FDA Holds Workshop on Hemoglobin Standards and Iron Stores in Blood Donors

The Food and Drug Administration and the Department of Health and Human Services (HHS) held a workshop last week to discuss blood donor hemoglobin and hematocrit eligibility standards as well as maintaining adequate iron stores in donors. The workshop was held on Nov. 8-9 at the National Institutes of Health (NIH) in Bethesda, MD. This workshop was planned in partnership with the HHS Office of the Assistant Secretary for Health, the National Heart, Lung and Blood Institute, America’s Blood Centers, AABB, and the Plasma Protein Therapeutics Association.

Low hemoglobin and hematocrit levels are the most common reasons for donor deferral. Donors cannot donate more than once in an eight-week period to ensure recovery of their red blood cells’ (RBCs) iron stores. Under FDA’s current regulations, allogeneic blood donors must have a hemoglobin level of no less than 12.5 g/dL or a hematocrit value of 38 percent prior to donation, unlike many other countries where there are different hemoglobin requirements for males and females. Any change in these eligibility requirements would have a substantial impact on the blood supply.

This workshop comes after FDA’s Blood Products Advisory Committee (BPAC) and HHS’s Advisory Committee on Blood Safety and Availability (ACBSA) have met a number of times since 2001 to discuss the possibility of changing the hemoglobin level and methods to maintain iron stores in blood donors. ACBSA has recommended adopting hemoglobin eligibility standards that more accurately reflect gender-specific hemoglobin levels. BPAC has supported a change to the current hemoglobin eligibility level to 13.0 g/dL for males, while it has not supported a change to 12.0 g/dL for females that some experts have suggested.

Experts at the workshop discussed the possibility of changing hemoglobin standards, potential impact on the blood supply of these changes, and iron stores in blood donors. Presenters also discussed measuring hemoglobin in blood donors and whether this is an accurate measurement of iron stores. Many presenters supported a change to the 13.0 g/dL hemoglobin standard for men, as a number of anemic men are permitted to donate under current standards, while there was little agreement on changing the hemoglobin standard to 12.0 g/dL for women. Increasing the interdonation interval and providing iron replacement to better maintain iron stores also was discussed.

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ABC President Dan A. Waxman, MD

A Unique Approach to Education

America’s Blood Centers has always had a unique approach to education. Through meetings and workshops, we offer experts in blood banking and transfusion medicine the opportunity not only to learn about new initiatives and research, but also to share their ideas. Until the early 1980s, ABC’s educational efforts focused mainly on scientific, medical, and technical issues (SMT). Today, ABC offers educational resources in dozens of interest areas, displaying ABC’s commitment to educating all of those who come together to ensure a safe and available blood supply.

ABC offers countless networks, webinars, Listservs, and workshops in the areas of communications and donor recruitment, fundraising, quality education, human resources, finances, cell therapies, hospitals services, government relations, regulatory affairs, information technology, and executive leadership. This of course includes ABC’s Annual meeting and the SMT Forum and Medical Directors’ Workshop at ABC’s Interim Meeting.

Perhaps one of ABC’s most defining moments in the education arena was developing a good manufacturing practices train-the-trainer program in the early 1990s. FDA had raised the quality assurance bar by applying drug GMPs to the manufacture of blood components. Blood centers were scrambling to figure out how to meet these new requirements, until Ortho Clinical Diagnostics offered to tailor its employee pharmaceutical training program to blood centers. The program, now called Improving Manufacturing Practices and Quality (IMPAQ) and developed by ABC, has trained countless blood center employees and assured regulatory compliance.

ABC also recognizes that education is a two way street, which is why we strive to educate not only those within the blood banking and transfusion field, but also patients, the public, regulators, the media, politicians, hospital employees, and healthcare officials. ABC members work to educate those outside our field about current issues and research level using tools and resources developed by ABC staff and member representatives. Many of our resources now have a national and international reach, such as the ABC Newsletter. Most recently, ABC’s Appropriate Inventory Management-II software (AIM-II) will provide patient-level data to doctors and other healthcare providers. The expansion of ABC’s available learning resources, workshops, and networks is a testament to our dedication to one of our organization’s four Core Values: Education.

Editor’s Note: This is the second in a series of columns on ABC’s Core Values: Innovation, Data Integration, Education, and Advocacy. See ABC Newsletter, 10/21/11 for the last Core Values column or visit:

FDA Workshop (continued from page 1)

The workshop began on Tuesday morning with a welcome from Jay Epstein, MD, director of the Office of Blood Research and Review, and an introduction from Richard Davey, MD, director of the Division of Blood Applications. The first session of the day featured presentations discussing hemoglobin standards for blood donors in the US.

Bryan Spencer, MPH, of the American Red Cross, discussed a study by the Retrovirus Epidemiology and Donor Study II (REDS-II) group that examined hemoglobin distribution and the deferral patterns in blood donors. The REDS-II Donor Iron Status Evaluation (RISE) study enrolled first-time, reactivated, and frequent repeat donors, and measured hemoglobin and iron status. Hemoglobin is used as an indirect measure of iron status, but measuring ferritin or soluble transferrin receptors (sTfRs) more accurately reflect the body’s iron stores and red cell iron deficit.

The data demonstrate that hemoglobin is a poor indicator of iron status in donors and that there is considerable variability in fingerstick sampling in hemoglobin measures. The REDS-II demographic data on hemoglobin deferrals showed that premenopausal women and older men are at high risk of deferral for both low hemoglobin and depletion of iron stores in the face of “acceptable” hemoglobin levels.

Several other presenters referenced this REDS-II data, agreeing that hemoglobin is a poor indicator of donor iron stores. Richard Benjamin, MD, chief medical officer of the American Red Cross, agreed with that sentiment, but said that changing hemoglobin criteria for men and women would have unintended consequences, including increasing errors, recalls, and withdrawal. He added that this change could also place an increased burden to donate on younger donors who are known to be iron poor and more susceptible to reactions and injuries. Other speakers acknowledged that younger first-time donors, especially teenagers, tend to be lacking nutritionally, often are already iron deficient, and are more prone to adverse outcomes.

Richard Forshee of the FDA’s Center for Biologics Evaluation and Research, presented a regression model used to predict hemoglobin deferral. It showed that if the hemoglobin threshold were changed to 12.0 g/dL for females, FDA predicts that 13.8 percent of female donors would be deferred under the current 56-day interdonation interval. Currently, 26.1 percent of females are deferred under the 12.5 g/dL threshold, using this model. If the limit were changed from to 13.0 g/dL for men, the predicted percentage of deferred donors would change from about 2.1 percent to 5.6 percent.

