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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2013 #9 **March 8, 2013**

INSIDE:

Age of RBC Controversy Continues to Produce Conflicting Data

The ability to preserve red blood cells (RBCs) for up to 42 days, as permitted by the Food and Drug Administration, has allowed for better inventory management and decreased wastage of RBCs. In recent years, however, controversy has arisen surrounding the optimal RBC age for transfusion; some studies suggest that patients fare worse when transfused with blood stored for longer time periods, while others have found there is no difference in clinical outcomes based upon RBC age at transfusion. Two recently published studies highlight the conflicting data.

Steven B. Solomon and colleagues of the National Institutes of Health Clinical Center, in a study published in *Blood* on Feb. 28, found increased mortality after transfusion with older stored blood in a canine model. In contrast, a retrospective, observational clinical study of 6,994 patients published in *Anesthesiology* by Leif Saager and colleagues, reported that RBC storage duration was not associated with increased mortality in non-cardiac surgical patients.

Storage of RBCs results in what is referred to as the "storage lesion," which is characterized by rheologic changes, metabolic derangements in oxygen affinity and delivery, oxidative injury to lipids and proteins, RBC shape change, loss of membrane carbohydrates and reduced RBC lifespan. Some studies have suggested that the storage lesion contributes to poorer clinical outcomes.

Many studies of RBC transfusion have associated storage age with clinical outcomes. However, they provide conflicting results and are limited by "retrospective analysis, different methodological and analytical approaches insufficiently adjusting for confounding factors or disease severity, single- vs. multiple-center populations, retrospective vs. prospective evaluation, variable population sizes, accrual time range, divergent patient populations, and variable erythrocyte processing and storage methods," note Jerrold H. Levy, MD, and Marie E. Steiner, MD, in an accompanying editorial in *Anesthesiology*.

RBC Age in Canines. To address these drawbacks, Solomon *et al*. conducted a randomized blinded trial in beagles assessing clinical outcomes of fresher blood vs. blood at the end of its storage period. Beagles with *Staphyloccus aureus* pneumonia were randomized for exchange transfusion with either 7- or 42-day old canine universal donor blood. The blood was leukoreduced, stored, and processed with procedures similar to those for human blood.

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OUR SPACE

ABC Vice President of Administration and Communications Matt Granato

Leaner Learning

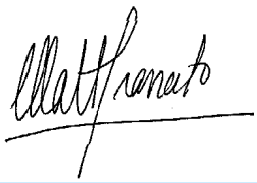
We continue to sift through hundreds of pages of SEQuaLS survey data, slicing and dicing it in many forms to find actionable ways to improve service to our membership. One clear message is that our members have been operating under financial strain during the past four years, likely because of increasing competition and hospitals' cost-cutting imperatives ahead of health care reform. SEQuaLS also shows that fewer members were able to attend ABC's in-person meetings and specialty workshops, citing "no budget" as the top reason for their non-attendance. So, it comes as no surprise that many survey respondents expressed interest in "... training tools and other resources that ABC offers that do not require traveling to attend a workshop."

Last year, in anticipation of tighter budgets, we standardized and consolidated in-person meeting registration fees, offering early bird discounts and standard fees for all two-, three-, and four-day workshops. We also offer one of the lowest registration fees for staff development and networking in the whole of blood banking. In essence, we've made it easier for our members to plan and budget accordingly.

But still, members want education, networking and training opportunities that do not require travel. For that, we have increased the number of ListServs in the past few years from just a few to 13, and are planning to ramp up the number of webinars. These webinars have proven to be very popular and a highly rated alternative to workshops and meetings. The topics and speakers on these webinars are just as high quality as those at our meetings and workshops, and ABC's committees complete a rigorous selection process to ensure the best results.

In addition, we have made the ABC Members' Website a treasure trove of resources. When was the last time you checked the SMT section, for instance? What about the e-catalog on school partnerships and youth recruitment initiatives developed by fellow members? Not to mention, webinars are recorded and posted on this website to review and share with colleagues.

Our work in bringing "leaner learning" options is just beginning. We have received a grant from the Foundation for America's Blood Centers to redevelop the members' website, which will allow us to expand content and features, while making it more user friendly. There's no denying that face-to-face learning and networking is the most effective; however, ABC will continue to invest in online and self-directed learning resources to ensure that we efficiently and effectively offer services that respond to the current needs of our diverse membership.



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.

America's Blood Centers
President: Dan A. Waxman, MD
Chief Executive Officer: Jim MacPherson
ABC Publications Editor: Betty Klinck
Business Manager: Leslie Norwood
Annual Subscription Rate: $390

Send subscription queries to mnorwood@americasblood.org.
America's Blood Centers
725 15th St. NW, Suite 700, Washington, DC 20005
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

Age of RBC Controversy (continued from page 1)

Mortality was 100 percent (12 out of 12) with 42-day-old blood, while 4 of 12transfused with seven-day-old blood died. Transfusion with the older blood was also associated with increased lung injury and degree of shock. Older blood was more vasoactive in that during transfusion, systematic pressures and pulmonary artery pressures were higher. The concentration of plasma cell-free hemoglobin increased progressively in animals receiving the older blood.

In addition to increased mortality, the data support increased *in vivo* hemolysis and the nitric oxide (NO) depletion as a mechanism of increased risks of older stored blood. The authors note the inability to generalize canine results to humans.

