According to the Food and Drug Administration, Transfusion Related Acute Lung Injury (TRALI) is the most common cause of transfusion-related death in the US, accounting for 74 fatalities (37 percent) over the past five years. Blood banking and transfusion medicine experts met at an AABB Public Workshop held in Bethesda, Md. on Monday to discuss TRALI risk reduction strategies that have proven successful and potential future interventions.

The meeting was convened to discuss proposed TRALI risk reduction standards set forth in AABB’s draft 29th edition of Standards for Blood Banks and Transfusion Services, which was published for comment on April 29. The draft Standards have generated concern and discussion regarding what interventions should be made to adequately meet the new TRALI risk-reduction standards.

An Introduction to TRALI and AABB TRALI Standards. The first two presentations provided an introduction to TRALI and AABB TRALI standards. TRALI is a complication that can result from transfusion, usually of plasma-containing products, characterized by acute respiratory distress. Since 2004, AABB has issued a number of Association Bulletins and Standards to address TRALI risk reduction, which have been effective, noted AABB President Susan Stramer, PhD, executive scientific officer at the American Red Cross, in her introduction at the meeting.

The current AABB Standards and recommendations in Association Bulletins, outlined by Dr. Stramer, focus on preventing the collection of blood, particularly high-plasma volume units, from donors who were previously implicated in or associated with TRALI cases. Since the majority of TRALI cases occur when the recipient receives blood from a donor who has certain antibodies, and these antibodies are contained in plasma, Association Bulletins have recommended mitigation strategies to prevent the transfusion of high-plasma volume units collected from donors at an increased risk for alloimmunization. The proposed 29th edition of Standards include the following TRALI risk reduction measures:

- **5.7.4.4.1**: Blood collection facilities shall prevent the preparation of plasma for transfusion from donors known to have leukocyte antibodies or known to be at increased risk of leukocyte alloimmunization.
Let Our Past be Our Rock for the Future

Sometimes when you seem overwhelmed by the challenges of the future, it is comforting to look back at the past. Not that the challenges of the past were less daunting, but knowing that we met those challenges and survived brings peace of mind.

When I first came to the Community Blood Center in Kansas City in 1975 as their controller, we did very little testing compared with today, we prepared our budgets by doing the expense side first, and our only real challenge was meeting the blood needs that were growing at a very rapid pace. Well, we met that challenge. Then came the eighties and the AIDS epidemic. AIDS, and its impact on the blood supply and the patients we served, rocked our whole world. We had a difficult time believing the good we did – providing blood – could actually cause harm and even death. We scrambled to develop new procedures and tests to protect patients. Well, we met that challenge.

Our blood supply is safer today than it has ever been. The 1990s began with rising costs for the addition of new tests, a move towards new quality standards, and leukocyte reduced red cells, all to protect the blood supply. Although, blood costs were a small part of a hospital total budget, it was large in the hospital laboratory budget. Hospitals began seeking cheaper blood; we no longer prepared our budgets from the expense side, and competition began among blood providers. Well, we survived those challenges. The 2000s have brought us more competition, more mergers and alliances, an ample blood supply, and the Great Recession. The result has been better blood management that has reduced transfusions significantly, more cost containment, and a push to provide appropriate healthcare to all through the Affordable Care Act.

Our crystal ball to help us predict the future might be cloudy right now, but I take comfort in knowing that, as we have with past challenges, we will survive. Our blood programs might change and many faces will too, but in the end we will survive. We will continue to bring the volunteer donor’s gift of life to the patients we serve.
TRALI Risk-Reduction (continued from page 1)

- **5.7.4.4.2:** Blood collecting facilities shall prevent the preparation of plasma-rich platelet components from donors known to have leukocyte antibodies or to be at increased risk of leukocyte alloimmunization.
- **5.7.4.4.3:** Blood collecting facilities shall prevent the release of allogeneic whole blood for transfusion from donors known to have leukocyte antibodies or to be at increased risk of leukocyte alloimmunization.

The proposed Standards also define “risk of leukocyte alloimmunization” in the Glossary as including “all females who have been pregnant.”

Dr. Stramer noted that AABB will release a bulletin shortly after this workshop to explain how the Standards should best be implemented. Despite the lack of an FDA licensed TRALI-reduction intervention, there are several strategies that have reduced TRALI incidence. These interventions focus on reducing the collection of high-plasma volume units from donors with an increased risk of alloimmunization, which includes females with a history of pregnancy. Many blood collection facilities strive to collect plasma-rich products primarily from male donors, never pregnant female donors, or female donors who have been pregnant but have been screened and have been found to have titers below a certain threshold to detect antibodies to human leukocyte antigens (HLA)-class I/II. (High-volume plasma-containing components include whole blood, fresh frozen plasma [FFP], plasma frozen within 24 hours after phlebotomy [PF24], cryo-poor plasma, apheresis platelets, and buffy coat platelets when re-suspended in plasma from a single donor.)

