director of the Cardiovascular research Institute, chairperson of the Department of Physiology, and professor of physiology and medicine at the Morehouse School of Medicine in Atlanta. He is expected to begin serving in his new role at NHBLI in summer of 2012. Dr. Gibbons' institute at Morehouse is recognized for its discoveries related to cardiovascular health of minority populations. His laboratory is focused on discovering novel mediators of vascular disease. "It is my sincere pleasure to welcome Dr. Gibbons to the NIH team," said Francis S. Collins, MD, PhD, NIH director. "His extraordinary scientific skills, tremendous energy and bold vision will be an asset to NHLBI and NIH." Susan B. Shurin, MD, will continue as acting director of NHLBI until Dr. Gibbons joins, at which point she will resume her role as the institute's deputy director. "I want to extend my deep gratitude to Susan for her strong leadership in this role," added Dr. Collins. Dr. Gibbons will oversee the third largest institute at NIH and will also direct his own NIH lab, focusing on predictive health and genomic medicine in minority populations. Dr. Gibbons has served as a member of the National Heart, Lung, and Blood Advisory Council (NHLBAC) since 2009, a position he resigned from after being selected to serve as director at NHBLI. He was also a member of the NHLBI Board of Extramural Experts, a working group of the NHLBAC. He has received 16 NHLBI-supported grants since 1997. Under his leadership of the Cardiovascular Research Institute, Dr. Gibbons directed NIH-supported research in the

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fields of vascular biology, genomic medicine, and pathogenesis of vascular diseases. The institute emerged as a center of excellence during his tenure. Dr. Gibbons earned his undergraduate degree from Princeton University in Princeton, N.J., and graduated magna cum laude from Harvard Medical School in Boston. He completed his residency and cardiology fellowship at the Harvard-affiliated Brigham and Women's Hospital in Boston. He has also held faculty positions at Stanford University in Stanford, Calif., and at Harvard Medical School. He has received numerous honors throughout his career such as election to the Institute of Medicine of the National Academies of Sciences. "It's an honor to join the NIH and lead the Heart, Lung, and Blood Institute," said Dr. Gibbons. "The globally recognized research and training supported by the NHLBI continues to advance biomedical knowledge in fields related to heart, lung, and blood diseases. I look forward to working with the institute staff and with the many researchers supported by the Institute to foster multidisciplinary approaches to improve disease prevention, diagnosis, and treatment that will advance the health of all Americans." (Source: NIH press release, 4/5/12)

## COMPANY NEWS

**The Food and Drug Administration recently cleared Fenwal to market two items: a therapeutic plasma exchange protocol on its Amicus separator and the Aurora system for plasma collection, announced Fenwal in press releases this week.** Fenwal's first announcement this week discussed FDA's approval of the Amicus separator from Fenwal available for therapeutic plasma exchange and mononuclear cell collection, both used to treat a wide variety of diseases and for clinical research. Therapeutic plasma exchange (TPE) removes substances like antibodies and enzymes from the blood that damage cells and tissues in the course of certain diseases. The procedure is performed in hospitals primarily to treat auto-immune diseases, reported Fenwal. In clinical trials, TPE on the Amicus separator achieved high plasma removal efficiency and low platelet loss, while maintaining accurate fluid balance control, Fenwal reported. The Amicus separator is currently used to collect platelets, concurrent plasma, and red cells. The TPE protocol is also available for the Amicus separator in Europe and Latin America. Fenwal's second announcement this week discussed FDA's clearance for marketing of a new source plasma collection system, Aurora. The Aurora plasmapheresis system is a new device that can support two-way wireless data communication designed to eliminate manual steps. "Aurora is a significant innovation for plasma collection professionals," William Cork, Fenwal chief technology officer, said in the release. "Aurora features powerful new capabilities, such as an interactive touch-screen display with intuitive menus and icons, and comes with the Fenwal DXT Relay software, which delivers productivity reports and enables remote procedure set-up and paperless documentation." Plasmapheresis is an automated process in which plasma is taken from donated blood and the remaining cellular components are returned to the donor. Source plasma is used by pharmaceutical companies to produce plasma-derived proteins like albumin, anti-hemophilic factors and intravenous immunoglobulins. Fenwal's press releases are available at:
www.fenwalinc.com/PressReleases/Pages/NewsAndEvents.aspx. (Source: Fenwal press releases, 4/2/12, 4/3/12)

**Haemonetics Corporation recently issued a voluntary recall of its 0694S-00-Plasma Bottle with Saline Adapter due to a labeling discrepancy, announced a Food and Drug Administration update.** Haemonetics recently discovered a label discrepancy on the outer carton of Haemonetics' Plasma Bottles with Saline Adapter lot 1201553B. An undetermined quantity of product from lot number 1201553B contains an incorrect expiration date on the outer carton label only. The individual bottles contained within these cases are labeled correctly with list number, lot number, and expiration date. The wrong

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expiration date is identified as 2014-10, while the correct expiration date should be 2012-01. Haemonetics has confirmed that this issue is isolated to this specific lot. Customers are asked to contact Haemonetics to arrange for product return. The FDA announcement is available at: http://1.usa.gov/I7PhXX. (Source: FDA Vaccines, Blood & Biologics Recalls, 3/27/12) ♦