"This study represents an important proof of principle," said Harvey G. Klein, MD, chief of the NIH Clinical Center's Department of Transfusion Medicine and one of the authors. "In an animal model of severe illness, we were able to compare transfusion of large volumes of the freshest blood with blood at the outdate, something that is not possible in clinical studies of patients."

He added, "Had we not observed a striking difference in mortality, we likely would have abandoned further studies of the clinical toxicity of stored blood. We now intend to pursue a series of studies related to the mechanism of this finding. We do not know if these results are limited to animals with severe pneumonia, infectious diseases in general, or any clinical situation in which mortality is high and large amounts of old blood are transfused. We are also interested in whether the mechanism in this model represents NO scavenging, iron release from red cells, other mechanisms or a combination of mechanisms. We do not believe that the finding is limited to the dog, but neither can we generalize these findings. All of these hypotheses can be studied in this model."

RBC Transfusion In Non-Cardiac Surgical Patients. Many studies linking RBC storage duration to postoperative morbidity have been in cardiac surgery, intensive care, and trauma populations. Saager and colleagues sought to evaluate whether or not RBC storage duration is associated with postoperative all-cause mortality among non-cardiac surgery patients. They used data from the Cleveland Clinic Perioperative Health Documentation System on 63,319 adult general surgery patients at Cleveland Clinic from January 2005 through June 2009.

Patients receiving leukocyte-reduced allogeneic RBC transfusions between two days before surgery and seven days after were included in the study. They were grouped into three storage duration groups based on whether their median storage duration was $\leq$ 14 days, > 14 days but $\leq$ 28 days, or > 28 days. A total of 6,994 patients receiving 19,462 transfusions were analyzed. As expected, patients included in the analysis were generally sick, with 80 percent in American Society of Anesthesiologists' Physical Classification of III or above.

There was no statistically significant relationship between median RBC storage duration and mortality. "Our study adds to the growing body of transfusion research showing that erythrocyte age may not be associated with increased postoperative mortality or morbidity," write the authors. They note that a controversial study conducted at the Cleveland Clinic by Koch *et al*. demonstrated an almost 60 percent increase in in-hospital mortality and significantly increased adverse events in patients receiving older blood. This discrepancy is likely due to the inability to adjust for unmeasured confounding in retrospective, observational studies, the use of different statistical methods, and the distinct clinical populations.

"The current study is an important addition to the literature because these surgical patients represent a less critically ill patient population compared with other age of erythrocyte storage studies," however this

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Age of RBC Controversy (continued from page 3)

data still does not answer the question of whether RBC age has an effect on clinical outcomes, write Dr. Levy and Dr. Steiner in their editorial. They note that assessing the impact of RBC age in critically ill patients presents issues because this "group is simultaneously at risk of multi-organ dysfunction because of causes that may also reflect their underlying illness and confound interpretation of the postulated effects of stored erythrocytes on transfused patients." It is hoped that ongoing large, randomized, controlled, clinical trials (e.g. RECESS and ABLE) may offer more definitive answers in the near future.

Citations: Levy JH, *et al*. Clinical studies of erythrocyte outcomes and mortality: size really counts. Anesthesiology. 2013 Jan;118(1):10-2.

Saager L, *et al*. Anesthesiology. 2013 Jan; 119(1):51-8.

Solomon SB, *et al*. Mortality increases after massive exchange transfusion with older stored blood in canines with experimental pneumonia. Blood. 2013 Feb 28;121(9): 1663-72.

Philippe Vanderckhove, MD, PhD, Elected Next EBA President

The European Blood Alliance (EBA), a partner of America's Blood Centers, recently announced that Philippe Vandekerckhove, MD, PhD, CEO of the Belgian Red Cross-Flanders, will succeed Jeroen de Wit as the next EBA president in January 2014. The election will be formally confirmed at the upcoming Copenhagen Board Meeting and Dr. Vandekerckhove's term will run from January 2014 to December 2016.

"I am very happy to have Philippe as my successor," said Mr. de Wit. "He is very capable and I am convinced that EBA will flourish under his leadership." Mr. de Wit and the EBA board have congratulated and expressed their full support for Dr. Vandekerckhove, who currently serves as EBA's vice president.

Prior to becoming CEO of the Belgian Red Cross-Flanders, Dr. Vandekerckhove worked as the clinical director of the University Hospital Leuven in Belgium, where he also obtained his medical degree, PhD, and his pathology degree. He completed further clinical and pathology training in South Africa at the University of Johannesburg and the University of Cape Town; in the US at Woods Hole Marine Biology Laboratory, the University of Hawaii, and New York University; and also in The Netherlands at the Erasmus University.

Dr. Vandekerckhove also studied healthcare management at INSEAD business school in France and general management at Harvard Business School. He has published about 50 articles in peer-reviewed journals, and five chapters in textbooks, mainly in the field of immunology, hematology, blood banking, and evidence-based medicine.

Dr. Vandekerckhove is an associate professor of medicine at the University of Leuven and the University of Ghent, president of the World Health Organization's Global Advisory Panel (GAP) on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies, board member of two general hospitals and the Institute of Tropical Medicine in Antwerp, Belgium, and is a member of the investment committee of Flanders' Care Invest (Flemish government).

"I hope to be a worthy successor and to continue along the path that Jeroen and the executives have defined and refined in recent years," said Dr. Vandekerckhove.

