



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2015 #2

January 16, 2015

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Some Donors Deferred for Low Hemoglobin May Have Underlying Health Conditions

More than 50,000 potential blood donors present daily at US blood centers to donate, with as many as 10 percent of donors deferred for low hemoglobin – the most common reason for donor deferral in the US. While it is well-known that frequent blood donation can lead to iron deficiency, less is known about the causes of anemia among infrequent blood donors. A new study in *Transfusion* suggests that anemia may be a sign of an underlying illness for an important number of infrequent blood donors, who may benefit from medical evaluation.

Most educational materials for donors deferred for low hemoglobin focus on increasing iron stores through dietary changes or iron supplementation, however, many do not explain to donors that newly recognized anemia may signal an unrecognized underlying illness. Previous studies have found medically important underlying illness in seemingly healthy blood donors deferred for low hemoglobin, including gastrointestinal bleeding, B12 deficiency, thyrotoxicosis, hyperthyroidism, uncontrolled diabetes, and malignancies.

Kyle Annen, DO, of Heartland Blood Centers, and colleagues, conducted a survey among infrequent donors deferred for low hemoglobin at BloodCenter of Wisconsin and Puget Sound Blood Center (PSBC) to define and further quantify underlying diseases among these donors. They surveyed men 18 years and older and women 50 years and older who were deferred for low hemoglobin (< 12.5 g/dL), had no more than one donation in the year prior to deferral, and did not successfully donate in the three months after their deferral.

Of 1,120 donors who were sent surveys at least three months after their deferral, 380 responded – a response rate of 34 percent. Only 37 percent of respondents reported seeing a physician, but of these 64 percent were confirmed to be anemic, and 73 percent reported having additional testing. They found that 3.4 percent of responding donors reported finding a previously unrecognized serious illness requiring treatment, including lymphoma, prostate cancer, autoimmune disease, and gastrointestinal bleeding.

“These results identify a subset of individuals presenting to donate blood who have a high likelihood for unrecognized and serious medical illness first presenting as anemia,” wrote the authors. “... Infrequent donors who are deferred for low hemoglobin should be given appropriate guidance as to the meaning of their hemoglobin level. An algorithm could be devised that focuses upon the sex and

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OUR SPACE

Matt Granato, ABC's Chief Operating Officer

Introducing the ABC Business Forum

By now, I hope you have had a chance to review the upcoming [ABC Annual Meeting program](#). You will notice an interesting new addition to the program: "The ABC Business Forum: The Economics of Plasma," on Saturday, March 21.

This addition could not be timelier or more relevant. First, it complements the executive management and scientific and medical discussions in the Blood Center Leadership and SMT Forums by providing valuable information and education on the operations side of blood banking. Second, it ties in with ABC's current advocacy agenda on the issue of plasma flexibility.

Recently, ABC requested that the Food and Drug Administration consider establishing a universal product label for component plasma. ABC's position, supported by our colleagues, industry partners, and patient groups, states that plasma should be regulated consistently, regardless of collection method. Our goal is to allow blood centers the necessary flexibility to maximize the donor's gift, including its use for therapeutic product manufacturing where appropriate. We have presented our position to FDA and are now awaiting a decision.

We believe that educating ABC members on the economics of plasma – by providing a global picture of the fractionation industry, describing how clinical needs can be met, examining the regulations of plasma for fractionation and their impact on different blood center operation models, and highlighting key initiatives and technology to increase plasma production – will enhance our members' abilities to plan and prepare for a regulation change, or conversely, to make the most of the status quo.

With our advocacy efforts, we aim to control and shape the environment in which blood centers operate. With our education, we supply our members with information, skills, and knowledge to navigate such an environment. In addition, the immediate feedback and information shared by participants is as enriching and "aha"-moment-inducing as the education provided by our event faculty. For these reasons, the ABC Business Forum needs you to attend to enrich the conversation. We hope you attend and make it whole.

(Editor's note: Register for the ABC Business Forum and the other Annual Meeting sessions through the e-mail invitations distributed by ABC or contact Lori Beaston at lbeaston@americasblood.org.)

mgranato@americasblood.org ♦

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

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DID YOU KNOW...?

‘79’ is the number of active lines – including four international attendees – during last week’s webinar “Small Changes, Big Impacts: Transatlantic Learnings,” which is part of ABC’s C-Suite Webinar Series, designed specifically for blood center executives.

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

Low Hemoglobin & Underlying Health Conditions (continued from page 1)

hemoglobin level; the donors could be given a different message by the phlebotomy staff or a specific brochure or pamphlet.”

BloodCenter of Wisconsin, an affiliate of the Centers for Transfusion and Transplant Medicine (CTTM), distributes an educational brochure to communicate the meaning of low hemoglobin levels to deferred donors, including information on when it may be appropriate to seek medical attention, said Dr. Annen. At Heartland Blood Centers, also an affiliate of CTTM, Dr. Annen said she coaches the collections staff on how to communicate with donors about deferral for low hemoglobin and has implemented an algorithm to guide the information provided to donors based upon their hemoglobin level.

PSBC has developed a follow-up letter for donors with low hemoglobin, addressing potential causes and providing suggestions for improving their iron levels. While this letter is distributed to all deferred donors in hopes that they will return soon to donate, it does provide additional information to help donors make an informed decision about addressing their iron level.

The authors note that current educational methods used at most blood centers to help these donors improve their low hemoglobin may be inadequate, as they often focus on frequent blood donors who develop iron deficiency secondary to repeat donation. Furthermore, there is wide variation in the information they receive on the medical significance of their deferral, when they should seek additional medical care, and what they should do to decrease the likelihood of deferral.

More research is required to develop the ideal donor algorithm and blend of donor education materials, as well as the best language to communicate the low, yet relevant risk of underlying medical conditions that may cause low hemoglobin, said Dr. Annen. She encourages all blood centers to have a plan in place for educating donors deferred for low hemoglobin, and to make the medical director available to donors who have questions.