**TRALI Pathogenesis.** Steven Kleinman, MD, AABB’s senior medical advisor, reviewed the pathogenesis of TRALI and its relationship to the interventions that have been implemented. Since the outset of TRALI recognition, it has been understood that there is an antibody-antigen mechanism that leads to TRALI. Researchers have come to further understand that TRALI is caused by a two-step, or neutrophil-priming, process. The first event seems to be caused by a transfusion recipient risk-factor that leads to priming of the neutrophils, and the second is associated with the transfusion, leading to sequestration of primed neutrophils and release of their contents causing leakage of the capillary walls and fluid movement into the alveolar spaces.

Over the years, researchers observed that both HLA antibodies to class-I and II antigens, as well as antibodies to human neutrophil antigen (HNA), have been implicated in TRALI. However, not all transfusion recipients with these antibodies will develop TRALI, suggesting that there are other risk-factors involved, said Dr. Kleinman. The TRALI SCCOR studies, conducted between 2005 and 2011 at the University of California-San Francisco (UCSF) and the Mayo Clinic, shed light on several of these recipient and transfusion risk-factors. Recognition of TRALI risk-factors lead to the implementation of risk reduction efforts aiming at avoidance of transfusing components with a high content of plasma from potentially alloimmunized donors. Among those TRALI mitigation strategies is the preferential transfusion of male-only plasma or plasma from never-pregnant females or from females who have been pregnant but tested negative for the presence of antibodies to HLA antigens. At both the Mayo Clinic and UCSF, these strategies proved extremely effective, reducing TRALI incidence by 67 percent.

**Interventions.** Darrell Triulzi, MD, medical director at the Institute for Transfusion Medicine, discussed HLA antibody testing as a TRALI risk-reduction intervention to exclude donors with HLA antibodies, particularly among females with a history of pregnancy. To reduce the operational burden, a selective approach is often taken to HLA testing, based upon findings of the REDS-II Leukocyte Antibody

(continued on page 4)
Prevalence Study (LAPS). LAPS found that the background rate of HLA antibodies in presumably non-alloexposed donors is similar for both genders, said Dr. Triulzi. LAPS also found that the HLA antibody prevalence increases with the number of pregnancies. Interestingly, LAPS did not find a significant effect of transfusion history on HLA antibody prevalence among males.

The LAPS findings suggest that blood collection facilities should obtain a pregnancy history and perform HLA antibody screening only in donors who report a history of pregnancy, said Dr. Triulzi. Also, donors should only be re-tested when they report a pregnancy since the last donation. While HLA testing offers a method of qualifying female donors with a history of pregnancy, there are some challenges, noted Dr. Triulzi. For example, there is a wide variability among different HLA tests using the manufacturers’ cut-off in determining HLA prevalence. He indicated that the available tests have been designed for transplantation and are highly sensitive, leading to the detection of antibody titers that are not relevant to TRALI prevention. Cutoffs need to be adjusted for blood donors screening tests and that there is a need for calibration and proficiency panels for determination of the appropriate cutoff value for these screening assays in this setting.

Brian Curtis, PhD, MT(ASCP)SBB, director of the Platelet & Neutrophil Immunology Laboratory at BloodCenter of Wisconsin, then discussed HNA antibody testing, a TRALI risk-reduction intervention. While some HNA antibodies, particularly HNA-3, have been identified as significant in TRALI, laboratory testing for HNA antibodies is cumbersome, difficult, and offered only in specialized labs, said Dr. Curtis. Widespread screening for HNA antibodies is not a practical strategy at this time, he added. Dr. Curtis and his group are studying the immunogenicity of HNA-3 antigens in the normal blood donor population, and are investigating the use of tests to screen blood donors for antibodies against HNA-3 as a TRALI risk-reduction measure.

Another potential TRALI intervention is the use of platelet additive solutions (PAS), which is used to replace a portion of the plasma used to store apheresis platelets. Each PAS currently available is device-specific and replaces about 60-70 percent of the plasma in a platelet unit, leaving about 80-100 ml of residual plasma, noted Dr. Triulzi in his presentation introducing this subject. The two PAS with FDA approval are Fresenius Kabi’s InterSol, which is used on the Amicus instrument, and Isoplate used on Terumo BCT’s Trima Accel System. In this country, there is limited experience with PAS. Dr. Triulzi noted that PAS can limit ABO plasma mediated hemolysis, reduce allergic reactions, and potentially reduce other types of reactions.