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INSIDE ABC

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

ABC Requests Topics for Future Blood Center Leadership Forums

America's Blood Centers has requested that ABC member blood centers offer their feedback to identify topics and speakers for the Blood Center Leadership Forum that takes place at every Annual and Interim meeting. ABC would like to offer its member blood centers the chance to express what current hot topics in blood center management, operations, and business sustainability that are most relevant at their centers.The proposed topics will be used to help develop the 2013 Interim Meeting (Milwaukee) and beyond. ABC members are asked to respond by Wednesday, March 13. The survey link can be accessed through MCN 13-036 at: http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=4191.

BOOTS Session 8 to Focus on Mergers and Acquisitions

With hospitals merging to form large healthcare systems, many blood centers have also formed various alliances, mergers, and partnerships – changes that are often met with anxiety and uncertainty about what the future holds for blood banking. America's Blood Centers has worked with ProGuide Management to develop a BOOTS (Blood bank Operations Optimization Training Sessions) workshop specifically focused on mergers and acquisitions (M&A) within the ABC network.

BOOTS is an industry-specific program sponsored jointly by ABC and Blood Centers of America in conjunction with ProGuide Management. The 8th BOOTS session will be held in Orlando, Fla. on April 23 and 24 at the Grand Bohemian Hotel, and will answer many common questions surrounding this complex topic. The session will bring blood center leaders up to speed on market dynamics, discuss the key drivers that lead to merger activity, and present what it takes for a successful outcome. The highlight will be the discussion led by several blood bank leaders on why they chose to merge.

Some of the main learning objectives include understanding the M&A process from start to finish, understanding key drivers and circumstances that lead to merger, setting reasonable expectations when merging, and hearing relevant success stories from other blood centers. ABC invites all blood center CEOs, chief operation officers, chief financial officers, and board chairs to participate in the M&A activity. To register for this or any of the BOOTS sessions, please visit http://www.cvent.com/d/1cqxb5/1Q. Questions regarding registration may directed to Lori Beaston at lbeaston@americasblood.org. ♦

Will You Have the "*Luck of the Draw*" at the FABC's Dart Throwing Contest?

The Foundation for America's Blood Centers will be hosting the Luck of the Draw Dart Tournament on March 17, St. Patrick's Day, during America's Blood Centers Annual Meeting. Attendees will enjoy light hors d'oeuvres and docent-led tours of Decatur House, the historic landmark nestled on Washington D.C.'s Lafayette Square with views of the White House, while mingling with peers. Come find out if you will have the "luck of the draw" at the FABC's dart throwing contest and fundraiser, to be held in the courtyard of the Decatur House. Participation is $100 per entry and there will be opportunities for "buy backs" during the event. Don't miss your chance to sign up for the Luck of the Draw Dart Tournament! If you did not sign up through the online ABC Annual Meeting registration and would like to do so, please contact Lori Beaston by Friday, March 15 at lbeaston@americasblood.org. Sponsor attendees may contact Abbey Nunes at anunes@americasblood.org.

BRIEFLY NOTED

A study by M. James Lenhard, MD, and colleagues in *Transfusion* suggests that screening blood donors for diabetes is accurate, convenient, and inexpensive. There is much discussion surrounding whether health screening tests offered to blood donors and the subsequent interventions are effective public health interventions. The researchers investigated the accuracy and cost of diabetes screening within the blood donor population. The Blood Bank of Delmarva, an America's Blood Centers member, implemented free, voluntary plasma glucose screening as part of the donation process between October 2007 and March 2008, screening 26,415 donors using a single random plasma level. Donors were able to access their test results through Blood Bank of Delmarva's secure website, and were instructed to follow-up with a healthcare provider if their value was more than 200 mg/dL. Individuals with blood glucose values of more than 400 mg/dL were called by blood bank staff. Blood bank staff also successfully contacted 139 out of 178 individuals identified with an random plasma glucose level of more than 200 mg/dL. They found that fifty-nine of these 139 high-risk donors (42 percent) had sought follow-up, but many had not contacted their physician. Of that 59, there were 33 new diabetes cases diagnosed by a physician while 26 indicated they were not diagnosed with diabetes. Cost analyses showed that the mean cost to screen was less than $1 per donor. The cost per case identified was estimated to be less than $500 for a RPG cutoff of 200 mg/dL. The authors note limitations that include the self-reported diagnosis of diabetes. Also, the estimated societal cost did not include the cost of false negatives. Furthermore, it is not possible from this study to determine the overall impact on long-term benefits and reductions on the cost to chronic disease management for diabetes in the community. The authors concluded that screening during blood donation appeared to be accurate, convenient, and inexpensive.

Citation: Lenhard MJ, *et al*. Screening blood donors for diabetes: analysis of use, accuracy, and cost. Transfusion. 2013 Mar 3.