“This study highlights that this problem is out there – we cannot deny that we are collecting blood from

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Low Hemoglobin & Underlying Health Conditions (continued from page 3)

people who have underlying illnesses that need to be addressed,” said Dr. Annen. “And while we still need to figure out the best way to do that, it certainly should not be ignored.”

While a majority of respondents did not seek medical attention and some expressed apathy regarding their results, others expressed their gratitude for the blood center’s guidance. “Trying to donate blood saved my life,” wrote one survey respondent who was diagnosed with mantle cell lymphoma.

“Blood centers are in a position to provide meaningful contribution to a patient’s health status. It is important that we keep donor health in mind as a public health function,” said study co-author Meghan Delaney, DO, MPH, of PSBC.

Citation: Annen K, Delaney M, Leitch D, Mast AE. The health implications of low hemoglobin in infrequent blood donors. *Transfusion* 2015 Jan;55(1):86-90. ♦



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

Make Your Contribution to the Jerry Haarmann Memorial Campaign Today

Last year, following the passing of Jerry Haarmann – a blood banking industry leader and visionary who was the guiding force behind Group Services for America’s Blood Centers (GSABC) – the Foundation for America’s Blood Centers (FABC) established a memorial campaign in his honor that will support ABC’s leadership development offerings. With the campaign closing April 30, the Foundation encourages those who wish to memorialize Mr. Haarmann to consider contributing to the [Jerry Haarmann Memorial Campaign](#).

Mr. Haarmann was known to have an eye for great talent and to foster professional development and leadership among his staff. To carry on this legacy, the FABC seeks to raise \$50,000 through this campaign to fund a leadership in blood banking certificate program in his name. The leadership program will eventually be offered to blood banking professionals through the ABC Professional Institute (API), which is currently being developed.

Contributions can be made through April 30 by visiting <http://bit.ly/JerryHaarmann>. Any personal donations of \$1,500 or more will receive a small brick on the API website, and corporate donations of \$10,000 or more will receive a large brick.

The FABC would like to thank the following individuals for contributing to the Jerry Haarmann Memorial Campaign:

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David & Pamela Allen

Celso Bianco

Scott Caswell

Bill & Kathy Coenen

Jeanne and Terry Dariotis

Jenny & Darin Ficenec

Larry Franzoi

Richard Gamble

Danny Garrick

Pascal George

John Guthrie

Nora Hirschler

Michelle & Dirk Johnson

Bryan Kreuger

Jim MacPherson

Jodi Minneman

Madonna Haarmann Moffett

Charlie Mosher

Mike Parejko

Marge & John Pierce

Tom Schallert

Mr. and Mrs. Mike Smith

Robert Travis

Christine Zambricki

The FABC would also like to thank the following organizations and corporations for supporting this campaign:

Blood Centers of America (BCA)

Fenwal, a Fresenius-Kabi company

SunCoast Blood Bank

The FABC hopes that you will join these individuals and organizations to support the professional development of blood bankers in honor of Mr. Haarmann by contributing to the [Jerry Haarmann Memorial Campaign](#).

ABC's Got Talent Spotlight on Lairett Gannon and Emily Shenk-DeMay

Have you checked out the talented performers participating in the first-ever ABC's Got Talent show fundraiser? The ABC's Got Talent virtual talent show allows contestants to show off their skills while raising money to support the Foundation for America's Blood Centers (FABC). Take a peek at the impressive acts below and check in next week to see two new acts highlighted!

Lairett Gannon, Central Jersey Blood Center (CJBC), singing "Look for the Silver Lining." Ms. Gannon joined the CJBC Team in 2007 because she wanted to make a difference in the lives of people in the community. Having worked on Broadway and in conjunction with New York City Mayor's Office and The White House on various diplomatic, special services, and theatrical events, including the Tony Awards, various Broadway Openings, and Theater Development Fund events, Ms. Gannon has an extensive background in fundraising and event planning, execution, and programming. Since joining CJBC, she has had the privilege of working in both the Donor Relations and Donor Services Departments. As a cancer survivor and recipient of hundreds of units of red blood and platelet donations more than 13 years ago, she is now thrilled to be part of the team at CJBC and is devoted to the mission of saving lives through blood donation. To view Ms. Gannon's video and help her "break a leg" by voting visit <http://bit.ly/LairettGannon>.



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INSIDE ABC (continued from page 5)

Emily Shenk-DeMay, Mississippi Valley Regional Blood Center, singing “God Bless America.”

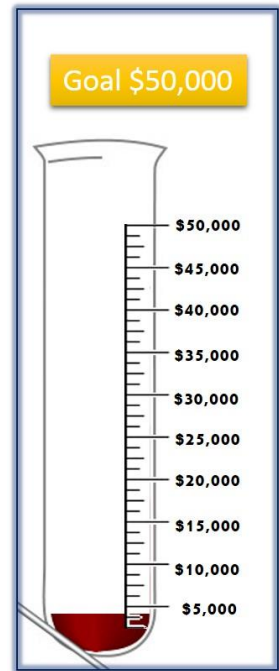
Emily Shenk-DeMay is the manager of Corporate Administration at Mississippi Valley Regional Blood Center (MVRBC). At one time, she considered a career in music. (And with good reason, as you’ll hear in her video!) Fortunately for MVRBC, she was drawn to the blood center’s mission after starting work as a scheduler in MVRBC’s volunteer program following her college graduation. Ms. Shenk-DeMay has always been a dedicated employee, but a health scare gave her an even greater understanding of the blood community’s lifesaving mission. In May 2013, Ms. Shenk-DeMay experienced a ruptured ectopic pregnancy, causing intense pain and internal bleeding. Through blood transfusions made possible by the generosity of blood donors in the region, her life was saved. Ms. Shenk-DeMay pays tribute to the American spirit of giving, particularly to those unknown donors who gave her the gift of life, by singing a moving rendition of “God Bless America.” Ms. Shenk-DeMay is currently on maternity leave, but is so moved by the spirit of giving that she came in to work with her blood center on her video. To view Ms. Shenk-DeMay’s moving performance and vote for her, visit <http://bit.ly/EmilyShenkDeMay>.