Karen King, MD, from the Division of Transfusion Medicine at Johns Hopkins, shared her institution’s experience with PAS platelets, which substantially reduced allergic transfusion reactions (by 46 percent). Dr. King and colleagues did not observe enough TRALI reactions to determine its effect on TRALI reduction. Claudia Cohn, MD, PhD, director of the Blood Bank Laboratory at the University of Minnesota, presented the results of a post-market study of transfusion related adverse events in patients receiving platelets stored in the InterSol PAS collected on the Amicus instrument. The multicenter, active surveillance study found that PAS significantly reduced the transfusion reaction rate.

**Current and Future Risk Reduction Strategies.** Following a Q&A session, several presenters discussed their organization’s current risk reduction strategies for plasma and platelets, as well as potential future interventions. Anne Eder, MD, PhD, executive medical officer of the American Red Cross (ARC) National Headquarters, presented ARC data highlighting that TRALI mitigation efforts have been successful thus far. After implementing a male-predominant plasma strategy in 2008, ARC saw an 80
percent reduction in reported TRALI cases. ARC recorded 24 fatalities related to plasma transfusion between 2003 and 2005, and three between 2008 and 2012.

Due to rising AB plasma demand, ARC is unable to meet the demand for AB plasma with only male donors – 60 percent of AB plasma is provided by men, while 99 percent of A, B, and O plasma is provided by men. Thus, while TRALI risk associated with plasma transfusion has decreased significantly for the other blood groups, the risk associated with AB plasma has remained about the same. In 2012, ARC distributed 62,187 units of group AB plasma from unscreened female donors and about 44,000 units (70 percent) are likely from female donors with prior pregnancy. ARC estimates that of those, 11,000 (25 percent) likely contained HLA antibodies. ARC therefore stands to lose a substantial number of units if it stops distributing plasma from female donors who report prior pregnancy.

Based on its 2012 data, ARC estimated that there was about a 1 in 5,500 chance that an HLA antibody-positive unit will cause TRALI. ARC is currently working to increase collection of group AB plasma from male or never-pregnant female donors, ceasing distribution of plasma from female donors who report any prior pregnancy. It is also exploring Octaplas, a solvent/detergent (S/D) treated pooled human plasma product, as an acceptable TRALI mitigation step and supplemental group AB supply, and working with customers to manage demand for group AB plasma. ARC supports the AABB proposed Standards and asks that AABB clearly define acceptable mitigation strategies for plasma, said Dr. Eder.

ARC implemented the same strategy for TRALI risk reduction in platelets as it did for plasma – preferentially recruiting males or never-pregnant females. In 2010, ARC phased in a donor qualification and HLA testing strategy, and also began using PAS in three regions. In 2012, 62 percent of apheresis platelet donors were male and 38 percent were female (72 percent of components from men, 28 percent from women). In 2012, ARC recorded seven TRALI cases from apheresis platelets, of which three were from female donors with HLA antibodies. With about 14,000 apheresis platelet units likely from women with HLA antibodies, the current estimated risk that an HLA antibody-positive unit will cause TRALI is 1 in 4,700. If a new AABB Standard regarding HLA testing were introduced for TRALI risk reduction in platelets, ARC would need to replace about 14,000 apheresis platelet units from repeat apheresis platelet donors who are probably HLA antibody positive.

While HLA testing may reduce TRALI risk, there are some limitations. Among these are the lack of standardization of donor screening and selective HLA antibody testing strategies, as well as criteria for interpretation of HLA antibody test results, noted Dr. Eder. She added that HLA tests are not approved or validated for TRALI mitigation, but it is reasonable to assume efficacy. Since apheresis platelets stored in PAS have less plasma than platelets stored entirely in plasma, implementing PAS may also be a TRALI-reduction strategy, she said. She mentioned that implementing PAS apheresis platelets would require time to license manufacturing sites by FDA.

Peter Tomasulo, MD, chief medical officer of Blood Systems, who discussed Blood Systems’ TRALI risk-reduction strategies, stressed that there is a need for a TRALI standard. Furthermore, the success of ARC’s TRALI mitigation efforts, as evidenced in Dr. Eder’s presented data, suggest that there are feasible interventions to reduce TRALI incidence. “It is feasible to provide an adequate supply of plasma and platelets which are TRALI mitigated,” concluded Dr. Tomasulo. He noted, however, that he believes it is premature to introduce PAS, noting the substantial amount of plasma that remains in these products.

Robert Maker, MD, PhD, of Massachusetts General Hospital, provided the hospital perspective on

(continued on page 6)
TRALI Risk-Reduction (continued from page 5)

TRALI mitigation for plasma, which has shown that using the donor health history questionnaire (DHQ) to identify ever-pregnant females as part of TRALI mitigation is effective. Also, he noted that TRALI risk-reduction efforts have decreased the amount of FFP produced at the hospital blood bank. Sara Shunkwiler, MD, medical director of LifeServe Blood Center, shared LifeServe’s TRALI risk-reduction efforts, which were implemented in July 2007, after which time LifeServe has seen very few TRALI cases.