Louis Katz, MD, executive vice president of medical affairs at Mississippi Valley Regional Blood Center (MVRBC), presented data collected at MVRBC showing that the impact of changing the hemoglobin standard on plateletpheresis collections would be substantial and similar to the impact on whole blood collections. He added that this observation needs confirmation elsewhere, and that a study is in progress to assess iron stores in platelet donors. Toby L. Simon, MD, spoke on behalf of the Plasma Protein Therapeutic Association, suggesting that no changes to the hemoglobin standard be made concerning plasma as there is no substantial RBC loss with plasmapheresis.

Session 1 concluded with a panel discussion highlighting studies in progress such as a UK study examining 50,000 donors and the interdonation period, as well as a REDS-II study investigating different hemoglobin levels for men and women. The panel also discussed lack of endurance and fatigue, increased referrals to physicians, restless leg syndrome, and pica as clinical effects of iron deficiency. The second session discussed hemoglobin measures in blood donors. Mindy Goldman, MD, of Canadian Blood Services, compared the various instrumentation and sampling methods to measure hemoglobin.

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FDA Workshop (continued from page 3)

She stated that measuring hemoglobin in donors is a compromise between the ideal and the operationally feasible.

Richard Cable, MD, scientific director of the American Red Cross, Northeast Division, compared fingerstick to venous samples in determining hemoglobin in donors. He analyzed RISE data showing that in six blood centers fingerstick testing overestimates venous hemoglobin in the upper range of hemoglobin, but underestimates venous hemoglobin in the lower range. Also, in most iron-depleted women and some iron-depleted men, fingerstick overestimates venous hemoglobin at the donation cutoff. Susan Leitman, MD, of the NIH Clinical Center, also discussed the possibility of using changes in the RBC mean corpuscular volume (MCV) to detect iron deficiency in apheresis donors. This session concluded with another panel discussion.

The final session on Nov. 9, featured presentations on iron stores and iron deficiency in blood donors. Joe Kiss, MD, of the Institute for Transfusion Medicine, presented data on a laboratory assessment of iron status in blood donors from the RISE study, and indicated that hemoglobin level is a late consequence of iron depletion and does not accurately reflect body iron status. He instead suggested more direct measurements of iron status such as ferritin and s TFRs. Ferritin is the iron storage vehicle and s TFRs result when a truncated form of the transferrin receptor is shed due to the RBC being deprived of iron or increased erythropoietic proliferative activity.

Alan Mast, of BloodCenter of Wisconsin, also presented RISE data, concluding that blood donation causes iron deficiency and recommending ferritin testing on frequent donors. He also added that donors are at different risks for low hemoglobin deferral depending on factors like age, sex, and race/ethnicity. He stressed that iron deficiency in young donors is an issue.

Barbara J. Bryant, MD, of the NIH, presented the results of the Iron Replacement or Not (IRON) NIH protocol, which investigated the value of oral iron replacement in blood donors. The researchers found that donors with low fingerstick hemoglobin and iron deficiency returned to a normal fingerstick and venous hemoglobin with oral iron supplements and could donate blood. Ferritin levels increased but leveled when donors returned to donate blood, and MCV also returned to normal range. She concluded that the results showed iron replacement therapy to be inexpensive, safe, and effective in preventing iron deficiency and that it leads to more productive donor visits and better donor retention. Anthony Keller, MD, of the Australian Red Cross also reported successful implementation of iron replacement.

Michael Busch, MD, PhD, Brian Custer, PhD, MPH, and Hany Kamel, MD, of Blood Systems Research Institute presented Blood Systems’ data on blood donors, hemoglobin, iron, and comparative effectiveness research strategies to mitigate iron deficiency in blood donors. The researchers presented several approaches, concluding that data supports using predonation hemoglobin levels and possibly prior donation frequency to target interventions to donors at greatest risk of deferral/iron depletion. This includes targeted use of ferritin testing to identify donors with low hemoglobin who are at greatest risk of donation induced iron loss and anemia.

Merlyn Sayers, MB, B.Ch., PhD, of Carter BloodCare, presented data on the effects of lengthening the RBC interdonation interval on community blood centers and inventory management. Dr. Sayers emphasized that hospitals use type O disproportionately to other blood types, which has resulted in aggressive retention efforts of type O donors. Making a longer interdonation period would challenge blood centers to find

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even more type O donors. He said that lengthening the interdonation period would compromise the availability of RBCs, especially type O and Rh negative units.

Jed Gorlin, MD, of Memorial Blood Centers, and chair of the AABB Interorganizational Task Force on Donor Hemoglobin gave a report on the task force’s progress. He noted several observations of the AABB task force, many of which were expressed in presentations throughout the workshop, such as the lack of gender-appropriate hemoglobin standards in the US. He said the task force considered the possibility of iron replacement or a longer interdonation interval in premenopausal women. He also noted that donors deferred for low hemoglobin receive varied information and guidance on iron replacement tactics and decreasing the likelihood for future deferral. He said that the preliminary background report has been drafted and that the committee’s report will incorporate new data shared at the workshop.

The workshop commenced with a summary of the presentations within each session. The workshop transcripts and minutes have not yet been posted on FDA’s website, but will be posted here: http://1.usa.gov/12rzs4.
Saving Grace Gala Raises $550,000 While Raising Awareness for Preeclampsia and Life-Saving Blood Donation

More than 500 attendees came out last Saturday evening to raise awareness for preeclampsia, a serious pregnancy-related disorder, as well as to support the life-saving work of the Preeclampsia Foundation and the Foundation for America’s Blood Centers (FABC) at the Saving Grace dinner gala in New York City.

Attendees enjoyed dinner at the Hilton New York Grand Ballroom, listened to touching stories of those affected by preeclampsia, participated in a live auction, and joined the two foundations in honoring individuals and organizations who have worked to improve maternal-fetal health. The event raised about $550,000, which will be split between the Preeclampsia Foundation and the FABC.

Preeclampsia is the leading cause of maternal-fetal death around the world, causing a sudden spike in the woman’s blood pressure and possibly seizures, stroke, multiple organ failure, and death of both mother and child. Mothers and babies suffering from preeclampsia often require blood transfusions to survive, which is what united these two organizations to co-host the seventh annual Saving Grace gala. Many ABC member blood centers were represented at the gala.

“My collabora10n with the Preeclampsia Foundation, the FABC was able to put a spotlight on one of the key patient groups who depend on a safe and adequate blood supply – moms and babies,” said the FABC President and Chief Ambassador Lauren Larsen. “And for future FABC galas, we’ll partner with other patient advocacy groups that also rely on blood transfusions. Because at the end of the day, everything we do is for the sake of the patient.”

Ms. Larsen was one of those patients who relied on blood transfusions to save her life when she battled a severe case of preeclampsia in the ninth month of her pregnancy, receiving more than 200 pints of blood. Chairman of the Board of the Preeclampsia Foundation Patrick Dignan was also affected by preeclampsia when the disorder claimed his wife’s life after the birth of their twins. The Saving Grace gala journal brought light to countless other individuals who – like Ms. Larsen and Mr. Dignan – use their stories to raise awareness for a disease that claims the lives of 76,000 women and half a million babies worldwide each year. Despite being one of the oldest diseases on record, there is still no definitive cure for preeclampsia.