ABC’S Got Talent Weekly Tally

The ABC’ Got Talent contestants are competing for your votes, which can be made via donation to their online campaign, for a chance to be among the top five who perform live at the ABC Annual Meeting in Washington, D.C. this March. Below are the acts that are currently in the lead at press time.

ABC’s Got Talent Weekly Top 5		
Contestant(s)	Amount Raised	Link to Campaign
1. Kim-Anh Nguyen, MD, PhD	\$2,120	http://bit.ly/DrNguyen
2. Sher Patrick	\$450	http://bit.ly/SherPatrick
3. Dan Eberts	\$339	http://bit.ly/DanEberts
4. Shepeard Blues Band	\$360	http://bit.ly/ShepeardBluesBand
5. Sharon Birzer	\$285	http://bit.ly/SharonBirzer



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INSIDE ABC (continued from page 6)

Don't see your favorite act listed in the top five? View and vote for your favorite by following the links below.

- **James AuBuchon, MD**, Puget Sound Blood Center, bagpipe playing: <http://bit.ly/DrAuBuchon>;
- **Laurett Gannon**, Central Jersey Blood Center, <http://bit.ly/LaurettGannon> (Note: the video for this campaign is coming soon);
- **Pascal George**, Central Jersey Blood Center, French song on mandolin: <http://bit.ly/PascalGeorgeCJBC>;
- **Emily Shenk-DeMay**, Mississippi Valley Regional Blood Center, singing "God Bless America:" <http://bit.ly/EmilyShenkDeMay> ;
- **Mindy Smith**, Oklahoma Blood Institute, singing "Art is Calling Me" from *The Enchantress*: <http://bit.ly/MindySmithobi>;
- **Chris Staub**, Unyts, "Appalachian Instrumental Tune & Original Song" with brother Tony Staub: <http://bit.ly/StaubBrothers> (Note: the video for this campaign is coming soon);
- **Eric Stone**, Blood Systems, musician, <http://bit.ly/EricStoneBSI> (Note: the video for this campaign is coming soon); and
- **Mary Townsend, MD**, Blood Systems, rope tricking: <http://bit.ly/DrTownsend> (Note: the video for this campaign is coming soon). ♦

RESEARCH IN BRIEF

A recently published systematic review and meta-analysis in *JAMA Pediatrics* suggests that umbilical cord blood milking is associated with some benefits and no adverse events in the immediate postnatal period in preterm infants. In recent years, physicians and researchers have recognized some benefits of delayed umbilical cord blood clamping and/or umbilical cord milking – procedures to transfer residual blood from the placenta to the infant. A number of studies have suggested short-term benefits from delayed cord clamping or cord milking in preterm infants – including fewer red blood cell (RBC) transfusions, decreased risk of intraventricular hemorrhage, and necrotizing enterocolitis – but the long-term impact is unknown. Heidi Al-Wassia, MD, of King Abdulaziz University in Saudi Arabia, and colleagues conducted a systematic review of randomized controlled trials investigating umbilical cord milking, identifying seven eligible studies in 501 full-term and pre-term infants. Of these, five trials compared umbilical cord milking with immediate clamping and two compared umbilical cord milking with delayed cord clamping. They found that in preterm infants with a gestational age of less than 33 weeks, umbilical cord milking was associated with no difference in mortality before discharge. However, it was associated with higher initial hemoglobin values, lower oxygen requirements at a postmenstrual age of 36 weeks, and a lower risk of intraventricular hemorrhage overall. There was no difference in severe intraventricular hemorrhage or death prior to discharge. While the hemoglobin level was greater in the umbilical cord milking group, the number of blood transfusions was not reduced. Long-term neurodevelopmental outcomes were not reported. The authors write that "further studies are warranted to assess the effect of umbilical cord milking on neonatal and long-term outcomes." Michael Posencheg, MD, and Haresh Kirpalani, BM, MRCP, FRCP, MSc, of Children's Hospital of Philadelphia, conclude that "for now it is prudent to proceed cautiously with full-scale implementation of either of these placental transfusion strategies in preterm infants, especially without knowledge of the impact on long-term outcomes."

(continued on page 8)

BRIEFLY NOTED (continued from page 7)

Citations: Posencheg M, Kirpalani H. Placental transfusion at birth: do we have all of the answers. *JAMA Pediatr.* 2015 Jan 1;169(1):9-11.

Al Wassia H, Shah PS. Efficacy and safety of umbilical cord milking at birth: a systematic review and meta-analysis. *JAMA Pediatr.* 2015 Jan 1;169(1):18-25.

A study in *Transfusion* suggests that DNA-based red blood cell (RBC) typing provides improved accuracy and expanded information on RBC antigens compared with standard serological methods. For frequently transfused patients, such as those with sickle cell disease (SCD), alloimmunization to RBC antigens remains a major complication. To reduce this risk, extended RBC antigen matching is recommended, and is generally done with labor-intensive serological methods. DNA-based assays offer a less-labor intensive alternative that can also provide information on RBC antigens for which standard serologic typing reagents are not available. Jessica Casas, MD, of the Children's Hospital of Philadelphia, and colleagues at New York Blood Center, compared RBC antigen phenotypes from single-nucleotide polymorphism analysis with serologic testing for 13 routinely tested RBC antigens and reported the prevalence of 35 antigens predicted by DNA in 494 patients with sickle cell disease. They determined the accuracy and potential benefits of RBC genotyping to replace extended serologic typing for patients with SCD. They identified 71 discrepancies among 6,360 antigen comparisons (1.1 percent). New specimens for repeat serologic testing were obtained for 66 discrepancies and retyping agreed with the genotype in 64 cases. Fifteen false-negative serologic results were associated with alleles encoding weak antigens or single-dose Fy^b expression. They conclude that "DNA-based RBC typing provided improved accuracy and expanded information on RBC antigens compared to hemagglutination methods." The authors acknowledge that "implementation of RBC genotyping for patient care requires acceptance of molecular typing without serologic confirmation, which represents a major practice change in transfusion services." However, they note that this study demonstrates that DNA-based methods are accurate to predict RBC antigen phenotype in patients with sickle cell disease. "Now, the field of transfusion medicine is poised to integrate RBC genotyping of both patients and donors into routine clinical practice, which can particularly benefit individuals with SCD," write the authors.