Christopher Gresens, MD, senior medical director and vice president of Global Medicine at BloodSource, discussed BloodSource’s TRALI mitigation efforts for platelets, which involves conducting HLA antibody screening for certain female platelethpheresis donors. HLA antibody testing has led BloodSource to defer 1,473 donors since 2009, but BloodSource is able to make up for this loss with its large platelethpheresis donor population. “It is important to recognize that not all blood donor centers have this capacity,” noted Dr. Gresens. Wrapping up the session on risk-reduction strategies, Brenda Grossman, MD, medical director of Transfusion Medicine Services at Barnes-Jewish Hospital/Washington University School of Medicine, discussed her institution’s TRALI mitigation experience with platelets. The hospital analyzed the use of PAS but the sample size was not large enough to observe a relationship between TRALI risk-reduction and PAS. She concluded that she “supports a TRALI risk-reduction standard focused on the product and outcome, not upon the methodology.”

AABB Standard and Comments. Following a Q&A session with the presenters on TRALI risk-reduction, Judy Levitt, MT(ASCP)SBB, laboratory manager of DeGowin Blood Center at the University of Iowa Hospitals & Clinics, and chair of AABB’s subcommittee on Blood Banks and Transfusion Services Standards Program, reviewed the proposed AABB Standards regarding TRALI (bulleted on pages 1-2), as well as comments received on the Standards. She noted that some concern had been expressed about maintaining an adequate plasma supply should more stringent TRALI risk-reduction requirements be implemented, and many requested clarity on what methods would suitably reduce TRALI risk. Also, several comments pertained to clarification of the definition of “increased risk.” Comments received also related to the lack of standardization in testing sensitivity and methodology. She acknowledged that many centers would need to change their practice to meet the new Standards, and that many of the centers submitting comments were reluctant that this could be implemented in time for the April 2014 deadline.

Prepared Statements and Discussion. The meeting ended with a Q&A period and prepared statements, which began with Andrea Neisser-Svae, PhD, of Octapharma, who discussed Octaplas. Studies suggest that S/D treatment may dilute substantially antibodies against white blood cells, thus reducing the risk of TRALI. Since beginning the use of Octaplas in Europe more than 20 years ago, more than 8 million units have been transfused to more than 2.6 million patients in 31 countries without a single report of TRALI, said Dr. Neisser-Svae. This product was recently approved by FDA and should become available in August.

Susan Rossmann, MD, chief medical officer of Gulf Coast Regional Blood Center, and vice president of America’s Blood Centers board of directors, presented ABC’s comments on the proposed TRALI Standards. ABC is not suggesting nor advocating particular language for the Standards, as ABC members have not reached consensus on this issue. She noted that ABC supports evidence-based interventions to enhance the safety of the blood supply and feels that the adequacy of the supply must be preserved. Furthermore, ABC commented that the proposed Standards are not clear and would be difficult to implement. ABC members believe that an AABB TRALI risk-reduction standard should be based on the

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TRALI Risk-Reduction (continued from page 6)

following three statements:

- Plasma for transfusion will be from males, females of defined parity, or from females who have been tested and found to be negative for antibodies to HLA antigens in a validated test;
- Platelets for transfusion will be from males, females of defined parity, or from females who have been tested and found to be negative for antibodies to HLA antigens in a validated test; and
- Whole blood for transfusion will be from males, females of defined parity, or from females who have been tested and found to be negative for antibodies to HLA antigens in a validated test.

In terms of “increased risk,” ABC recommends that parity continue to be determined by blood centers and that transfusion not be considered a risk factor. Also, ABC does not support a requirement to use antibody screening. Dr. Rossmann also noted that to maintain the blood supply, non-mitigated components might be necessary in some circumstances, particularly with AB plasma. She concluded that AABB should clarify these points in writing before new Standards are issued, and Interim Standards maybe necessary. Next, Beth H. Shaz, MD, chief medical officer of New York Blood Center, provided their experience with TRALI mitigation in apheresis platelets, which led to a 60 percent decrease in the risk of TRALI associated with transfusion of platelets. They have essentially introduced a donor history question about the number of pregnancies, and any pregnancies since the last donation. A positive response to any number of pregnancies or a new pregnancy leads to testing for HLA antibodies.

During the open Q&A portion, several attendees discussed Octaplas and PAS and where these products may fit in a risk reduction strategy. Attendees recognized that theoretically, the reduction in titers achieved by pooling should reduce the risk of TRALI (manufacturing pools contain from 630 to 1520 individual donations), but they also recognized that there are no controlled trials documenting TRALI mitigation. Also during this discussion period, Dr. Grossman emphasized again how important it is for AABB to consider that many TRALI mitigation methods may be appropriate to reach the same outcomes in terms of safety and reduced TRALI risk. Dr. Tomasulo added that when finalizing its Standards, AABB should recognize that blood centers will likely be able to adjust to a new Standard, despite concern over implementing new processes. “If AABB thinks it is necessary to set a new Standard to close gaps in patient care and to better serve patients, then make the Standard and set a timeline and we will adjust,” he said.