## MEETINGS

May 15-16 **FDA Blood Products Advisory Committee Meeting, Gaithersburg, Md.**

The Food and Drug Administration has announced a meeting of the Blood Products Advisory Committee on May 15 and 16 at the Hilton Washington DC/North Gaithersburg in Gaithersburg, Md. The agenda for May 15 includes an evaluation for safety and effectiveness of OraQuick In-Home HIV Test. On May 16, the committee will discuss the evaluation of possible new plasma products frozen following in-process storage at room temperature for up to 24 hours, namely plasma for transfusion prepared from whole blood held at room temperature for up to 24 hours prior to separation and freezing, or from apheresis plasma held at room temperature for up to 24 hours before freezing. In the afternoon, the committee will hear update presentations on the following: Health and Human Services activities related to the evaluation of the donor deferral policy for men who have sex with other men; a summary of the Nov. 8-9, 2011 public workshop on hemoglobin standards and maintaining an adequate blood supply; and a summary of the Nov. 29, 2011 public workshop on data and data needs to advance risk assessment for emerging infectious diseases for blood and blood products. FDA intends to make background materials available no later than two business days before the meeting at: www.fda.gov/AdvisoryCommittees/Calendar/ucm298625.htm. Those interested in submitting information or data to be presented at the meeting must submit these materials to the contact person by May 8. The Federal Register announcement is available at: www.gpo.gov/fdsys/pkg/FR-2012-04-05/html/2012-8167.htm.

Contact: Bryan Emery of Rosanna Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD. Questions may be directed to (301) 827-1297 ♦

## 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 $390 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: mnorwood@americasblood.org.

## POSITIONS AVAILABLE:

**Quality Assurance Specialist (Lane Blood Center, Eugene, Oregon).** Analyze and interpret blood banking regulations and inform management how to stay in compliance. Coordinate FDA variance reporting; process donor deferrals and other required notifications. Manage the research and submissions of Biological Product Deviation Reports, the Annual Report and Biologic License Amendments to the FDA. Manage all document control policies and procedures. College

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**POSITIONS** (continued from page 24)

degree required; prefer biologic science. Minimum two years QA experience in regulated environment. Project management skills and close attention to detail required. Ability to think critically, solve problems and make decisions related to compliance. Conflict resolution skills essential. Must have basic understanding of FDA regulations; quality systems and cGMPs. Apply at www.laneblood.org, "Job Opportunities." Lane Blood Center, 2211 Willamette Street, Eugene, OR. (541) 484-9112.

**Chief Executive Officer (CEO), Greater Chesapeake and Potomac.** The American Red Cross is seeking a Chief Executive Officer (CEO) in Baltimore, MD. The CEO leads region wide activities to accomplish goals and objectives for the blood region; works in a collaborative fashion on project teams and leads change initiatives; develops and implements projects and plans to increase collection efficiency and collection totals and to identify and exceed hospital customer expectations; and insures that all region activities are carried out in compliance with Red Cross, FDA, and other applicable Fed, state, and local regulations. Additionally, the CEO monitors budgets, forecasts, and operational results and takes appropriate actions. Qualified candidates possess a bachelor's degree/equivalent experience and ten years' experience in a multi-task operational environment with budget responsibility or a profit/loss focus. Ideal candidate holds a master's degree and has health care experience. Occasional travel outside region required. To apply, visit www.americanredcross.apply2jobs.com and search for requisition number NHQ20333. EOE, M/F/D/V

**Sr. Clinical Product Consultant.** Fenwal is a global medical technology company focused on improving blood collection, filtration, separation, storage and transfusion to ensure the availability, safety, and effectiveness of blood and blood components. Fenwal employs approximately 4,000 people worldwide, and operates five manufacturing centers. We currently have an opportunity for a Sr. Clinical Product Consultant to design and develop training materials for clinical consultants and customers, as well as consult with R&D on product development and updates. This position is located in our corporate office in Lake Zurich, Ill. Requires: bachelor's degree or equivalent experience; six to nine years of clinical or blood bank experience; experience developing and delivering formal training; medical technician or nursing experience preferred; knowledge of apheresis preferred; strong project management, problem solving and troubleshooting experience and ability to travel up to 50% (air and use of personal car) For more information about this position and to apply, visit our website: http://www.fenwalinc.com/Pages/Opportunities.aspx.

**Regional Manager.** LifeSouth Community Blood Centers is seeking an individual with a passion to make a real difference in the community as a Regional Manager in Dothan, Ala. Responsibilities include, but are not limited to: oversee established goals for percentage to inventory for all departments; ensure that region operates within its budget; represent and promote the company and its mission to the community; review weekly recruitment goals and projections.; implement corrective action when projections and goals are not being met; assist the Regional and/or District Director with the oversight of blood collection, donor recruitment, component production, blood labeling and blood distribution. Bachelor's degree required. Three years of supervisory or management experience required. This is a full-time position. Salary range $50,000 - $55,000. 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=1346341.