Citation: Casas J, *et al.* Changing practice: red blood cell typing by molecular methods for patients with sickle cell disease. *Transfusion* 2015 Jan 9. [Epub ahead of print]

Portola Pharmaceuticals Inc. said in a Jan. 9 press release that its experimental drug Annexa-R (andexanet alfa) met the primary goal of its phase 3 trial, reversing the effect of anticoagulant drug Xarelto. Data showed that an intravenous shot of andexanet alfa immediately reversed the anticoagulation activity of Xarelto, developed by Johnson & Johnson and Bayer AG, in healthy participants aged 50 to 75 years. Portola is developing andexanet alfa as a universal antidote for patients treated with oral and injectable Factor Xa inhibitors who are experiencing a major bleeding episode or who require emergency surgery. Further data on the study is expected in mid-2015, reported Portola. "The statistically significant Phase 3 Annexa-R study data, together with results presented previously with apixaban, provide compelling evidence that this groundbreaking agent could serve as a universal antidote for Factor Xa inhibitor anticoagulants," John T. Curnutte, MD, PhD, executive vice president of Research and Development for Portola, said in the statement. More information can be found in the [press release](#). (Source: Portola press release, 1/9/15) 💧



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JOIN US FOR AMERICA'S BLOOD CENTERS' 53RD ANNUAL MEETING

A MUST-ATTEND EVENT, REGISTER NOW!

March 20-24, 2015 – Washington, DC | Ritz-Carlton (Pentagon City)

SIGNATURE NETWORKING EVENTS

Benefiting the Foundation for America's Blood Centers

A Monumental Affair: Delight in a performance by world renowned political satire and musical comedy act "[The Capitol Steps](#)" while enjoying great food and a monumental view of the Washington skyline at DC's famed Top of the Town (Sunday, March 22)

FABC VIP Tour: Experience the history and beauty of the Washington DC monuments and landmarks through the eyes of luxury, as you embark on a moonlight limousine tour with other VIP guests (Sunday, March 22)

18th Annual Awards of Excellence & Talent Show: Join us as we recognize community and industry leaders alike, while being entertained by the best in the business at the inaugural "ABC's Got Talent" show – NEW! Free ticket with Annual Meeting registration (Monday, March 23)

“Come for the networking and education – stay for the experience. Washington, DC is a world-class city with something for everyone – history, monuments, Smithsonian museums, the Cherry Blossom Festival and of course, politics!”

– Christine Zambricki, DNAP, CRNA, FAAN
Chief Executive Officer, America's Blood Centers

2015 ANNUAL MEETING SCHEDULE

Download full schedule details, including speakers and presentation descriptions.

International Blood Safety Forum (IBSF): Co-hosted by Global Healing – Engage in dialogue with leading experts from around the world who are forging into the next horizon of global blood safety (Friday, March 20)

Business Forum: *The Economics of Plasma* – Stay up-to-date on the business of plasma for fractionation and learn how to optimize plasma collections (Saturday, March 21)

ABC Members Meeting: Hear how ABC is working for you and make your voice count (Sunday, March 22)

SMT Forum: Learn from the experts as they address hot topics in blood science impacting care provided to patients and donors (Sunday, March 22)

Blood Center Leadership Forum: Discuss legal and strategic aspects of cooperation in blood banking, navigating the hospital supply chain, board engagement and leadership succession (Monday, March 23)

Advocacy Forum: Learn from a US Congressperson what's ahead in the healthcare horizon and join your fellow advocates in educating Members of Congress about the issues affecting blood centers (Tuesday, March 24)

ABC AND EBA MEMBER FEES

ANNUAL MEETING: \$945 (register and book hotel by February 27, 2015)

Business Forum through Advocacy Forum (Sat. through Tues.): \$725

IBSF & Business Forum (Fri. & Sat. only): \$395

IBSF (Fri. only): \$265

ABC and EBA Members register through direct email invitation or contact Lori Beaston at lbeaston@americasblood.org.

Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation and registration fees and information. Sponsorship opportunities available. Contact Abbey Nunes at anunes@americasblood.org for details.

BRIEFLY NOTED

The Centers for Disease Control and Prevention reported in the Jan. 9 [Morbidity and Mortality Weekly Report](#) that HIV transmission through needlestick injuries at the workplace among healthcare workers has become extremely rare. CDC reported that in the last 14 years, only one known healthcare worker – who was stuck by a needle in a lab – has acquired HIV from the workplace. From 1985 to 1999, 57 confirmed and 150 possible cases of occupationally acquired HIV Infection among healthcare workers were reported to CDC. Only one case has occurred since 1999. CDC reports that the dramatic decrease is due to a wide variety of safety measures to prevent needlestick injuries implemented in the 1990s and the use of occupational post-exposure prophylaxis with antiretrovirals to prevent infection. CDC highlights the continued need to report all suspected occupationally acquired HIV cases to state health officials and CDC. (Source: CDC Morbidity and Mortality Weekly Report, 1/9/15) ♦

REGULATORY NEWS

The Food and Drug Administration granted the first waiver to allow a nucleic acid (NAT)-based test, the Alere i Influenza A&B test, to be used outside medium-and high-complexity laboratories, according to a Jan. 6 FDA [press release](#). Because FDA granted a waiver under Clinical Laboratory Improvement Amendments (CLIA), the Alere i Influenza A&B test can be distributed to a broad variety of non-traditional sites, including physicians' offices, emergency rooms, health department clinics, and other healthcare facilities. The waiver, while not directly related to the needs of the blood community, sets an important precedent with regard to the expanding role of NAT testing. (Source: FDA press release, 1/6/15)