To close the meeting, Dr. Stramer thanked the Workshop organizers and those who attended. She outlined the process for further development of the Standards, which will involve input from the Standards Committee, TRALI workgroup, and AABB board of directors. Further information and clarifications will be published in AABB Weekly Reports and similar AABB publications as it becomes available. No definite date for the publication of the final Standards has been set, but the target date for implementation of the 29th edition of Standards is April 1, 2014.

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We Welcome Your Letters

The ABC Newsletter welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the ABC Newsletter. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.
ABC Names Medical Directors Workshop Scholarship Awardees

America’s Blood Centers has announced the recipients of the Medical Directors Workshop Scholarships. As previously publicized, ABC launched the ABC Specialty Workshops Scholarship Program, made possible by a grant from the Foundation for America’s Blood Centers. This program provides 28 scholarships to ABC’s member blood centers to supplement costs for attendance to an ABC Specialty Workshop during fiscal year 2014 (April 1 to March 31, 2014).

ABC named the following four scholarship recipients for the Medical Directors Workshop to take place on Aug. 3 in Milwaukee, Wis.: Marsha Bertholf, MD, medical director, The Blood Alliance; Richard Gammon, MD, medical director, OneBlood; David Oh, MD, chief medical officer, San Diego Blood Bank; and Sara Shunkwiler, MD, medical director, LifeServe Blood Center.

ABC would like to congratulate all of the scholarship recipients! Questions regarding the ABC Specialty Workshop Scholarship Program can be directed to Abbey Nunes at anunes@americasblood.org.

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Q&A with ABC’s Communications & Member Services Department
America’s Blood Centers’ Staff Answers your Questions

America’s Blood Centers recently conducted its SEQuaLS assessment, a customer service survey that solicits feedback from member blood centers on ABC’s activities. Through this assessment, members were able to pose questions to the ABC staff. Each ABC department will respond to these questions through this weekly Q&A column in the Newsletter.

Q: How does ABC help my blood center with Donor Recruitment?

A: America’s Blood Centers does not conduct “donor recruitment” – which is executed successfully at the local level. With a small staff of 12.75, it is important for America’s Blood Centers to focus on our mission of helping member blood centers serve their communities. We strive to assist our membership through providing leadership, advocacy and educational opportunities at the national level. However, under our core values of Advocacy and Education, America’s Blood Centers assists the membership in matters of donor management.

- Education – Donor recruitment staff, as well as others, have the opportunity to learn from experts in the field at an ABC Workshop. These workshops also offer plenty of opportunities to network and share with those in similar positions at blood centers across the country. In addition, the Communications and Donor Management Committee hosts six educational webinars throughout the year. Upcoming topics include corporate partnerships and telerecruitment.

- Donor and Blood Drive Leads – ABC often fields unsolicited requests from potential blood donors and blood drive coordinators looking for further information on working with community blood centers. In addition, through www.AmericasBlood.org, existing and potential new donors can enter their zip code to find the closest blood center.*

- Partnerships – Programs like the Nexcare give campaign and the Cesar E. Chavez National Blood Drive Challenge are facilitated through America’s Blood Centers with minimum resources. Such initiatives provide blood centers with the opportunity to partner with organizations that would not normally have sought them out. These initiatives often generate significant local and national earned media, and provide blood centers the opportunity to reach out to and strengthen relationships with new and/or existing donor groups.

- Donor Group Advocacy – ABC has been called to intervene when national donor groups’ HR and administrative policies restrict member access to blood donors. ABC provides information and tools to members to ensure their access to these groups is maintained.

- Resource Sharing – ABC both facilitates and encourages resource sharing amongst the membership. Donor Recruitment professionals can share ideas, programs, and best practices through the Listserv (http://listserv.americasblood.org), the members’ website (http://members.americasblood.org) and resources such as the SPYRRS e-Catalogue (bit.ly/SPYRRS).

ABC is not involved in grassroots donor recruitment, but provides a strong network and support system with resources, educational opportunities, and partnerships to assist member blood centers in their efforts of maintaining a safe, stable, and appropriate blood supply.

*If you have any blood center location changes or updates that are not currently reflected on www.AmericasBlood.org, please contact Abbey Nunes at anunes@americasblood.org.
Every minute of every day, blood is on a critical journey.

A blood banker’s work is vital for patients like Nick. Today, blood bankers are asked to do more with less while maintaining the highest safety standards. We know—we talk to hundreds of you every year. Your input is helping us build smarter, more intuitive blood analyzers. For science-driven safety and efficiency. For you. For Nick.