The Food and Drug Administration alerted healthcare providers on Feb. 24 of a voluntary nationwide recall of all lots of Omontys Injection (peginesatide) by Affymax and Takeda Pharmaceuticals. Omontys is a drug used to treat anemia in patients on dialysis, and it was recalled due to reports of anaphylaxis, a serious and life-threatening allergic reaction. FDA advised healthcare providers to stop using the drug until further notice. According to the companies, serious and fatal hypersensitivity reactions have been reported in some patients within 30 minutes after receiving the first dose of the drug. There have been no reports of reactions following subsequent dosing, or in patients who have completed their dialysis session. The companies reported that they are investigating these adverse reactions. More information about the recall can be found at http://1.usa.gov/13Bdb9x. (Source: FDA press release, 2/24/13) ♦

REGULATORY NEWS

The Food and Drug Administration has granted 510(k) approval to Terumo BCT's Spectra Optia Apheresis System's Mononuclear Cell Collection (MNC) Protocol. The MNC protocol on the Spectra Optia system has been available since July 2010 in Europe and in select countries in the Middle East, Asia, and Africa. The Spectra Optia system's therapeutic plasma exchange protocol has already been approved by the FDA. Terumo BCT conducted extensive laboratory testing to verify and validate the functionality and effectiveness of the MNC procedure. The FDA documents can be found at http://1.usa.gov/ZqxIfQ.

AABB recently published a summary of the November 2012 Cell Therapy Food and Drug Administration Liaison Committee meeting, along with corresponding speaker presentations. The meeting focused on the globalization of cellular therapies. The first session identified the key issue of reconciling ISBT 128 labeling with the required labeling for FDA-approved cellular therapy products. The speaker noted that ISBT 128 registration is increasing due to the growing number of cellular therapy facilities. The second session focused on the unique biology of origin of mesenchymal stem cells, and the final session highlighted the expansion of cellular therapy science and practice. The meeting was hosted by the International Society for Cellular Therapy. The meeting summary can be accessed at www.aabb.org/events/government/fdaliaison/ct/Pages/ctmeeting121119.aspx. (Source: AABB Weekly Report, 3/1/13)

AABB recently published the proposed 11th edition of Standards for Relationship Testing Laboratories. It is available for public comment until April 22, 2013. The AABB Relationship Testing Standards Program Unit encourages all interested individuals to submit comments during this time. The 11th edition will go into effect on Jan. 1, 2014. The draft can be viewed at www.aabb.org/sa/standards/Pages/propstdsrt11.aspx. (Source: AABB website, 3/1/13)

BLUE PLATELET SPECIAL

Lauren Ward Larsen

In Suffering, Connection

To say that Al Klein and I knew one another when we both worked at a Fortune 50 company years ago would be misleading. More like we knew *of* one another. Despite working in the same department, the corporate culture never quite felt like it supported authentic connections. Clever and pithy exchanges among co-workers took precedence over sincere and heartfelt conversations. Bravado was king, and the shark-infested halls were no place to show fear, doubt, or vulnerability. *Especially* vulnerability.

Twenty years after leaving the company, I received an email from Al. He was almost finished reading my book, and he felt the need to connect with me. Six months earlier – and after years of headaches and misdiagnoses – Al had been diagnosed with a malignant brain tumor. Following an emergency brain surgery, he underwent chemo and radiation, and was now adjusting to the reality of his post-cancer life, which included the strong likelihood that the tumors would return.

Within a handful of e-mails, Al and I had formed a nice friendship. No topic was off limits: spirituality, dream interpretation, relationships, our fears, our hopes, and the many ways that our medical challenges had changed us. Though we'd originally met through work, it was our mutual experience with suffering that truly forged our bond. The details of our respective illnesses were almost irrelevant. What we quickly discovered was that we shared similar responses to life-threatening illness: the difficulty in learning to sit (or more accurately, lie) still and allow others to care for us, the need to embrace the vulnerability that goes hand in hand with serious illness, and the desire to be better people and to help others, especially after receiving all that love and support and help while we were each the ones in need.

I believe Al put it best when he said, "I have a great family and great friends, and I've been overwhelmed by the love and support they've shown – that's the silver lining through this ordeal. Actually, the love is so much more important than the ordeal."

In 2011, I invited Al and his wife to join me in New York City for a gala benefit I was chairing, but he told me he no longer enjoyed attending large events with lots of strangers. Instead, he invited me to join him for lunch after the benefit if I could stay in the area for another day. I declined, feeling the need to return to Colorado shortly after the fundraiser, but promising to get together during my next trip to New York.

The minute I received an email from Al's wife months later, I regretted not having stayed that extra day to have lunch with Al. The email's subject line read: A Note of Sorrow. The tumors had returned, this time more aggressively. Al had passed away the previous evening.

This life, for every one of us, is filled with suffering. Nowhere is this more apparent than in blood services. Every blood recipient is suffering in some regard, be it with an acute medical challenge or a lifelong transfusion-dependent illness. Every parent of a child who needs a blood transfusion understands suffering – both their child's and their own.

But amidst all this suffering is that undeniable silver lining – the gift of authentic connection between people. Between a patient and a nurse. Between a blood recipient and a donor. Even between two former business colleagues who were once too clever to be vulnerable.

Lauren Ward Larsen is the author of "Zuzu's Petals: A True Story of Second Chances," which shares her story of becoming a 200-pint blood recipient and the unexpected life that unfolded as a result. She is a former president of the FABC and can be reached at laurenwardlarsen@me.com, or via her website at www.laurenwardlarsen.com. 🩸

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SAVE THE DATE

America's Blood Centers'
Fund Development, Communications
and Donor Recruitment Workshop
San Antonio, TX – June 18-21, 2013
Hosted by **South Texas Blood & Tissue Center**

Negotiated hotel room rate: $159 + tax (incl. free internet and fitness center access)
www.hotelvalencia-riverwalk.com

2013 Workshop Schedule
Fund Development topics: June 18-19
Communications topics: June 19-20
Donor Recruitment topics: June 20-21

2013 Workshop Fees (early bird/regular)
2-day registration: $375/$425
3-day registration: $440/$490
4-day registration: $490/$540

Sponsorship opportunities available. Contact Abbey Nunes at *anunes@americasblood.org* for details.