The evening kicked off with a welcome from the gala co-chairs, Mr. Dignan and Ms. Larsen. “This event has always been known as ‘Saving Grace: a Night of Hope’ because hope is exactly what we strive to create with our many initiatives. Hope toward finding a definitive cure for preeclampsia … hope for more research in this area … and hope for families already impacted by the devastation that preeclampsia can leave in its wake,” said Mr. Dignan.

Giving an introduction to the gala was a familiar face of broadcast news, Diana Williams, an award winning reporter and anchor for WABC-TV Eyewitness News. Ms. Williams, the gala’s mistress of

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Saving Grace Gala (continued from page 6)

ceremonies, is a well-recognized journalist for her coverage of breaking news events such as the critical hours following the 9/11 terrorist attacks in New York City. She also hosts Channel 7’s weekly political roundtable Eyewitness News Up Close.

Ms. Larsen, Mr. Dignan, and Eleni Tsigas, executive director of the Preeclampsia Foundation, were featured speakers at the gala, as each have used their personal experiences with preeclampsia to motivate efforts to bring awareness to the disorder and improve outcomes for those suffering with it. Attendees enjoyed musical performances by the New Jersey Youth Chorus and Jim Papoulis, a well-known composer and conductor.

“Our gratitude to the blood banking community cannot be overstated,” said Ms. Tsigas. “Not just in terms of the blood donors who have literally saved countless mothers and babies, but also the organizational and financial support of the blood centers and related industries. These organizations now understand what a critical complication of pregnancy preeclampsia is, and the life-saving role that blood often plays to bring hope to new families everywhere.”

During one of the more poignant moments of the evening, several attendees walked across the stage one by one, placing a single white rose — representing a loved one who they lost to preeclampsia — in a vase. During this “rose ceremony,” some of New York Blood Center’s most frequent donors also placed a red rose in the vase, symbolizing the hope that their blood brought to new moms and babies who needed transfusions.

The keynote speaker for the evening was James N. Martin, Jr., MD, president of the American College of Obstetrics & Gynecologists (ACOG). He emphasized the need to generate more research about preeclampsia, a goal he is making a priority during his presidency.

Gala attendees could also participate in a live auction for some enticing prizes, including tickets to a Mets baseball game for four, a weekend getaway for two in Palm Beach, Florida, and a trip for four to Disney World.

Five New York-area physicians were honored for their dedication to maternal-fetal healthcare including Phyllis August, MD, MPH, Mary E. D’Alton, MD, Charles J. Lockwood, MD, Andrei

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Saving Grace Gala (continued from page 7)

Rebarber, MD, and Daniel W. Skupski, MD. Sandra Founds, RN, PhD, a certified nurse midwife and family nurse practitioner and faculty member of the School of Nursing and member of the Magee-Womens Research Institute at the University of Pittsburgh, received a Vision Grant to further her research. Nihar Nayak, DVM, PhD, an assistant professor and director of Translational Research in the Division of Maternal Fetal Medicine at Stanford University School of Medicine, also received a Vision Grant.

Becky Sloan received the Hope Award for the Preeclampsia Foundation’s Volunteer of the Year for her work as National Walk Director of the Promise Walk for Preeclampsia. Ms. Sloan is a preeclampsia survivor and has overseen scores of walks that have raised over $400,000 to fund research and education. NYBC was also recognized for its dedication to providing life-saving blood to those who need it most. Accepting the award was NYBC President and CEO, Christopher Hillyer, MD. The Hope Award for Outstanding Corporate Partnership was granted to Roy Davis and Johnson & Johnson for years of support of both the Preeclampsia Foundation and the Saving Grace event.

The Saving Grace gala has been held in a different city each year since 2005, beginning with Minneapolis, Minn., raising national awareness and forming relationships in each of the host cities. Since 2005, the gala has raised more than $1,137,748 to support the Preeclampsia Foundation’s mission of reducing maternal fetal illness and death due to preeclampsia and other pregnancy-related hypertensive disorders. The Saving Grace gala steering committee would like to thank everyone who made the gala possible, especially the gala’s sponsors. To view more photos visit: [http://bit.ly/2012galaphotos](http://bit.ly/2012galaphotos)
Scientists Find Possible Target for Future Malaria Vaccines

A group of British researchers has found a target for preventing the most deadly malaria parasite, *Plasmodium falciparum*, from infecting red blood cells. Researchers say that this finding could offer the key to developing a vaccine for malaria, which kills 781,000 people each year, mostly children in Africa.

Julian Rayner, MD, of the malaria program at the Wellcome Trust Sanger Institute in Cambridge, UK, led the study, and was assisted by several colleagues also from the Wellcome Trust Sanger Institute and other research centers. The results were published on Nov. 9 in *Nature*.

Malaria spreads to humans by a bite from a mosquito infected with one of several species of the *Plasmodium* parasite, which infect the liver and invade red blood cells (RBCs). The parasite cannot replicate outside of the RBCs, making the point of RBC invasion a vital target in preventing malaria infection. The *P. falciparum* parasite causes the most serious disease.

Researchers therefore sought to identify the red blood cell receptor and the protein on the surface of the *P. falciparum* that interact and allow the parasite to invade the RBCs. Previous research has shown that the PfRh5 protein on the surface of the *P. falciparum* parasite allows it to bind with RBCs. The researchers created a library of proteins on the RBC surface that could react with the PfRh5 protein on the parasite, and then used the Avexis assay (avidity-based extracellular interaction screen) to test for interactions between the two proteins. They identified an RBC receptor called basigin that interacts with PfRh5, allowing the parasite to infect RBCs.

“First, we were able to completely block invasion using multiple different methods. Using antibodies targeting the interaction we could essentially stop all invasion of red blood cells with parasites,” said Dr. Rayner in an article in a UK newspaper, *The Guardian*. “The second critical thing is that it seems to be universally used.” The researchers were able to prevent all detectable RBC invasion by every *P. falciparum* strain tested using modest concentrations of anti-basigin antibodies, wrote the authors.

Scientists could develop a drug to block the interaction between PfRh5 and the basigin receptor, but the more effective method would be to develop a vaccine against the parasite’s Rh5 protein. By injecting that protein into a human, the body would develop antibodies that would recognize the protein and cause an immune response, thus preventing the parasite from invading the RBCs, explained *The Guardian* article.

A vaccine preventing the spread of *P. falciparum* malaria would be especially ground-breaking in areas like Africa, where about one in five childhood deaths is caused by the disease, according to the World Health Organization. While there are medications to treat malaria, it has become resistant to these drugs in parts of the world where the disease is rampant. Malaria can be passed through blood transfusions, and in the US there is a 12-month deferral period following travel to a malarial area. Up to 2 percent of presenting blood donors in the US are deferred for this reason.