The Food and Drug Administration provided 510(k) clearance to Blood Bank Computer Systems, Inc. (BBCS) for its new ABO Wheels product, part of its ABO Suite. [ABO Wheels](#) is the second product in the ABO Suite to receive 510(k) clearance; the first was [ABO QuickPass](#). ABO Wheels allows blood centers to conduct efficient, safe, paperless processing for registration, questionnaire, screening, and collection at a reduced cost per donation. This mobile collection application can be used either at a collection facility or at a non-fixed site, regardless of connectivity to the main database, and is able to control multiple blood drives or remote events simultaneously. "Real-time entry of blood collection information and comprehensive data transfer to the blood establishment computer system (BECS) unlocks many opportunities for blood centers to escape the burden of double entry, or manual data entry. Ultimately, allowing blood to move through the supply chain at an accelerated rate and a lower cost," said Brian Forbis, vice president of BBCS, who also explained that ABO Wheels includes the ability to scan donor fingerprints for secure donor identification. More information is available in the [FDA 501\(k\) approval documents](#). (Source: BBCS press release, 1/14/15)

The Food and Drug Administration has made available an [online database](#) of the agency's guidance documents that can be searched by product type or FDA office. Results can be organized by date and whether the documents are in draft or final form. The Web page also provides links to information about FDA guidance documents, commenting on documents, and FDA acronyms and abbreviations. (Source: AABB Weekly Report, 1/9/15)

The Food and Drug Administration and the Centers for Disease Control and Prevention provided an [update](#) on Jan. 14 on its ongoing investigation into instances of patients receiving non-sterile saline solution. FDA and CDC are investigating how patients received infusions of Wallcur Practi-0.9

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REGULATORY NEWS (continued from page 9)

percent Sodium Chloride solution, which was shipped to medical clinics, surgical centers, and urgent care facilities in multiple states. More than 40 patients have received infusions of the solution, which is meant to be used for teaching purposes. Adverse events associated with the infusions – including fever, chills, tremors, and headache – have been reported in Colorado, Florida, Georgia, Idaho, Louisiana, New York, and North Carolina. Normal saline solution continues to be in limited supply, and FDA has been working with manufacturers to increase available inventory. In addition, FDA is not objecting to the temporary distribution of additional IV normal saline solution from alternate sources Fresenius Kabi, Baxter Healthcare Corp., and B. Braun Medical Inc. (Source: FDA Drug Safety and Availability notice, 1/14/15)💧

THE WORD IN WASHINGTON

The House and Senate were in session this week. The House is working on unfinished homeland security appropriations, and the Senate on the Keystone XL pipeline issue. If you have seen your legislators at home, let ABC know how your visits went and send pictures to pr@americasblood.org. To see when members of Congress are in Washington or in their home states, visit [House schedule](#) or [Senate schedule](#).

The House last week took up legislation (HR 30) amending the Affordable Care Act so that its provisions apply to employers counting the number of persons working a 40-hour week, not a 30-hour week as the law now requires. If enacted, the bill would reduce the number of employers required to offer health coverage. Similar legislation passed the House but died in the Senate in the previous Congress. It now goes to the Senate for consideration. The President has promised to veto it if it lands on his desk. More information about this legislation can be found in a recent [NPR piece](#). You can see how your US Representatives voted at <http://clerk.house.gov/evs/2015/roll014.xml>. Follow the bill at <https://www.congress.gov/bill/114th-congress/house-bill/30>. (Source: NPR, 1/8/15)

Who is serving on House Committees critical to the blood community? Most health policy critical to blood bankers moves through specific congressional committees – and members of those committees in the new 114th Congress are critical for community blood centers to know. Last week the *ABC Newsletter* highlighted key Senate committees. This week, we list the key House committees and key members within each committee.

- **House Energy and Commerce Committee:** Republicans: Fred Upton (MI) (Chairman); Marsha Blackburn (TN) (Vice-Chairman); Joseph Pitts (PA) (Chairman, Health Subcommittee), Brett Guthrie (KY) (Vice Chairman, Health Subcommittee). Democrats: Frank Pallone, Jr. (NJ) (Ranking Member); Gene Green (Texas) (Ranking Member, Health Subcommittee). See other members [here](#).
- **House Ways and Means Committee:** Republicans: Paul Ryan (WI) (Chairman); Kevin Brady (Texas) (Chairman, Health Subcommittee). Democrats: Sander Levin (MI) (Ranking Member), Jim McDermott (WA) (Ranking Member, Health Subcommittee). See other members [here](#).
- **House Veterans Affairs Committee:** Republicans: Jeff Miller (FL) (Chairman); Gus Bilirakis (FL) (Vice Chairman). Democrats: Corrine Brown (FL) (Ranking Member). House Veterans Affairs Health Subcommittee members have not yet been released. See other members of the [here](#); as of Jan. 13, not all committee members have been assigned.
- **House Appropriations Committee:** Republicans: Harold Rogers (KY) (Chairman), Robert

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THE WORD IN WASHINGTON (continued from page 10)

Aderholt (AL) (Chairman, Agriculture, Rural Development, Food and Drug Administration and other related agencies Subcommittee). Democrats: Nita Lowey (NY) (Ranking Member), Sam Farr (CA) (Ranking Member, Agriculture, Rural Development, Food and Drug Administration and other related agencies Subcommittee). See other members of the committee [here](#).

This week America’s Blood Centers CEO Christine Zambricki, DNAP, CRNA, FAAN, and Chief Medical Officer Louis Katz, MD, met with James Berger, MS, MT(ASCP), SBB, senior advisor for Blood Policy and Richard Henry, ML, MPH, advisor for Blood Policy at the Department of Health and Human Services offices in Rockville, Md.



The HHS advisors and ABC leaders (pictured right of text) discussed strategies to assure sustainability of a safe and adequate blood supply in the US. The HHS Advisory Committee on Blood and Tissue Safety and Availability will likely play a key role in bringing the “Value of Blood” issue to the forefront.