"South Texas Blood & Tissue Center is proud to support this year's Fund Development, Communications and Donor Recruitment Workshop and is looking forward to welcoming ABC members from across the country to our vibrant city for a week of learning, sharing and networking. We hope to see you there!"

– Carmen Davila
Vice President of Corporate Communications
South Texas Blood and Tissue Center

San Antonio International Airport (SAT) is served by all major US airlines, including discount carriers Southwest and AirTran. It offers non-stop service to/from 27 major and secondary US airports; check www.sanantonio.gov/aviation for more information.

INFECTIOUS DISEASE UPDATES

BABESIOSIS

The American Red Cross recently published data regarding *Babesia microti* real-time polymerase chain reaction (PCR) testing of Connecticut blood donors, which also highlights the case of a PCR positive, antibody negative infected blood donor (i.e., a donor in the seronegative window period). B. microti is the tick-borne parasite that causes babesiosis in infected individuals. During the past three decades, B. microti has emerged as a concern in the blood community as more than 160 transfusion-transmissions have been reported. A study in the Connecticut Region of the ARC demonstrates a seroprevalence of B. microti in blood donors over a 10-year period of 1.1 percent. The current study was designed to ascertain the frequency of parasitemic donors, as determined by prospective real-time PCR testing of donors from a highly endemic area. Blood samples from consenting donors in southeastern Connecticut were collected from mid-August through early October 2009 and tested by IFA for immunoglobulin G antibodies and real-time PCR for B. microti DNA. Of 1,002 donors, 25 (2.5 percent) were IFA positive and three (0.3 percent) were PCR positive, of whom two were also IFA positive, while one was IFA negative. The two IFA-and real-time PCR positive donors appeared to subsequently clear infection. The other real-time PCR-positive donor did not provide follow-up samples. These results suggest that nucleic acid testing, in addition to serology, will need consideration as mitigation strategies are planned for B. microti.

Citation: Johnson ST, *et al*. Babesia microti real-time polymerase chain reaction testing of Connecticut blood donors: potential implications for screening algorithms. Transfusion 2013 Feb. 27.

INFECTIOUS DISEASE UPDATES (continued on page 10)

INFECTIOUS DISEASE UPDATES (continued from page 9)

HIV

A two-year old child born with HIV infection and treated with antiretroviral drugs beginning in the first days of life no longer has detectable levels of virus using conventional testing. The child appears to be functionally cured of HIV despite not taking HIV medication for 10 months. The case was presented this on Monday by Deborah Persaud, MD, of Johns Hopkins Children's Center, and Katherine Luzuriaga, MD, of the University of Massachusetts at the Conference on Retroviruses and Opportunistic Infections in Atlanta. It is the first well-documented case of an HIV-infected child who may have been functionally cured of HIV infection – that is, without detectable levels of virus or antibody and no signs of disease in the absence of antiretroviral therapy. Dr. Persaud and Dr. Luzuriaga led the analysis of the case, which was funded by NIH. In July 2010, the child was born prematurely in Mississippi at 35 weeks, to an HIV-infected mother who had received neither antiretroviral medication nor prenatal care. Because of the high risk of exposure to HIV, the infant was started at 30 hours of age on antiretroviral treatment consisting of zidovudine (AZT), lamivudine, and nevirapine. HIV infection was confirmed in two separate blood samples on the second day of life, analyzed with highly sensitive polymerase chain reaction (PCR) testing. The baby remained on the prescribed antiretroviral treatment regimen until 18 months of age, after which the child was lost to follow up and treatment was discontinued. When the child was seen again by medical professionals in the fall of 2012, blood samples revealed undetectable HIV levels and no HIV-specific antibodies. Longer follow up and further evaluation are needed to be certain the child is uninfected and to understand whether the experience of this child can be replicated in clinical trials involving other HIV-exposed children. The abstract describing the case is available at www.retroconference.org/2013b/Abstracts/47897.htm.

Citation: Persaud D *et al*. Functional HIV cure after very early antiretroviral treatment of an infected infant. 20th Conference on Retroviruses and Opportunistic Infections. ♦

PEOPLE

J. Michael Lee, DBA, FACHE, announced that he will retire as president and CEO of Hospital Central Services, Inc. (HCSC), where he has served since 1980. Headquartered in Allentown, Pa., HCSC is comprised of HCSC-Laundry, HCSC-Group Purchasing, and Miller-Keystone Blood Center (an America's Blood Centers member), in addition to HCSC-Enterprises, which serves as the management arm of the organization. During his tenure as president and CEO, HCSC-Laundry grew from serving about 15 healthcare facilities out of one laundry plant to serving more than 400 healthcare facilities out of five laundry plants. Also during this timeframe, Miller-Keystone Blood Center grew from serving eight regional hospitals to serving 25 hospitals in 12 Pennsylvania and New Jersey counties. Last year, the blood center scheduled nearly 124,000 donors, collecting more than 104,000 units of blood. Dr. Lee is a fellow in the American College of Healthcare Executives (ACHE), and a founding member of the regional ACHE Chapter, The Eastern Pennsylvania Healthcare Executive Network. He is also a member of the Academy of Management, the American Marketing Association, and AABB. Over the past 30 years, he has served as board or committee member with numerous organizations throughout the Lehigh Valley area in Pennsylvania. "When I moved to Pennsylvania in 1980, I never expected that I would remain here for the next 33 years of my career," said Dr. Lee. "It has been a privilege to work with Miller-