Scientists have reported successful malaria vaccine trials in humans, such as the RTS,S/AS01 vaccine that researchers found prevented about half of malaria cases in young children observed in a phase-III trial. These results were published on Oct. 18 in *The New England Journal of Medicine*. An international research team also found that the FMP2.1/AS02A malaria vaccine had a 64.3 percent efficacy rate in preventing clinical malaria caused by the *P. falciparum* parasite. These results were published on Sept. 19 in *The New England Journal of Medicine*. (Source: *The Guardian*, 11/9/11)

Citation: Crosnier, C, *et al.* Basigin is a receptor essential for erythrocyte invasion by *Plasmodium falciparum*. Nature. 2011 Nov. 9. [Epub ahead of print]
My favorite thing about my job isn’t the satisfaction of raising money for great blood services initiatives. It isn’t my funky little D.C. office that’s spitting distance from the White House and 1.5 blocks from a fabulous oyster bar. It isn’t even the paycheck (trust me – it’s not the paycheck).

Corny as it sounds, my favorite aspect of this work is the people I get to meet while I’m out there doing my thing. Sure, I meet a lot of fellow “train wrecks,” as we multi-gallon blood recipients often jokingly refer to ourselves. And I meet a lot of “angels” – those multi-gallon blood donors who often demur that it’s nothing. But every so often, I have the privilege of meeting someone like Pete.

Pete has no personal tie to the blood cause. He doesn’t work for a blood center or for any sort of company remotely in the transfusion medicine arena. I don’t even know if he donates blood (though 10 bucks says he does).

Pete owns Alignment Enterprises, a brand-building company that specializes in live event production. I was introduced to him eight months ago via e-mail when a mutual friend suggested he get in touch with me. His first correspondence began with this: Mary Richardson sent me your way. I would be honored to support you, the Foundation for America’s Blood Centers and the Preecampsia Foundation with your important gala event, Saving Grace.

Now, me being me, I assumed I had another vendor on my hands willing to help me – for a hefty fee – with the huge fundraiser I was co-chairing. So, I shot Pete a quick email back: I hope Mary clarified that we do not have an event budget to work with – hopefully that won’t scare you away. Pete’s reply was immediate and emphatic: Count me in!

Thus began a working relationship I would come to cherish.

Pete stepped in with a team of professionals who each brought a special talent to the gala-planning process: writing, production management, audio-visual, photography, videography. He launched weekly conference calls, during which a dozen of us would participate in the development of the live program for the first-ever public dinner gala being co-hosted by the foundation I head up. He even secured the (pro bono) help of a world-renowned musical composer and conductor, who then wrote an original song for the cause to be performed live at the gala.

Having worked on some fairly major events in my PepsiCo brand management days, I knew how much time and effort Pete’s team was putting into the creation of the Saving Grace program. And every time I sent Pete yet another e-mail of gratitude, the response was pretty consistent: It’s my honor to be involved, Lauren.

When “game day” arrived (last Saturday), Pete and his crew were as supportive and upbeat as they’d been at the outset. They hustled about the grand ballroom adjusting lighting, testing microphones, marking up the stage. My co-chair, Patrick, and I were joking during the rehearsals that we would have been “dead in the water” if not for Pete. And by joking I mean not really.

Last February, Pete was a complete stranger. But by the time he and I shared a celebratory cocktail in the hotel bar at midnight, this complete stranger had become a dear friend.

It’s all about the people.

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 also the president and chief ambassador of the Foundation for America’s Blood Centers. She can be reached at llarsen@americasblood.org, or via her website at www.laurenwardlarsen.com.
ABC is turning 50 and we’re having a ball … and you’re invited! Save the date: March 24-26, 2012, Scottsdale, Ariz., hosted by Blood Systems, Inc., in connection with ABC’s Annual Meeting. To be added to the invite list, e-mail meetings@americasblood.org with the subject line: “ABC Golden Anniversary Invitation.”

Have a good memory? Been around blood for a while? The Newsletter will be featuring a series of stories detailing the last 50 years in blood banking. To contribute your story, e-mail newsletter@americasblood.org.

BRIEFLY NOTED

Mismatched umbilical cord blood transplantation produced similar outcomes as matched bone marrow transplantation in patients with myeloablatve conditioning for acute leukemia or myelodysplastic syndromes, according to a recent study from Japan, said The MDS Beacon. The MDS Beacon covers news related to myelodysplastic syndromes. The study was led by Yoshiko Atsuta, MD, PhD, of the Department of Hematopoietic Stem Cell Transplantation Data Management/Biostatistics, Nagoya University School of Medicine, in Japan. The results were published on Oct. 28 in the Biology of Blood and Marrow Transplantation journal. Stem cell transplantation is currently the only treatment for patients with myelodysplastic syndrome, and only about 30 percent of transplant-eligible patients have human leukocyte antigen (HLA) matched donors, said the study. Bone marrow transplants require a more exact HLA match than do umbilical cord blood transplants, which is why many researchers are exploring the treatment capabilities of cord blood. In this study, Japanese researchers retrospectively analyzed data from 1,028 patients in Japan who underwent bone marrow transplantation and 351 patients who underwent umbilical cord blood transplantation to compare outcome between the two procedures. They found that the three-year survival rate for patients who received an umbilical cord blood transplant was 47 percent. This was similar to patients who received single-mismatched bone marrow transplants: 41 percent for mismatches at HLA DRB1 and 47 percent for mismatches at HLA A, B, or C. The survival rate for patients who received bone marrow transplants from donors with two HLA mismatches was the lowest, 38 percent. (The MDS Beacon, 10/28/11)

The company conducting the first government-approved test in the US of a therapy developed using human embryonic stem cells announced on Monday that it would be halting the study, according to a Monday Washington Post article. In a statement, Geron Corp., Menlo Park, Calif., cited financial reasons for stopping the study, saying that the company wanted to focus exclusively on developing cancer therapies. “By narrowing our focus to the oncology therapeutic area, we anticipate having sufficient financial resources to reach these important near-term value inflection points for shareholders without the necessity of raising additional capital. This would not be possible if we continue to fund the stem cell programs at the current levels,” said Geron’s CEO, John A. Scarlett, MD, in the statement. The company also announced that it was eliminating 66 full-time positions, representing 38 percent of its workforce. In 2010 FDA approved two experiments testing therapies created from embryonic stem (continued on page 12)
cells, including Geron’s treatment of 10 patients partially paralyzed by spinal cord injuries. Geron has not released detailed results of this study, saying only that none of the patients have experienced significant adverse effects. Advocates of such therapies took Geron’s halting their embryonic stem cell work as a major blow, although another trial that began in July, at the University of California, Los Angeles Jules Stein Eye Institute, is testing the use of embryonic stem cells to treat people with incurable eye ailments, said The Washington Post. Geron will continue to monitor the patients already treated, and to update FDA and the medical community on their progress, Geron said in the release. The company is also seeking partners with the technical and financial resources to enable further development of its stem cell therapy. (Sources: The Washington Post, 11/14/11; Geron press release, 11/14/11)