ABC CEO Christine Zambricki, DNAP, CRNA, FAAN, (pictured right) met with health economist Gail Wilensky, PhD, (pictured left) this week to discuss ABC’s “Value of Blood” initiative. Dr. Wilensky directed the Medicare and Medicaid programs from 1990 to 1992 and served in the White House as a senior health and welfare adviser to President George HW Bush. She is an elected member of the Institute of Medicine and has served two terms on its governing council. From 1997 to 2001, she chaired the Medicare Payment Advisory Commission, which advises Congress on payment and other issues relating to Medicare. 💧

**INFECTIOUS DISEASE UPDATES****HEPATITIS E VIRUS**

An analysis of recent National Health and Nutrition Examination Survey (NHANES) data demonstrates that hepatitis E virus (HEV) seroprevalence in the US has decreased from 1988-1994 to 2009-2010. Eyasu H. Teshale and colleagues of the Centers for Disease Control and Prevention compared anti-HEV prevalence and risk factors using the same serologic test in both the 2009-2010 and the 1988-1994 NHANES cohorts. They found that the estimated anti-HEV immunoglobulin (IgG) prevalence in the US has declined by 40 percent from 1988-1994 (10.2 percent) to 2009-2010 (6 percent). “Whether this decline is a consequence of factors such as a decrease in exposure of susceptible persons due to lifestyle or behavioral changes or a change in the etiologic agent over time remains to be answered,” write the authors. In a previous analysis of these data published in September 2014 in *Hepatology*, the authors reported a 3.5-fold decline in HEV seroprevalence from 21 percent during the 1988 to 1994 period, compared with 6 percent during the 2009 to 2010 period (see [ABC Newsletter, 9/26/14](#)).

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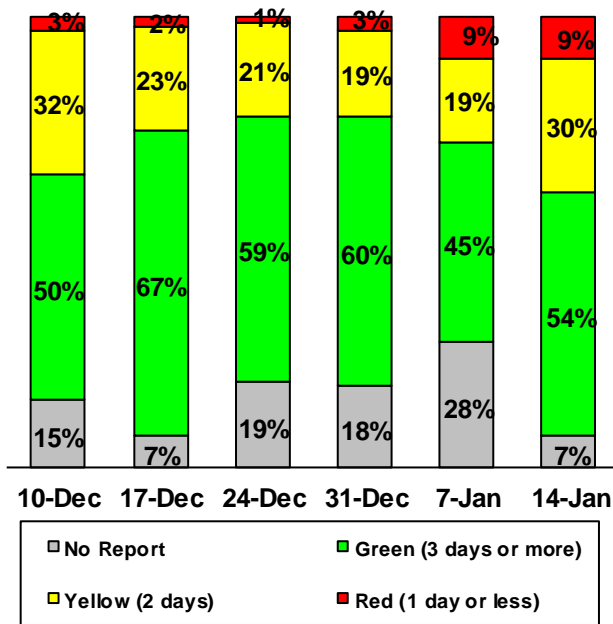
INFECTIOUS DISEASE UPDATES (continued from page 11)

Citations: Teshale EH, *et al.* Decline in hepatitis e virus antibody prevalence in the US from 1988-1994 to 2009-2010. *J Infect Dis.* 2015 Feb 1;211(3):366-73.

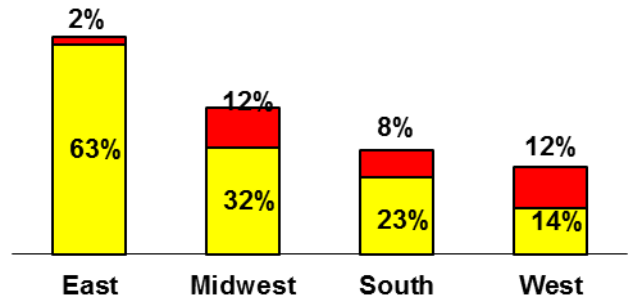
Ditah I, *et al.* Current epidemiology of hepatitis E virus infection in the US: Low seroprevalence in the National Health and Nutrition Evaluation Survey. *Hepatology.* 2014 Sept; 60(3):815-22. 2014 July 17. ♦

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, January 14, 2015



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

MEMBER NEWS

Community Blood Center of the Carolinas (CBCC) and Be The Match bone marrow registry have expanded their longtime partnership to now include all five CBCC donation centers as designated locations for the Be The Match to Go Kits. Since 2006, CBCC and Be The Match have teamed up to host joint blood donation and marrow registration drives. Through this expanded partnership, blood donors and visitors at CBCC’s centers can join the registry and get their cheek cells swabbed. “We appreciate the ongoing support of the Community Blood Center of the Carolinas in helping raise awareness about and participation in the Be The Match Registry,” Addie Sanders, a



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MEMBER NEWS (continued from page 12)

community engagement representative at Be The Match of Southeast, said in a CBCC press release. “Designating all five of their centers as Be The Match To Go locations will help us increase potential marrow matches and continue to give patients hope.” A bone marrow transplant can be a cure for patients in need of lifesaving transplants. Only 30 percent of patients find a match within their family, leaving many to depend on the Be The Match Registry – the world’s largest registry of potential marrow donors – to find a match. “We are honored to be selected as official sites for the Be The Match To Go Kits and to involve all of our donor centers throughout the region in helping grow the Registry and increase the chance of finding a match for a bone marrow patient in need,” said Martin Grable, president and CEO of CBCC. “Since blood and bone marrow go hand in hand, we see this partnership as a natural fit to help increase the number of potential registry participants and to help save lives.” (Source: CBCC press release, 1/12/15) ♦

PEOPLE

Bob Albee, retired from his role as vice president of Business Development at LifeStream, San Bernardino, Calif., on Jan. 9, announced the center this week. During Mr. Albee’s years with LifeStream, the organization grew annual revenues from \$33 million to \$63 million, while increasing the number of hospitals served from 33 to 85. Mr. Albee’s career in blood banking also includes roles as executive director and CEO of Community Blood Bank, Rancho Mirage, Calif.; executive vice president, chief operating officer, and chief financial officer at LifeBlood/Mid-South Regional Blood Center, Memphis, Tenn.; executive director and CEO at Keystone Community Blood Bank, Reading, Penn.; and board of directors member at America’s Blood Centers. He served three terms on AABB’s board of directors, presented numerous papers, and participated in industry workshops at national, regional, and state blood banking association meetings covering a variety of topics. LifeStream also recently