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PEOPLE (continued from page 10)

Keystone Blood Center's board of directors, staff, and volunteers, as well as the hospitals and other organizations in our community, to ensure the transfusion needs of our region are met. I am proud of Miller-Keystone's past achievements, and look forward to watching its continued success in the years to come." (Source: HCSC press release, 3/4/13)

Walter Ott, Carter BloodCare's chief financial officer (CFO), was recently recognized as *Fort Worth Business Press's* Nonprofit CFO of the Year. *Fort Worth Business Press* published an article highlighting Mr. Ott on Feb. 14, including a Q&A with him. Mr. Ott, a veteran in the blood banking and nonprofit industries, is considered an expert in the field. After receiving his degree in accounting from the University of Houston, he served at Gulf Coast Regional Blood Center in Houston for 10 years before moving to Fort Worth in 1995 to serve as Carter BloodCare's CFO. "I have always enjoyed numbers, percentages, averages, etc. I have always worked as an accountant in some type of industry and enjoy working with other people on running a successful business while providing a needed service," said Mr. Ott in the article. "The position in 1985 with the local blood bank in Houston was my first job with a charitable not-for-profit company. I quickly realized the great feeling you receive when you see first-hand how lives are changed by what the organization does and you are a part of it." Colleagues describe Mr. Ott as a problem-solver and a team builder who has been instrumental in both strategic and financial planning for the center. He has served on the financial committee of America's Blood Centers and collaborates with fellow CFOs at other blood centers to identify and implement best practices. Under Mr. Ott's leadership, his colleagues say, Carter BloodCare is in sound financial shape. The article and Q&A are available at http://bit.ly/Zu5Ves.

Several employees of America's Blood Centers' member centers will be recognized with awards at the upcoming 2013 South Central Association of Blood Banks (SCABB) Annual Meeting in Baton Rouge, La. in April. **Mary Beth Bassett, BS, MT(ASCP)** executive vice president and chief quality officer at Blood Systems, will be honored as SCABB's Administrative Award Lecturer. Ms. Bassett has served in her role at Blood Systems since 1996. She is responsible for the development and execution of quality and regulatory programs for Blood Systems and their affiliates, as well as Creative Testing Solutions. She directs the performance improvement program for Blood Systems and leads the organization's quality consulting service. She will present "Two Sides of the Same Coin ... The Business of Quality AND the Quality." **Susan T. Johnson, MSTM MT(ASCSP) SBB,** director of Clinical Education at BloodCenter of Wisconsin, will be recognized as the Technical/Scientific Award Lecturer. She is also the director of Clinical Education and the director of the Specialist in Blood Banking Program and the Transfusion Medicine program at Marquette University Graduate School. She is the associate director of the Indian Immunohematology Initiative. She will speak on "Serologic Strengths – Limitations in Automated Age." **Marion E. Reid, PhD,** New York Blood Center's head of the Laboratory of Immunochemistry, will give the John Moulds Memorial Lecture. Dr. Reid trained as a medical technologist and later obtained a PhD and an honorary DSc. Her career of more than 50 years in England, California, and New York, has focused on various aspects of immunohematology. She has co-authored more than 400 peer-reviewed articles and several books and has received numerous awards. Dr. Reid will give a talk called "Blood Group Systems: An Update." Mark E. Brecher, MD, chief medical officer and senior vice president of Laboratory Corporation of America, will give the Karen Williams Memorial Lecture. More information about the annual meeting and awards can be found at www.scabb.org. (Source: SCABB press release, 3/4/13)

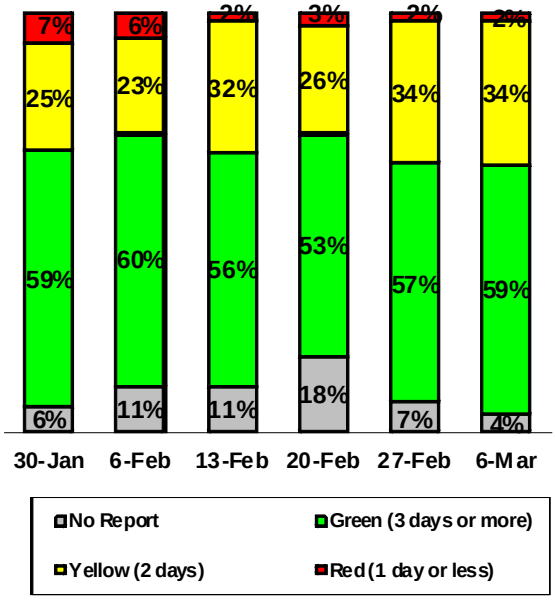
PEOPLE (continued on page 12)

PEOPLE (continued from page 11)