The US Supreme Court said Monday that it will hear a case brought by 26 states challenging the individual mandate requirement of the healthcare reform law. The case was sent up by the 11th Circuit Court of Appeals, which ruled in August that the Patient Protection and Affordable Care Act’s (PPACA) individual mandate is unconstitutional. Under the mandate, all individuals must buy health insurance by 2014 or pay a penalty. However, the appellate court said the provision could be severed without affecting the rest of the law. The Supreme Court will review the individual mandate and its severability. It will also consider the PPACA’s expansion of Medicaid and whether the federal Anti-Injunction Act prevents challenges to the healthcare reform act before it can take effect. The justices announced they will hear five-and-a-half hours of arguments from lawyers on the law next spring. That will give them plenty of time for a decision in the summer, just months before the general election. (Sources: AHA News Now, 11/14/11; Bloomberg Businessweek, 11/14/11)

LEGISLATIVE NEWS

The head of the agency that oversees the clearance process for medical devices told a Senate committee on Tuesday that great strides have been made toward improving review times and training reviewers. However, he said that constant “demonizing” by critics has quashed morale at the agency and contributed to high employee turnover. Jeffrey Shuren, MD, director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration, said that he doesn’t favor scrapping a system that works “reasonably well” despite an Institute of Medicine recommendation to do just that. He also said that comparing review times in the US with the European Union (EU) was unfair because CDRH’s counterparts in the EU don’t require device makers to show that a new product is effective, nor do they report adverse events. “A number of devices that have been approved in Europe have turned out to be unsafe when they have sought clearance in the US,” he said, giving as examples certain stents and artificial joints. Dr. Shuren made his remarks before the Senate Health, Education, Labor and Pensions (HELP) Committee. The hearing was the latest in a series that the HELP Committee has held to gather information related to the reauthorization of the Medical Device User Fee Act, which allows the FDA to collect fees from companies to help facilitate the clearance process for getting new or improved medical devices on the market. The last reauthorization was in 2007; Congress must reauthorize the act by Sept. 30, 2012. Dr. Shuren said that turnover at CDRH is twice what it is at the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research. He used charts and graphs to show that recent review times have shortened, but said that incomplete or poorly written applications are also responsible for longer review times in many cases. Democrats, led by Sens. Tom Harkin (D-Iowa) and Barbara A. Mikulski (D-Md.) said that review times are less important than the safety of medical devices. Sen. Harkin said that flaws in the 510(k) clearance process for substantially equivalent devices have “sometimes led to catastrophic consequences for patients” and that the realities of the system would “alarm most Americans if they knew about it.” Sen. Mikulski said she has to balance safety with the con-
concerns of medical device companies taking their business – and jobs – overseas. She said that she is upset with the demonizing of “dedicated federal employees who are on the frontlines of protecting America every day – inspecting our food and ensuring the safety of our drugs and devices.” Republicans such as Sens. Richard M. Burr (R-NC) and Orrin Hatch (R-Utah) were critical of the lag in clearance times, saying that the many companies and venture capitalists are reluctant to invest in new medical device technologies because the FDA’s 510(k) and premarket approval reviews are so long and arbitrary. Sen. Al Franken (D-Minn.) used the opportunity to announce the introduction of the Patient Access to Medical Innovation Act, a bill that would provide incentives for manufacturers to develop devices for treating patients with rare diseases and ease the rules that govern how industry experts can consult with the FDA.

– Robert Kapler, rkapler@americasblood.org

REGULATORY NEWS

The Food and Drug Administration has approved Hemacord, the first licensed cord blood product, which is manufactured by New York Blood Center (NYBC), NYBC announced Thursday in a release. Hemacord is a hematopoietic progenitor cells-cord (HPC-C) therapy licensed for allogeneic hematopoietic stem cell transplantation. Hemacord is “indicated for use in hematopoietic stem cell transplantation procedures in patients with disorders affecting the hematopoietic (blood forming) system. For example, cord blood transplants have been used to treat patients with certain blood cancers and some inherited metabolic and immune system disorders,” FDA said in a press release. Hemacord contains hematopoietic progenitor cells from human cord blood, as opposed to those gained from bone marrow or peripheral blood. “The use of cord blood hematopoietic progenitor cell therapy offers potentially life-saving treatment options for patients with these types of disorders,” Karen Midthun, MD, director of FDA’s Center for Biologics Evaluation and Research, said. In 2009 FDA issued a draft guidance requiring that all HPC-C manufacturers submit either a biologics license application or an investigational new drug application, and this requirement came into effect on Oct. 20. NYBC submitted data proving the product’s safety and effectiveness to FDA, and showed that the product and facilities meets FDA requirements. NYBC included safety data from the transplantation of more than 4,000 cord blood grafts, and moved its cord blood manufacturing and storage resources to a state-of-the-art facility in Long Island, New York. “We are thrilled to be the first public cord blood bank with an FDA-licensed product for transplantation,” Christopher D. Hillyer, MD, president and CEO of NYBC, said in the release. NYBC’s National Cord Blood Program at the Howard P. Milstein National Cord Blood Center has been providing cord blood units for transplantation under an investigational new drug exemption since 1996. (Sources: FDA press release, 11/10/11; NYBC press release, 11/10/11)

GLOBAL NEWS

The Agence française de sécurité des produits de santé (AFSSAPS), the French regulatory agency, recently requested the phasing out of plasma treated with methylene blue (MB plasma), one of the methods used to produce fresh frozen plasma, the agency announced in a press release last month. AFSSAPS said this decision comes as a result of observing an increased number of infrequent allergic reactions following transfusions with MB plasma in comparison to other types of plasma. The agency also said that it identified “a larger variability in the concentration of fibrinogen in MB plasma than in other therapeutic plasma.” Fibrinogen is an important coagulation factor. The agency has removed MB plasma from the list of approved blood products, and the French blood supplier will substitute the two other types (continued on page 14)
GLOBAL NEWS (continued from page 13)

of plasma for MB plasma until March 2012. To reduce the risk of disease transmission, AFSSAPS currently uses three types of plasma: solvent-detergent treated plasma (SD plasma), amotosalen treated plasma (IA plasma), and methylene blue treated plasma. MB plasma is currently not approved for use in the US or Canada. Macopharma, the primary manufacturer of MB plasma, issued a press release disputing the French findings of increased allergic reactions and safety risks. Macopharma said that “the lower frequency of reports of serious allergic reactions to methylene blue treated plasma outside of France confirms the French nature of the controversy.” Macopharma also disputed AFSSAPS’s claim that there is variability in the concentration of fibrinogen, saying that there are no clinical studies demonstrating what mean concentration of fibrinogen is required in a therapeutic plasma unit. (Source: AFSSAPS press release, 10/12/11; Macopharma press release, 10/12/11)