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RESEARCH IN BRIEF

A study from Duke Medical Center published in the *Proceedings of the National Academy of Sciences of the United States of America* (PNAS) supports prior findings that storage of red blood cells (RBCs) diminishes S-nitrosohemoglobin (SNO-Hb) and suggests that renitrosylation therapy could improve oxygen delivery of banked blood. During storage, RBCs undergo multiple biochemical changes, one of which is reduced levels of SNO-Hb, which in turn impairs the ability of stored RBCs to effect regulation of local blood flow in response to low oxygen tension. Some researchers have suggested that these changes during RBC storage make RBCs less effective and may contribute to alleged poorer clinical outcomes attributed to transfusion. The researchers hypothesized that restoration of SNO-Hb levels would improve transfusion efficacy. Investigators conducted four experiments across three animal species to examine the effect of banked blood deficient in SNO-Hb. In mice, administration of banked RBCs decreased skeletal muscle oxygen tension (pO2), but infusion of renitrosylated cells maintained tissue oxygenation. In rats, hemorrhage-induced reductions in muscle pO2 were corrected by SNO-Hb-replete RBCs, but not stored RBCs. In anemic, awake sheep, stored renitrosylated, but not control (stored) RBCs, produced sustained improvements in O2 delivery; in anesthetized sheep, decrements in hemodynamic status, renal blood flow, and kidney function observed following transfusion of banked blood were also prevented by renitrosylation. “Collectively, our findings lend support to the idea that transfusions may be casually linked to ischemic events and suggest a simple approach to prevention (i.e., SNO-Hb repletion). If these data are replicated in clinical trials, renitrosylation therapy could have significant therapeutic impact on the care of millions of patients,” conclude the authors.

Citation: Reynolds JD, *et al.* S-nitrosylation therapy to improve oxygen delivery of banked blood. Proc Natl Acad Sci USA. 2013 July 9;110(28): 11529-34.

A study published on June 11 in *ACTA Obstetricia et Gynecologia Scandinavica* found that administering anti-D antibodies to pregnant women who are Rhesus D (RhD)-negative in weeks 28 to 30 of their pregnancy could prevent hemolytic disease in the infant. Newborn hemolytic anemia resulting from Rh incompatibility between the mother (Rh-negative) and the baby (Rh-positive) has become an infrequent, yet still worrisome and severe, complication of pregnancy. Since the introduction of postnatal anti-D prophylaxis in the 1960s, the risk of being sensitized decreased from 13 percent to about 1 percent. And the rate has been further reduced to between 0.2 and 0.3 percent since routine antenatal anti-D prophylaxis was introduced in several countries. However, anti-D prophylaxis has not been introduced in Sweden, and nearly one percent of pregnant women have anti-D antibodies. Eleonor Tibald, MD, and colleagues of Karolinska University Hospital in Sweden retrospectively reviewed a cohort of all RhD-immunized pregnant women in Stockholm from 1990 to 2008. During this time, all pregnant women with red blood cell antibodies were managed at the Karolinska University Hospital. Of the 290 RhD-immunized women in the study, 147 (51 percent) were sensitized with their first-born child, and 96 (33 percent) were sensitized with their second child. The researchers found that anti-D antibodies developed during the second or third trimester in 2012 (73 percent) of the women and in 61 women (21 percent) at term or after delivery. In subsequent pregnancies, 144 of 259 neonates (56 percent) required treatment for hemolytic disease. “Based on our study, at least half of the cases could potentially have been avoided by routine antenatal anti-D prophylaxis in the beginning of the third trimester,” conclude the authors. “To optimize the beneficial effects of new prevention programs, we propose providing anti-D prophylaxis in gestational week 28-30 selectively to all RhD-negative women with RhD-positive fetuses.” The study also suggests that non-invasive screening for fetal RhD genotype may be valuable.

BLUE PLATELET SPECIAL

Lauren Ward Larsen

If she Dies

The story goes like this: After receiving the “you’d better come now” phone call from our mother, my sister Karen arrived in San Francisco on the 5th of 38 days I would spend in the intensive care unit. I was nearing the triple-digit mark in pints of blood transfused, and apparently – though I can’t confirm this because I was comatose at the time – I looked like hell.

My brother, ever the family patriarch since our father’s untimely death when we were kids, felt the need to warn Karen before taking her into my hospital room. “Heads up,” Tim said to her in the ICU hallway. “Lauren is twice her usual size and looks as if she’s been floating face-down in a river for weeks. It’s not a pretty sight.”

They entered my room and took their places on either side of the high-tech bed, where Karen – both my best friend and nemesis growing up – got her first glimpse of me: bloated, unconscious, amber-yellow skin, lips curled back from my teeth, and tubes, wires, and machinery crowding and connecting to my barely functioning body. Despite years of working with the sick and dying in hospitals and nursing homes, Karen’s expression betrayed her shock that the ghastly and unresponsive body in the bed was indeed her little sister. It was at this point that my brother leaned across my distended abdomen (thank you, liver failure) toward my sister and said, “If she dies, I get her bike.”