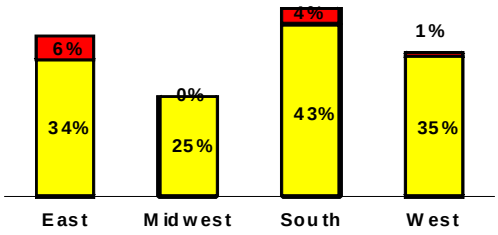
Asim K. Debnath, PhD, a researcher at New York Blood Center's (NYBC) Lindsley F. Kimball Research Institute (LFKRI), has been awarded a $3.5 million grant over five years from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), announced NYBC in a press release. The grant will support research to design novel inhibitors against HIV-1 and bring the most potent inhibitors to pre-clinical testing as potential new HIV drug candidates. "The first step in HIV-1 infection is the entry of the virus into the host cell," said Dr. Debnath, head of Molecular Modeling and Drug Design at LFKRI and the principal investigator of the NIH grant. "We pioneered the identification of small molecule inhibitors which bind to a specific site that is highly conserved among HIV-1 strains and critical for viral entry, and therefore, vulnerable to inhibition by new drugs. This award will support our continued research in designing next generation inhibitors as potential new HIV drugs." (Source: NYBC press release, 2/28/13)

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, March 6, 2013



Percent of Total ABC Blood Supply Contributed by Each Region

East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily Updates are available at:
www.AmericasBlood.org

Larry Frederick Gives Inspirational Talk to Blood Donors

Larry Frederick, a blood donation advocate and motivational speaker, recently spoke at Blood Center of the Pacific's Bucket Brigade Awards Luncheon on Feb. 26. He is pictured (left) shaking hands with Middletown Fire Blood Drive Coordinator, Babe Vecellio. The luncheon was held to honor the 17 fire departments that participated in the 7th Annual Bucket Brigade Blood Drive Challenge, which recruited 818 people to give more than 700 units of blood. Over the past seven years, 7,500 donors have participated in the Bucket Brigade Blood Drive Challenge. Mr. Frederick moved the room to tears when he shared his personal story during the luncheon and expressed his gratitude for first responders and blood donors. He is a member of America's Blood Centers' Conversations About Life Speakers Bureau.

COMPANY NEWS

Cerus reports that it has reached an agreement with the Food and Drug Administration to proceed with filing the premarket approval application (PMA) for INTERCEPT platelets using existing clinical data. In discussions with FDA last week, Cerus reviewed hemovigilance data, including that obtained in the EU, which included more than 130,000 INTERCEPT platelet transfusions in France and Switzerland, said Laurence M. Corash, MD, senior vice president, chief medical officer, and chief scientific officer of Cerus. The data also included a recent presentation at the 15th International Hemovigilance Seminar in Brussels, Belgium by Swissmedic for 62,500 INTERCEPT platelet transfusions over two years demonstrating a reduction in severe adverse events, including respiratory events, after national adoption of INTERCEPT platelets. In consideration of this body of hemovigilance data, in conjunction with prior US data and EU randomized clinical trial data, FDA agreed that the combined data were sufficient to file a PMA for INTERCEPT platelets without conducting another prospective clinical trial. Cerus will also be working with FDA to define a Phase IV post-marketing study plan, said Dr. Corash. This agreement is an important step for Cerus in gaining FDA approval of INTERCEPT platelets after a 2009 FDA Blood Products Advisory Committee meeting put progress for this product's approval on hold, potentially requiring further clinical trials. "We believe 2013 will be a pivotal year for Cerus in which we plan to both complete our INTERCEPT plasma PMA submission and begin planning for the PMA filing for INTERCEPT platelets," said William "Obi" Greenman, president and CEO of Cerus. (Source: Cerus fourth quarter and year-end 2012 financial report, 2/28/13)

Ortho Clinical Diagnostics sent a letter to its customers on March 6 indicating that Novartis Diagnostics has decided to discontinue the manufacturing of the entire RIBA product line. This letter was sent as a follow-up to a previous OCD notification issued on Oct. 3, 2013 about an inventory shortage of CHIRON RIBA HCV 3.0 SIA (RIBA HCV). FDA published approved alternative hepatitis C virus testing methods, which are available at http://1.usa.gov/T2Xrqk. ♦

MEETINGS

June 11-12 **2013 Plasma Protein Forum, Reston, Va.**

The Plasma Protein Therapeutics Association announced that it will hold the 2013 Plasma Protein Forum from June 11-12 at the Hyatt Regency in Reston, Va. The forum will address policies and regulations that impact consumers' access to plasma-derived and recombinant analog therapies. Consumers, physicians, caregivers, regulators, and policymakers in the industry are invited to attend. Panel discussions include 30 Years of the Orphan Drug Act, Rare Disease Profiles in Emerging Countries, and IVIG – Associated Hemolysis. More information and registration can be accessed at www.pptaglobal.org/pptaregistration/home.aspx.

July 29-31 **18th Annual GMP By The Sea, Chesapeake Bay, Md.**

Pharma Conference Inc. announced the 18th Annual GMP By The Sea conference at the Chesapeake Bay Hyatt in Chesapeake Bay, Md. from July 29-31. GMP (Good Manufacturing Practices) By The Sea provides attendees with the opportunity to learn from and meet government and industry experts, and each year, the conference provides attendees with the knowledge and tools to keep their compliance current. This year's conference will allow guests to discuss hot topics with Food and Drug Administration Officials, get FDA's latest thoughts on GMP matters, and interact with peers. More information is available at www.pharmaconference.com/index_pharm.htm. ♦

Correction

In last week's *ABC Newsletter*, we listed in front-page article all of the founding members of the Alliance of Blood Operators (ABO), but inadvertently omitted the American Red Cross. We would like to apologize for this error, and we thank our readers who bring such issues to our attention.