Bob Albee



George Hurrell, MA, MBA

announced the promotions of **George Hurrell, MA, MBA** to the position of vice president of Business Development and **Kevin Moore, MT(ASCP)SBB** to vice president of Manufacturing and Laboratory services. Mr. Hurrell has more than 30 years’ experience in the blood banking industry and healthcare. Before joining LifeStream in 2009 as the director of Business Development, he served as executive vice president for Annenberg Center for Health Sciences affiliated with Eisenhower Medical Center, Rancho Mirage, Calif. Prior to that, he served as director of Disease Management at Caremark Therapeutic Services Division for CVS/Caremark, Inc., Redlands, Calif. Mr. Moore has more than 30 years’ experience in the blood banking industry. He was a member of

Kevin Moore, MT(ASCP)
SBB

the executive team for Blood Bank of Hawaii, originally serving as technical director, managing the manufacturing, distribution, and immunohematology reference laboratory service functions, then serving as director, hospital services. He also served as director of Testing and Production for the National Testing Laboratories in Philadelphia for the American Red Cross. (Source: LifeStream announcement, 1/12/15) ♦

IN MEMORIAM – Lisa G. Swinton McLaughlin, MD, JD

Lisa G. Swinton McLaughlin, MD, JD, of Montgomery Village, Md., an executive medical officer at the American Red Cross, passed away on Jan. 4. She was also the National Diversity Advisory Council appointee for the American Red Cross. After giving birth to two healthy boys a week ago, Dr. McLaughlin was at home recuperating when she collapsed unexpectedly. Resuscitation proved unsuccessful. “We are terribly shocked and saddened at the sudden loss of such a dear friend and valued Red Cross colleague,” stated Richard Benjamin, MD, chief medical officer of Biomedical Services at the American Red Cross. “Lisa was always a pleasure to work with, bringing a joyous and exuberant personality to everything she did. Her laughter echoed through the office hallways and coworkers admired her glamorous style and elegance. She will be greatly missed, and our thoughts are with her family and friends during this difficult time.” Dr. McLaughlin worked at the Red Cross in various capacities since 2007, beginning as the medical director in the Greater Chesapeake and Potomac Blood Services Region and then serving as senior medical officer. Most recently, she led the expansion of the Red Cross Clinical Services program across the nation and drove recruitment of diverse blood donor populations to better serve sickle cell disease patients. Previously, she was an attorney and special assistant attorney general in the Nebraska Department of Social Services where she championed the cause of neglected and abused children. Dr. McLaughlin earned a Bachelor of Arts and Juris Doctor degrees from Creighton University in Omaha, Neb. She earned her Doctor of Medicine degree and did her residency at the University of Kansas Medical Center in Kansas City, Kansas. Dr. McLaughlin completed a fellowship at Washington University/Barnes-Jewish Hospital in St. Louis, Mo., with a focus on transfusion medicine. The family asks that, in lieu of flowers, donations be made to help support the boys. For donation details, please contact Linh Chamaj at linh.chamaj@redcross.org. (Source: American Red Cross announcement, 1/8/15)◆

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: mnorwood@americasblood.org.

POSITIONS AVAILABLE

Laboratory Supervisor – Blood Bank (Dartmouth-Hitchcock, Lebanon, NH; Full time, 30-40 hours per week, 8:00AM - 4:30PM). The Section Supervisor is responsible for the overall management of operations and performance of the Blood Bank in the Department of Laboratories at Dartmouth-Hitchcock Medical Center. The Blood Bank is a complex, high-volume lab supporting both local and regional needs, along with the Norris Cotton Cancer Center at Dartmouth-Hitchcock. The Section Supervisor plans, organizes, and manages section activities and personnel. The ideal candidate for this position will possess current and relevant Blood Bank experience, solid technical skills, and supervisory experience in a management or lead technician role. Responsibilities: Supervising all personnel within section including reviewing workload, scheduling, and adjusting staffing coverage to meet demands. Qualifications: Applicants must be a CMT with five years of

laboratory experience including at least two years in a supervisory role. A master's degree is preferred. Familiarity with regulatory agencies is also required. Candidates must be familiar with regulations affecting FDA registered and CAP regulated laboratories. CPT & ICD-9 coding experience and Medicare reimbursement knowledge desired but not required. Please apply online at: www.dartmouth-hitchcock.org. EOE.

Director, Donor Services. The Mississippi Valley Regional Blood Center is searching for a dynamic individual to join our Donor Services management team as a Director, Donor Services. This position is based in Davenport, IA. We are excited to announce this opening

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POSITIONS (continued from page 14)

as an expansion to our current team. This individual will support our current operations with oversight to the assigned mobile and fixed site staff located in eastern Iowa and western Illinois. As Director, Donor Services you can expect to be involved in all aspects of staffing management including; but not limited to, interviewing and hiring, staff development, annual performance reviews, counseling and coaching. Additionally, this position will ensure compliance to established regulations, procedures, cGMP, criteria, and standards. The ideal candidate will have two to five years' experience in previous blood center setting or similar experience with supervisory experience preferred. A Bachelor's degree in biology or related science or business field is preferred. This position does require the ability to travel 25-50% of the work-week within the MVRBC service territory. We offer a competitive salary and excellent benefits including health, dental, vision, life, and 401(k). Apply online at www.bloodcenter.org, click on join our team. *Equal Opportunity Employer of Minorities, Females, Protected Veterans, and Individuals with Disabilities.*

QA Technical Specialist – Full time (Carter Blood-Care – East Texas). This position performs quality assurance functions which include: review of technical (laboratory operations) and other departmental quality assurance activities; review and approval of technical and other departments' operating procedures; preparation of QA departmental reports and procedures; perform quality assurance audits; and provide quality assurance support to all operational departments with an emphasis in technical areas. MT(ASCP) or equivalent required. Three years' experience in a hospital laboratory or transfusion service operation required; two years' experience in Quality System function application preferred. Carter BloodCare (CBC) is an EEO/Affirmative Action employer. CBC provides equal employment opportunities (EEO) to all employees and applicants and will not discriminate in its employment practices due to an employee's or applicant's race, color, religion, sex, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. CBC is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing. Qualified candidates may apply online at www.carterbloodcare.org.