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

<table>
<thead>
<tr>
<th>Total ABC Red Cell Inventory</th>
<th>Percent of Regional Inventory at 2 Days Supply or Less, Nov. 16, 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>East: 20%; Midwest: 25%; South: 24%; West: 31%</td>
<td>East: 34%; Midwest: 31%; South: 6%; West: 6%</td>
</tr>
</tbody>
</table>

Daily Updates are available at: www.AmericasBlood.org
INFECTIONOUS DISEASE UPDATES

H3N2 INFLUENZA

Two new cases of human infection with the influenza virus that has been jumping from pigs to people have been detected by the Centers for Disease Control and Prevention, said a Canadian Press article. The CDC reported on Nov. 4 that the two new cases were in Maine and Indiana, bringing the number of cases seen in the US since July to seven. Most of the infections have been in young children, although one case was in a 59-year-old. The two children from Maine both had a lot of contact with pigs. The virus is a strain of influenza A H3N2 that has picked up the M gene of the H1N1 influenza strain that caused the 2009 pandemic. CDC says the H3N2 virus probably picked up the M gene from the H1N1 virus when a pig was co-infected with swine H3N2 and the H1N1 strain. The swine-origin H3N2 is related, though not closely, to the H3N2 strain that circulates each winter among humans. The H3N2 component in the annual flu shot would not be expected to protect against the swine-origin variety, CDC says. CDC says that these cases bring the total number of confirmed human infection with swine-origin influenza A virus in the US to 28 since 2005. CDC’s news release on these infections is available at: www.cdc.gov/media/haveyouheard/stories/H3N2_virus2.html. (Source: The Canadian Press, 11/4/11; CDC “Have You Heard” update, 11/4/11)

MEMBER NEWS

The Institute for Transfusion Medicine’s (ITxM) blood centers, Central Blood Bank in Pittsburgh and LifeSource in Chicago, have successfully merged procedures in an effort to go completely paperless, ITxM staff said in a presentation at last month’s AABB Annual Meeting in San Diego. Eric Shulties, vice president and chief information officer for ITxM, Melanie Heuston, RN, DNP, director of Nursing for UPMC Passavant Hospital in Pittsburgh, Penn., and Anne Lassinger, BS, MT(ASCP), manager of Education and Training for the Donor Services Department of ITxM, gave the presentation jointly. The ITxM centers went through a massive transformation process in order to implement a full electronic process and donor record system. ITxM created teams with specific roles in the process, and abided by several guiding principles or goals: fully electronic/paperless, all collections (donor types and locations), one set of medical criteria/standard operating procedures (SOPs), one software configuration, and one hardware solution. Going paperless meant making changes at every step of the way in the donation process. At the blood center operational end, that meant changing processes and standard operation procedures, while at the frontend, this process entailed making all documentation for donor services staff electronic. The check-in for donors is now electronic, the donor health history is completed electronically, and even labeling is done electronically so that there is no more writing on the bag itself. The donor completes the health history questionnaire online on the same day as the donation, and the answers are then encrypted into barcodes. Staff are alerted to any issues in the questionnaire. The presenters said that one of the most time-consuming aspects of this project was that the centers had to merge their SOPs. In the end, 37 percent of existing SOPs were revised, 11 percent were retired, and 52 percent were newly created. Merging procedures also meant merging donor records, which often entailed creating new medical criteria and consulting ITxM’s medical experts. The centers created a new electronic donor record and a new a paper record in the case that the electronic one cannot be used. ITxM also considered several mobile devices for use at the donor centers before deciding upon a Panasonic touch notebook. ITxM had to submit forms to the Food and Drug Administration 30 days before the paperless system launched. The centers sought staff input and provided training before beginning the rollout (continued on page 16)
MEMBER NEWS (continued from page 15)

of the paperless system. ITxM reported at the AABB meeting that there has been a generally positive staff and donor feedback, and that the electronic system reduces errors, saves time, and reduce lost units. Looking forward, the centers are moving toward mobile deployment, fingerprint ID for donor search, software enhancements, and implementing radio-frequency identification (RFID).

Kentucky Blood Center (KBC), in Lexington, Ky., received a new 2012 Toyota Highlander Hybrid Limited this week as part of Toyota’s 100 Cars for Good Program. The Toyota 100 Cars for Good program awarded 100 vehicles over the course of 100 days to 100 deserving non-profit organizations based on votes from the public. 100 Cars for Good engages the public to help determine how corporate philanthropic donations are awarded. On July 8, KBC asked donors, supporters, vendors, and friends, including ABC members, to vote for KBC on Facebook. KBC received the most votes on that day. The Toyota Highlander will be used to deliver blood products to area hospitals. (Source: KBC Press Release, 11/14/11)

Carter BloodCare Presents the FABC with Links for Life Proceeds

Lauren Larsen, FABC president and chief ambassador of the Foundation for America’s Blood Centers, recently accepted, on behalf of the FABC, the proceeds raised during the second annual “Links for Life” golf tournament. BJ Smith, vice president of Regional Operations at Carter BloodCare, presented the check on behalf of the center, which hosted this year’s tournament. The tournament was held on Oct. 4 in Grapevine, Texas, at the Cowboys Golf Club and raised $86,039.97 for the FABC (see ABC Newsletter, 10/14/11).

GSABC Annual Report Now Available

The 2011 Group Services for America’s Blood Centers (GSABC) Annual Report is now available online. The report contains highlights from the previous fiscal year, April, 2010 through March 31, 2011. GSABC is the group purchasing enterprise that serves the members of America’s Blood Centers. The annual report is available here: http://www.gsabc.com/c/document_library/get_file?p_l_id=18628&folderId=18691&name=DLFE-2690.pdf.
PEOPLE