It’s an age-old family joke that elicits a scowl from our mother every time my siblings and I say it to one another, usually when one of us is embarking on a lengthy journey or precarious endeavor. “I love you” has never come easily for my family, and humor – served with a healthy dose of “noogies” – was our preferred expression of affection growing up. Tim’s utterance of those seven words, at a time most would deem highly inappropriate, brought an immediate smile to Karen’s face while simultaneously incensing the attending nurse, who hadn’t yet come to know, or appreciate, my family’s sick sense of humor.

The off-color jokes continued over the coming weeks, most frequently during the worst of times. While sitting in the ICU waiting room after receiving particularly disconcerting news about my prognosis, my family and a few close friends had a group meltdown. Not one of them was able to muster any of the optimism they had taken turns providing when one or another of them would lose faith in my ability to recover. Then, without warning, my sister started laughing. “She can’t die,” she said with such certainty the others stop crying long enough to hear her reasoning. “Why not?” someone asked. “Because,” Karen said, as if stating the obvious, “that would deprive us of the pleasure of killing her for putting us through this nightmare!” And with that, the tension broke and tears were transformed to laughter, offering the briefest of reprieves – but a reprieve nonetheless.

Inappropriate? You bet. Lacking tact? Yup. Necessary for my family as they dealt with the devastating probability that I wouldn’t pull through? Absolutely!

Not only do I enjoy hearing the dark humor anecdotes of my time spent in the ICU, but I applaud my siblings for having had the courage to “go there.” Sometimes, the only way to face the horrific is with irreverence and absurdity. In the toughest of times, I find that humor is like chocolate: the darker it is, the better it is for you.

And thanks to the amazing work of blood services professionals, my bike remains unequivocally in my possession.

Lauren Ward Larsen is the author of “Zuzu’s Petals: A True Story of Second Chances,” which shares her story of her path to becoming an international blood donation advocate. More of her stories can be found at http://laurenlarsensovelightlaughter.blogspot.com. She can be reached at Lauren@LaurenWardLarsen.com.
BRIEFLY NOTED

America’s top health experts published a paper this week recommending a series of specific strategies to reduce five medical interventions or treatments that are commonly used but not always necessary – including blood transfusion. In the paper released by The Joint Commission and the American Medical Association-Convened Physician Consortium of Performance Improvement (PCPI), advisory panel work groups offer approaches to address the overuse of antibiotics for viral upper respiratory infections, over-transfusion of red blood cells (referred to as appropriate blood management), tympanostomy tubes for middle ear effusion of brief duration, early-term non-medically indicated elective delivery, and elective percutaneous coronary intervention. The paper, “Proceedings from the National Summit on Overuse,” provides detailed recommendations on curbing overuse of the five identified medical interventions or treatments, as well as an overview of the September 2012 National Summit on Overuse, which brought together representatives from 112 professional organizations and associations. The five advisory panel work groups that tackled the five areas of overuse are suggesting common strategies to inspire physician leadership, support a culture of safety and mindfulness, promote further patient education, remove incentives that encourage overuse, encourage further study, and spur other professional organizations to collaboratively address overuse. The recommendations for appropriate blood management include:

- Developing a tool kit of clinical education materials for doctors;
- Expanding education on transfusion avoidance and appropriate alternatives to transfusion; and
- Developing a separate informed consent process for transfusion that communicates the risks and benefits.

“Overuse is a serious problem that involves many complex decisions between doctors and patients,” said Mark R. Chassin, MD, president and CEO, The Joint Commission. “The recommendations from the summit will raise awareness that will help both doctors and patients make better decisions going forward, and ultimately improve quality and patient safety.” The paper can be downloaded at www.jointcommission.org/overuse_summit.