Medical Director. The Mississippi Valley Regional Blood Center (MVRBC) is searching for a full-time Medical Director in Springfield, Illinois to support our operations throughout Illinois and Missouri. The Medical Director is primarily responsible for supporting the Chief Medical Officer and providing quality service to our hospital clients. The Medical Director will support

medical processes and procedures to ensure optimal medical care and regulatory compliance of IRL, have medical oversight of research endeavors, clinical consultation, medical support of clients, donor collections and counseling. This position will oversee and validate all Laboratory Standard Operation Procedures in conjunction with the Laboratory Director to establish compliance with manufacturer's directions, cGMP, and QA. This position will work closely with MVRBC Executive Management regarding laboratory issues and represent MVRBC to physicians and other public outreach regarding laboratory services. Requirements: MD Equivalent from an accredited medical institution, license to practice in assigned state(s) or ability to obtain, Board Certified in AP/CP or CP from American Board of Pathology (ABP), and Board Certified or eligible in Blood Banking/Transfusion Medicine from ABP. To apply, visit <http://www.illinoisdiversity.com/j/10170631>. MVRBC is a not-for-profit 501(c)(3) organization and an exclusive provider of blood products and services to hospitals in Illinois, Iowa, Missouri, and Wisconsin. EOE: M,W,V,D.

Regulatory/Compliance Director. BPL Plasma, Inc. is seeking a Regulatory/Compliance Director for our 33 US based plasmapheresis centers. The Regulatory/Compliance Director shall be responsible for adherence to all FDA, EU, IQPP, OSHA, CLIA, COLA and customer regulations and standards as they pertain to automated plasmapheresis collection. Respond to external audits, define and develop regulatory strategies and coordinate the preparation and implementation of compliance standards. Maintain key relations with individuals within the regulatory agencies and various customers. Work in conjunction with the Quality Department to promote continued improvement of corporate compliance. Must have the ability to work with cross-functional departments including Corporate Training, Quality Assurance, IT, CAPA, and Operations. Compliance Director will monitor trends and movements within the Industry. The Regulatory/Compliance Director will report to the Vice-President of Technical Affairs. Must be available to relocate to Austin, TX. Education/Experience: BS in related field or equivalent experience. 10 plus years' experience with plasma, blood, or medical industries, both in an operations and corporate capacity. Excellent communication skills (written and verbal) including ability to discuss regulatory requirements with senior management. Must have knowledge of CFR 21 series 200-299 and 600-799. To apply, please submit resumes fax to (407) 854-9883 or email mhafley@bplplasma.com. Please feel free to visit our website: www.bplplasma.com.

Account Manager. Mississippi Valley Regional Blood Center (MVRBC) is searching for an Account Manager

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POSITIONS (continued from page 15)

(AM) to cultivate successful relationships with assigned client accounts. The AM will develop relationships with hospitals to include specific, technical education on blood; blood industry updates; and support hospital regulatory compliance. This dynamic position will consist of approximately 25%-50% travel primarily in the Central Illinois to St. Louis region. The AM will support distribution of blood products by supporting sales and conducting inventory management as appropriate. This position requires a high understanding of laboratory science, specifically blood banking, in order to effectively communicate between hospital clients and lab staff. The ideal candidate will also possess experience in customer service/product marketing and/or understanding of inventory management. Statistical and data analysis experience is preferred. Candidates should have a bachelor's degree in Biology or related science field, business degree with demonstrated science background, or equivalent combination of experience and education will be considered. To apply, complete our online application, attaching a resume, at <http://www.illinoisdiversity.com/j/9734720>. Pre-employment drug screen and background check required. MVRBC is a non-profit organization and an exclusive provider of blood products and services to hospitals in Illinois, Iowa, Missouri, and Wisconsin. EOE: M, W, V, D

Marketing Director. Community Blood Center of the Carolinas, located in Charlotte, NC is seeking an experienced Marketing Director to oversee all organizational marketing, branding and public communication activities of our growing blood center. Responsibilities include donor and sponsor marketing efforts, website development, social media and print materials, such as newsletters, press releases, etc. Additional duties include developing and maintaining media contacts/opportunities in the Central Piedmont region of the Carolinas. Our ideal candidate has a minimum of five years of experience in marketing and communications, demonstrated creative writing skills and the production of internal and external communications. Email resume and salary requirement to cbccteam@cbcc.us, resumes without salary requirements will not be considered. EOE/Drug Free Work Zone.

National Scientific and Technical Services Roles (Australia). The Australian Red Cross Blood Service is currently seeking a National Scientific and Technical Services Manager and two National Scientific and Technical Services Senior Advisers. These roles, based in Australia, will contribute to the leadership and implementation of scientific and technical processes within the manufacturing division to ensure the reliable, efficient and effective supply of blood and blood products within Australia. The roles require a university degree in science in a biomedical discipline, experience in a sen-

ior scientific and technical management role preferably within a manufacturing environment, experience leading and implementing change according to a national agenda and strong analytical and communication skills, including stakeholder engagement experience. Please contact the Australian Red Cross Blood Service before **30th January 2015** for further information international@redcrossblood.org.au.

IRL Technologist. Puget Sound Blood Center is seeking an experienced immunohematology reference Technologist on weekends. Technologists in this lab conduct workups on complex antibody problems and red cell reference testing, prenatal testing, testing for suspected hemolytic transfusion reactions, compatibility testing and antibody titration studies for potential donor/recipient of progenitor cells, bone marrow and solid organ transplants. Technologists also maintain a frozen red cell inventory consisting of rare antigen negative units. Requirements include: BS CLS/MT or equivalent, MT(ASCP) or equivalent certification and two years of immunohematology reference laboratory experience. SBB(ASCP) strongly preferred. More information at www.psbcc.org. Qualified applicants send resumes to humanresources@psbc.org Attention: Job #7429ABC. Puget Sound Blood Center is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law.

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