Paul Mintz, MD, has recently been appointed deputy director of the Division of Hematology at the Food and Drug Administration’s Center for Biologics Evaluation and Research. Dr. Mintz served on the faculty of the University of Virginia School of Medicine from 1979 until 2011, where he was appointed as a tenured Professor of Pathology and Internal Medicine. He also served as chief of the Division of Clinical Pathology and medical director of the Clinical Laboratories and Transfusion Medicine Services at the University of Virginia Health System. He was the founder and co-director of the Transfusion Medicine Fellowship Program. In addition, Dr. Mintz served as co-medical director of Virginia Blood Services from 2008 until 2011. He received a certificate of completion from the University of Virginia’s Darden Graduate School of Business Administration’s Health Sciences Leadership Program. Dr. Mintz is a former President of AABB, served on AABB’s Board of Directors for nine years, chaired and was a member of many AABB committees. He testified before Congress advocating a number of issues on behalf of the AABB. He has also served as a member of the Board of Trustees of the National Blood Foundation and as a member of the Medicare Coverage Advisory Committee of the Centers for Medicare and Medicaid Services. Dr. Mintz was recently a member of the Maintenance of Certification in Clinical Pathology Committee of the American Board of Pathology. On a regional level, he served as president of the Mid-Atlantic Association of Blood Banks (MAABB). At the University of Virginia, Dr. Mintz was an elected member of the Clinical Staff Executive Committee. A recipient of a Transfusion Medicine Academic Award from the National Heart, Lung and Blood Institute, Dr. Mintz also was awarded a research grant from the National Blood Foundation (NBF) and is an NBF Scholar. His role as an educator was recognized with a Dean’s Award for Teaching Excellence at the University of Virginia. He is a recipient of the MAABB’s Charles E. Walter Memorial Award. Dr. Mintz has authored or co-authored more than 150 journal articles, editorials and book chapters related to transfusion medicine. He has also served as the Transfusion Medicine Section Editor for the American Journal of Clinical Pathology and on the editorial board of the Annals of Clinical and Laboratory Science. In addition, he has designed and served as principal investigator for numerous clinical and device trials. He is the sole editor of all three editions (1999, 2005, 2011) of Transfusion Therapy: Clinical Principles and Practice (AABB Press). Dr. Mintz reports that he is pleased to be working at CBER and looks forward to participating in its many activities including the advancement and protection of public and individual health.

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.

POSITIONS:

Supervisor, Donor Group Recruitment. The Puget Sound Blood Center in Seattle, Wash. is recruiting for a supportive and assertive leader of a team of Donor Representatives that serves as the primary community contact and ensures an adequate supply of blood for a 15-county region of Western Washington. Responsibilities include motivating, training, and coaching staff to plan effective strategies to meet their goals, and demon

POSITIONS (continued on page 18)
**POSİTİONS (continued from page 17)**

stratıng and modelıng effective commuınicaıon. Requiремents include: mımıın three years in direct customer contact environmenı; BÁ in relatıed field or equıvalent combınatıon educatıon and experıence; high-
ly effective commuınicatıon skılls; mımıın one year supervisory experıence; project management, effective negotiatıng and personnell management skılls; efıcıency
with MS Windows, Word, Excel, Outlook Calendar preferred. Must have consistent and reliable transportation
and a valid Washington state driver’s license. This
is a full time, salaried position. Salary range $39,614 -
$63,683 annualized. For additional information see
posting at www.psbc.org/careers. Cover letter and
resume to humanresources@psbc.org. Include job #
6608 on all correspondences. Deadline for submittal is
Friday, November 25, 2011.

**Associate Director, Chief Operations Officer (COO).**
Hoxworth Blood Center seeks a proven leader with a
passion for our mission to oversee all operations of the
center. The COO is responsible for developing and
leading strategic initiatives to improve organization
performance and maintain overall financial health. This
position collaborates with management staff to assure
patient’s needs are met; introduce innovation and ser-
sıces that our customers desire and assure positive
relationships with them. The ideal candidate must pos-
sess the education and experience to enable management
of a highly regulated organization. Progressive, signifi-
cant and successful experience in operations of a blood
center is desired. Must have outstanding communication
abilities, customer service and relationship development
skılls. Minimum Qualifications: master’s degree in
Healthcare or Business; eight years’ progressıvely re-
sponsible experience in a blood center, or other relevant
environment; five years’ experience in positive man-
agement of multiple direct reports. The University of
Cincinnati offers an excellent salary and fringe benefits
package. To apply for the above position, apply online

**Lab Technician (MT).** Looking for a stable, friendly
organization that values teamwork, high standards and
excellence in quality work? Then come take a look at us
today! Rock River Valley Blood Center has a full-time
Lab Tech opportunity open. Our successful candidate is
someone who is analytical, a strong problem solver,
precise and enjoys detail oriented work. Incumbent will
handle blood specimen processing, routine/non-routın
testing, instrumentation used in testing and handle main-
tenance, quality control, calibration and troubleshoot-
ning. BS in chemical, physical, biological or clinical
laboratory science required. MT certification plus one
year experience in high complexity testing preferred. To
apply please visit our website at www.rrvbc.org and
e-mail resumıe to jobs@rrvbc.org. EOE M/F/D/V

**Director, Donor Services.** The Rhode Island Blood
Center is currently seeking a Director of Donor Services
to manage blood collection activities and collections
staff. Key Responsibilities: This position reports to the
vice president/COO administratively and the vice presi-
dent/chief medical officer clinically. Provide leadership
to the managers, supervisors and staff of DS to achieve
collection goals of the Community Blood Program;
ensure compliance with all Quality Management Plans
and all standards related to the quality program; prepare
the department’s annual operating budget. Monitor and
adjust budget as necessary; effectively communicate
new developments, goals, objectives and other general
information to managers, supervisors and staff; develop
effective intra departmental relationships to achieve
RIBC goals. Work with peers to develop new programs
and resolve issues between departments to meet the
RIBC’s mission; and responsible for hiring, training and
performance evaluations. Educational Requirements:
BS/BA in science, nursing, or business required. Expe-
rıence/qualifications: Candidate must have at least three
to five years of progressively responsible management
experience, preferably in a health care setting. Demo-
strated ability to manage both supervisor and staff level
positions required. PLEASE APPLY ONLINE AT
WWW.RIBC.ORG. Follow the links to “About Us” and
“Careers” for an online application. Only applicants
who are selected for interviews will be contacted direct-
ly. EOE

**Manager Donor Recruitment (Indianapolis, Ind.).**
The Manager Donor Recruitment manages the daily
operations of all field and fixed site donor recruitment.
The Manager provides direct support and supervision to
the representatives in the field and at fixed sites. This
person is responsible to establish individual recruitment
collection goals for his/her team members and assures
that these goals are obtained in assigned regional territo-
ries. The Manager is also responsible for all fixed site
and field recruitment activities including planning and
follow-up of mobile blood drives. Qualifications: bache-
lor’s degree in marketing, sales or a related field
required. Three to five years of successful people man-
germent in a sales environment with proven sales
accomplishments required. Valid driver’s license, ac-
ceptable driving record and reliable transportation
required. Must be proficient in all Microsoft Office

**Testing Lab Clinical Laboratory Scientist (Indianap-
olis, Ind.).** The Testing Clinical Laboratory Scientist
(CL Ş) is responsible for performing low, moderate, and
high complexity testing on blood samples sent to the
Indiana Blood Center Donor Testing Laboratory. Ana-
lyzes donor and patient blood samples using automated
systems and manual procedures. The Testing
CLS troubleshoots laboratory procedures and instrumen-
tation as needed. Performs quality control and
maintenance procedures as required. Reviews clerical
work for accuracy and completeness. Please note: This
position is 2nd or 3rd shift. Qualifications: bachelor’s
**Positions (continued from page 18)**

degree in Medical Laboratory Science (ASCP certification preferred) or bachelor’s degree in Biology, Chemistry or Physical Science with a minimum of one year of clinical laboratory or blood center experience required. Apply at www.indianablood.org/Pages/Employment.aspx.