**Laboratory Services Director – IRL & Specialty (Job Code: LA001).** QualTex Laboratories an affiliate of the South Texas Blood & Tissue Center (STBTC), seeks an individual to manage, supervise, and coordinate all activities for Immunohematology Reference and Specialty Laboratories (includes IRL, Confirmatory, Microbiology, and Research and Development) for QualTex Laboratories in Norcross, GA and San Antonio, TX. The position will be based at the Norcross, GA facility. QualTex Laboratories at present screens millions of whole blood and plasma donations for infectious agents each year for biotechnology companies locally and across the globe. Qualifications required include a bachelor's degree in Science, Medical Technology, Microbiology or related discipline, six years laboratory experience and extensive management experience in laboratory operations. An MT (ASCP), SBB certification is also required along with a working knowledge of clinical laboratory techniques and current knowledge of regulatory/quality requirements (national and international, i.e. FDA, EU, GHA, ISO, OSHA & cGMP). For information, call Human Resources at (800) 292-5534, Ext. 1559. EOE/AAP. To apply, e-mail resume to hr_dept2@bloodntissue.org or fax to (210) 731-5581.

**Hospital Services Manager.** LifeStream, a $53M healthcare organization providing blood services for more than 70 hospitals in Southern California, is searching for a Hospital Services Manager to serve as LifeStream's customer service representative and technical resource. Proactively ensures customer complaints, suggestions, and process problems are reported, documented, and pursued; works with other blood center departments to resolve problems. Manages, maintains, and analyzes statistical databases to support blood component inventory management and budgeting. Conducts

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**POSITIONS** (continued from page 25)

periodic customer surveys to determine level of service satisfaction; tracks and trends survey results. Researches new business opportunities and assists VP Business Development in managing hospital contracts. Four-year bachelor's degree (BA or BS) in biological sciences or medical related discipline required. MT (ASCP) and or SBB (or equivalent) desirable. Minimum four years experience in blood banking or five years in hospital laboratory with transfusion service experience, (or equivalent). Must have exceptional interpersonal communicative skills developed and cultivated through extensive managerial and customer service experience. Excellent compensation and benefits plan. Apply online: www.LStream.org. Or send cover letter, resume and salary history to: LifeStream, Attn: HR, 384 W. Orange Show Rd. San Bernardino, CA 92408. E-mail: employment@LStream.org. EOE

**RN/LPN Therapeutic Apheresis Specialist.** Florida's Blood Centers (FBC) seeks a full-time RN/LPN Therapeutic Apheresis Specialist to perform Hospital Therapeutic Apheresis collection, as ordered by physicians. Requirements: graduate of an accredited school of nursing, current active Florida RN/LPN. license, current CPR certification, strong computer skills, valid driver's license, good driving record, reliable car and proof of insurance. Must be available for travel, and customer focused. For more information & to apply on-line please visit our website at www.floridasbloodcenters.org. Position will remain open until filled. Florida's Blood Centers is an Equal Opportunity Employer (AA/M/F/D/V) & Drug Free Work Place.

**Associate Medical Director.** BloodCenter of Wisconsin seeks physician to join growing Transfusion Medicine (TM) service of the Medical Sciences Institute. Physicians in TM direct transfusion services within three healthcare systems in Milwaukee area; provide direct patient care for therapeutic apheresis; consult with physicians re: transfusion medicine issues and bleeding disorders; promote blood management; provide medical direction of specialized laboratories; and participate in on-call responsibilities. More than 110,000 blood products are transfused annually and nearly 2,000 therapeutic apheresis and stem cell collection procedures are performed at the institutions directly served. Successful candidate expected to participate in clinical and/or applied research. BloodCenter has Transfusion Medicine Fellowship and SBB Program. MD or DO degree and board-certification in Pathology, Internal Medicine or Pediatrics required, as well as board certified/eligible in Blood Banking/Transfusion Medicine. We offer a competitive salary and excellent benefits. Apply online at www.bcw.edu/careers. We embrace and encourage diversity in our workforce. EEO/AAP

**Laboratory Services Manager.** Position available in Gainesville, FL responsible for overseeing all laboratory testing activities performed in LifeSouth facilities. This includes meeting the needs of internal and external customers for accurate, timely and high-quality immunohematology reference laboratory testing and, when appropriate, transfusion services, for providing oversight for compliance with established laboratory policy and for providing required quality control laboratory testing for blood and cellular therapy components. Bachelor's degree in clinical laboratory, chemical or biological science required; master's degree preferred. SBB certification required. Clinical laboratory training program and five years of clinical laboratory experience at a licensed, certified or accredited facility required. Previous supervisory experience required. Master's degree may compensate for less experience. Current Florida license as a Medical Technologist with pertinent current certification (MT(ASCP), CLS(NCA), MT(AMT), MT(ABB) and/or NRCC). Florida Agency for Health Care Administration, Board of Clinical Laboratory Lab Personnel Supervisor's Licensure in Immunohematology, Hematology, Serology/Immunology, Microbiology and/or Molecular Pathology required. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Please click the link to apply https://home.eease.adp.com/recruit/?id=1312671.