CLASSIFIED ADVERTISING

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

EQUIPMENT AVAILABLE:

For Sale. TANGO®optimo Automated Blood Bank Analyzer – purchased from Bio-Rad in August 2011. Only used for antibody screen testing from January 3, 2012 – November 25, 2012. Less than 100,000 tests performed. To make an offer, please contact Bobby Merrill at (859) 519-3763 or bmerrill@kybloodcenter.org.

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POSITIONS AVAILABLE:

Director, Scientific Affairs. Fenwal, Inc., a Fresenius Kabi company, is a medical technology company focused on improving transfusion medicine through unique expertise in blood separation, collection, filtration, storage and transfusion. Fenwal employs approximately 5,000 people worldwide, and operates five manufacturing centers.We have an opportunity for a Director, Scientific Affairs who will be responsible for building strong relationships between Fenwal and the transfusion medicine, therapeutic apheresis and cell therapy communities, and developing and leading various scientific advisory boards. Will act as the scientific liaison between customers, regulatory agencies and Fenwal, and assist the Fenwal commercial team in understanding and discussing clinical concepts with customers. Requires: PhD and an established and recognized track record in the transfusion medicine industry/ health sciences; in-depth scientific and therapeutic knowledge within transfusion medicine and cellular therapy areas. Please visit: www.fenwalinc.com for more information and to apply to job # 547. Fenwal is an Equal Opportunity Employer.

Assistant Medical Director. LifeStream, a $53M healthcare organization providing blood services to more than 80 hospitals in Southern California, is searching for an Assistant Medical Director. This position provides leadership and direction for the medical programs needed to support all laboratories, product management, hospital relations, donor collections, donor counseling, national marrow donor activities, and quality departments. Requirements: medical degree and board certification by a board registry recognized by the American Board of Medical Specialties. Meet eligibility requirements to obtain appointments to the medical staff of hospitals served by the center. Completion of primary medical internship and residency with minimum one year medical practice (transfusion medicine) or fellowship preferred. Valid license (or eligibility) to practice medicine in the state of California. Must be available to work on-call two weeks per month. Must pass pre-employment background check, drug screen, and physical exam. Apply online: www.LStream.org. LifeStream is an Equal Opportunity Employer, M/F/D/V.

Cord Blood Laboratory Manager. The Puget Sound Blood Center is seeking an experienced leader to manage our laboratory operations and oversee the development and coordination of protocols and procedures. The Manager is responsible for quality control, technical audits, and developing strategies for implementing new methodology, products, and services. This opportunity involves interaction with other medical organizations and supervision of laboratory personnel. The requirements for this position include: baccalaureate degree in medical technology or equivalent certification, two years' experience in cellular therapy, or related, two years' experience at the manager level; outstanding communication skills, knowledge cellular therapy standards, including cGMP and cGTP; familiarity with QA, cryopreservation, microbiology, sterile technique and safe handling of potentially infectious human blood/tissues. To apply, send application materials via email HumanResources@psbc.org or fax (866) 286-8495 with reference number 6917. Should you have a disability that requires assistance and/or reasonable accommodation with the application process, contact the HR department at humanresources@psbc.org, or at (206) 292-6500, or at 921 Terry Avenue, Seattle, WA 98104. Puget Sound Blood Center is an Affirmative Action / Equal Opportunity Employer.

Quality Assurance Regulatory Affairs Manager (Lifeblood, Memphis, Tenn.). The QA Regulatory Affairs Manager works under the supervision of the director of QA and the vice president, QA. Responsibilities include: review of procedures, processes and validation documentation to assure that current practices meet or exceed regulatory guidelines and industry standards, hosting external auditors/inspectors to include preparation of audit reports and response to audit findings as needed, performing internal audits, as assigned, assisting with management of licenses and certificates, reviewing/completing error reports and corrective/preventative actions, as assigned, managing staff. Minimum qualifications include: Bachelor of Science in related field or associate degree with commensurate experience, at least five years of management experience required, at least five years blood banking experience and/or operations in regulated industry, regulatory experience required, working knowledge of regulatory and accreditation standards including FDA, OSHA, and CLIA, and previous auditing and/or technical writing experience preferred. For more information or to apply, please visit http://lifeblood.iapplicants.com/.

Director, Quality Assurance (Virginia Blood Services). The Quality Assurance Director is responsible for assuring compliance to the ITxM Quality Plan and regulatory compliance for the Virginia region. Assist in the development and implementation of changes within the quality unit. Leads QA meetings. Provide quality presence for operational changes. Standardize QA processes between Pittsburgh, Chicago and Virginia. Assist and monitor the annual review of SOPs. Supervise staff. Bachelor of Science or Arts is required with a master's degree highly desirable. ASQ certification also highly desirable. Ten plus years progressive experience required with five years in a QA role in an FDA/cGMP regulated environment essential. Experience in a blood center setting is highly preferred. Progressive supervisory experience is required. Interested candidates can read a complete job description and apply online at www.vablood.org. Virginia Blood Services is an equal opportunity and affirmative action employer.