**Assistant Manager Blood Collections (Noblesville, Ind.).** The Assistant Manager Blood Collections ensures that all blood collection functions are performed according to prescribed procedures of state and federal regulatory agencies. This individual assists the Blood Collection Manager in overseeing the collection of blood donors at assigned sites. Qualifications: Associate’s or bachelor’s degree in business, healthcare or related field required. Three to five years supervisory or managerial experience required. Supervisory experience in a highly regulated industry strongly preferred. Must be proficient in all Microsoft Office products. Apply at www.indianablood.org/Pages/Employment.aspx.

**Manager Blood Collections (Columbus, Ind.).** The Manager Blood Collections manages and oversees blood collection associates in the overall procurement of blood products from donors to support production requirements, recruitment of donors for automated blood collection as applicable and the safe transport of associates and equipment to and from scheduled work locations. Assists in the management of recruitment and production staff when applicable. Maintains, motivates, encourages and develops staff to attain their full potential through positive reinforcement and corrective action as necessary. This individual ensures that all blood collection functions are performed according to prescribed procedures of state and federal regulatory agencies. Accountable for all management functions including budget development, policy and procedure development/review, annual performance reviews, competencies and staffing. Serves as an IBC representative demonstrating proficiency and modeling professionalism and excellent interpersonal skills with the public. Qualifications: bachelor’s degree required. Four years management experience required. Experience in a highly regulated environment preferred. Valid driver’s license required. Must be proficient in all Microsoft Office products. Apply at www.indianablood.org/Pages/Employment.aspx.

**Manager, Quality Resources Transfusion Services Laboratories.** Puget Sound Blood Center is seeking an experienced Manager to provide leadership for the quality, customer service, education, and staff development within the Transfusion Service (TS). Most time is expected to be spent managing department quality programs. Additionally, the Manager will oversee department customer service and internal and external educational programs. Must meet CLIA requirements for General Supervisor; MT(ASCP) & SBB preferred; five years in Transfusion Service or a similar lab; minimum five years supervisory experience; a business, compliance, customer service, and training experience desired. Additional skills necessary include: demonstrated leadership, outstanding organizational, communication and people skills; functional proficiency with MS Office. Candidates send resume and cover letter to: HumanResources@psbc.org. This is a full-time, exempt level position, based at our main Seattle, Washington location. More information at www.psbc.org.

**Hospital Transfusion Safety Officer.** Puget Sound Blood Center is seeking an experienced RN to provide on-site consultation at Overlake and Evergreen Medical Centers regarding the safe administration of blood components. Position will provide expertise and training on blood component ordering, distribution, and monitoring; identify and evaluate transfusion-related incidents; promote excellence and partnership between PSBC and hospital staff. Requirements: BS Nursing or equivalent; current WA State Nursing license; minimum two years in transfusion therapy and progressing Nursing leadership. Also required: the ability to write/evaluate procedures, perform effectively in stressful situations, experience in providing education for health professionals, knowledge of standards of practice regarding blood component administration and related regulatory surveys, self-motivation, and appropriately seek assistance from medical staff. Full-time, exempt position based at hospital campuses in Bellevue, WA. Send resume/cover letter to HumanResources@psbc.org - Job #6602ABC. PSBC is a recognized leader in transfusion medicine, serving patients in Western Washington. More info at www.psbc.org.

**Vice President, Operations - Blood Center Division.** Blood Systems is seeking a professional to join our leadership team in Scottsdale, AZ. This position directs and manages the operating activities of all assigned operating units in accordance with policies, goals and objectives. The selected candidate must possess a participative management style with the ability to lead and motivate senior/executive-level managers. Thorough knowledge of healthcare or blood service operations, general and fiscal management practices and strategic planning required, must have a good understanding of working in a heavily regulated industry. Relevant bachelor’s degree (Business Administration, Management, etc.) or equivalent experience required; MBA, MHA or MD preferred. A minimum of ten years operations management experience, to include five years at a senior management level and prior blood banking or healthcare operations management experience required. Submit resume via e-mail to: jobs@bloodsystems.org ATTN: HR/2011/60. Open until filled. Pre-employment drug testing required. EOE M/F/D/V.
CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Norwood by e-mail (mnorwood@americasblood.org) or by fax to (202) 393-5527. (For a more detailed announcement in the weekly “Meetings” section of the Newsletter, please include program information.)

2011

Nov. 17. Cellular, Tissue and Gene Therapies Advisory Committee Meeting, Washington D.C./Silver Spring, MD. Those unable to attend may view the live web cast here: http://fda.yorkcast.com/webcast/Viewer/?peid=041ef376b144f599be568b1b2893e85d1d. Contact: Gail Dapolito at gail.dapolito@fda.hhs.gov or Sheryl Clark at sheryl.clark@fda.hhs.gov.

Nov. 16-17. FDA Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice Workshop, Philadelphia, Pa. Contact: Anne Johnson, 215–597–4390, e-mail: anne.johnson@fda.hhs.gov; or Society of Clinical Research Associates (SoCRA), 215–822–8644, e-mail: SoCRAmail@aol.com, Web site: http://www.SoCRA.org.


2012

Jan. 22-24. CEO Summit, Group Services for America’s Blood Centers, St. Petersburg, Fla. Attendance restricted to GSABC members and invited guests. Contact: Marge Pierce. Phone: (952) 818-9355; e-mail: mpierce@gsabc.com.

Jan. 24-27. Eighth Annual FDA and the Changing Paradigm for HCT/P Regulation Conference, Optional One-Day Pre-Conference Program, and 15th Annual FDA and the Changing Paradigm for Blood Regulation Conference, San Antonio, Texas. Contact: Pharma Conference Inc.: (830) 896-0027 or contactus@pharmaconference.com.

Feb. 1-5. BMT Tandem Meetings, San Diego, Calif. The deadline for both online early meeting registration and for online abstract submission is Oct. 13. The deadline for online housing reservations is Jan. 3. To register for the meeting and for housing please visit www.cibmrtn.org or www.asbmt.org.

Mar. 24-27. Annual Meeting, America’s Blood Centers, Scottsdale, Ariz. Celebrating ABC’s 50th Anniversary! Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

May 23-24. IPFA/PEI 19th International Workshop on “Surveillance and Screening of Blood Borne Pathogens.” To learn more visit: www.ipfa.nl. Contact: ipfa@sanquin.nl or m.mooijekind@sanquin.nl or +31 20 512-3561.

Aug. 4. Medical Directors Workshop, America’s Blood Centers, Buffalo Niagara, N.Y. Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Aug. 5-6. Interim Meeting, America’s Blood Centers, Buffalo Niagara, N.Y. Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 393-5725; fax: (202) 393-1282; e-mail: meetings@americasblood.org.