REGULATORY NEWS

The Food and Drug Administration approved on June 27 the first recombinant coagulation factor IX that is specifically indicated for routine use in preventing bleeding episodes (prophylaxis). FDA approved Rixubis [Coagulation Factor IX (Recombinant)] for use in people with hemophilia B who are 16 years of age or older. Rixubis, manufactured by Baxter Healthcare Corp, is indicated for the control and prevention of bleeding episodes, perioperative management, and routine use to prevent or reduce the frequency of bleeding episodes. Rixubis is a purified protein produced by recombinant DNA technology. It does not contain human or animal proteins. It is supplied in single-use vials of freeze-dried powder and is administered by intravenous injection after reconstitution with sterile water for injection. When used for the routine prevention of bleeding episodes, it is administered twice weekly. The efficacy of Rixubis was evaluated in a multicenter study in which a total of 73 male patients between 12 and 65 years of age received Rixubis for routine prophylaxis or as needed in response to symptoms of bleeding (on-demand). Overall, patients in the prophylaxis study had a 75 percent lower annual bleeding rate when compared to patients who have historically received on-demand treatment. An additional study in pediatric patients is ongoing. Although serious side effects including anaphylaxis can occur, the most common side effects observed were dysgeusia (distorted taste), pain in an extremity, and atypical blood test results. The approval letter can be viewed at http://1.usa.gov/156dn2H. (Source: FDA press release, 7/3/13)
The Food and Drug Administration issued on June 28 a proposed administrative order to reclassify the implanted blood access device pre-amendments class II device into class II (special controls) and subject to premarket notification, and to further clarify the identification. Comments must be submitted by July 29, identified by Docket No. FDA—2012—N—0303, at www.regulations.gov/, or by mail to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. More information can be found in the Federal Register announcement www.gpo.gov/fdsys/pkg/FR-2013-06-28/html/2013-15504.htm (Source: Federal Register, 6/28/13)

The Food and Drug Administration published on its website a notice of a voluntary recall by Merck Sharp & Dohme Corp. of its RECOMBIVAX HB [Hepatitis B Vaccine (Recombinant)] Adult Formulation. Merck initiated the voluntary recall due to the potential for a limited number of cracked vials to be present in the lot. If the vial was cracked, the integrity of the vial and the sterility of any product remaining in the vial could not be assured. Lot Number J001183 of RECOMBIVAX HB Adult Formulation is the only lot impacted by the recall and was distributed solely within the US. The lot was distributed by Merck between March 12, 2013 and May 2, 2013. There is adequate inventory to replace recalled product at this time. If product from this lot has been administered, revaccination is not necessary. Customers are asked to inventory and quarantine all products from Lot J00183 and follow Merck’s instructions on the product. More information is available at http://1.usa.gov/18vt8oV. (Source: FDA Safety update, 7/3/13)

The Department of Health and Human Services (HHS) announced last week that it has awarded more than $916 million to continue improving preparedness and health outcomes for a wide range of public health threats within every state, eight US territories, and four of the nation’s largest metropolitan areas. “Recent events underscore the critical role these preparedness programs play in ensuring our health care and public health systems are poised to respond successfully to emergencies and recover quickly from events like Hurricane Sandy, large explosions such as the chemical plant in Texas, or terrorist attacks like the Boston Marathon bombings in April,” said Nicole Lurie, MD, HHS assistant secretary for preparedness and response. The fiscal year 2013 HHS funding to support healthcare and public health preparedness programs included approximately $332 million awarded for the Hospital Preparedness Program (HHP) cooperative agreement and more than $584 million awarded for the Public Health Emergency Preparedness (PHEP) cooperative agreement. HHP funding supports preparedness for healthcare systems, organizations, and coalitions. HHS’ Centers for Disease Control and Prevention administers PHEP funding to strengthen national health security and advance state, local, and territorial preparedness capabilities. More information about HPP and PHEP can be found at www.cdc.gov/phpr/coopagreement.htm and www.phe.gov/Preparedness/planning/hpp/Pages/default.aspx. (Source: CDC press release, 7/3/13)

The Food and Drug Administration published this week a draft guidance for industry titled “Considerations for the Design on Early-Phase Clinical Trials of Cellular and Gene Therapy Products.” This guidance provides sponsors of investigational new drug applications (INDs) for cellular and gene therapy products with recommendations to assist in designing early-phase clinical trials of these products. The design of early-phase clinical trials for cellular and gene therapy products often differs from the design of clinical trials for other types of pharmaceutical products. The draft guidance document describes features of cellular and gene therapy products that influence clinical trial design, including product characteristics, manufacturing considerations, and preclinical considerations, and suggests other documents for additional information. Consequently, this document provides recommendations with (continued on page 14)
REGULATORY NEWS (continued from page 13)

respect to these products as to clinical trial design, including early-phase trial objectives, choosing a study population, using a control group and blinding, dose selection, treatment plans, monitoring, and follow-up. The draft guidance also encourages prospective sponsors to meet with FDA review staff regarding their IND submission and offers references for additional guidance on submitting an IND. To be considered in the final guidance, comments must be submitted by Nov. 22 at http://www.regulations.gov. Written comments may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The draft guidance is available at http://1.usa.gov/13mlM65. (Source: Federal Register, 7/2/13)

LEGISLATIVE NEWS

The General Assembly of Rhode Island gave final passage last week to legislation to guarantee the adequacy of the blood supply in the state and the availability of blood products and services for patients and hospitals in the state. Approved and now headed to the governor’s desk were companion bills – 2013-H 6095 and 2013-S 0904, reported the Narragansett-SouthKingstown Patch, a local news website. The legislation will require that any entity collecting blood in Rhode Island must maintain a facility within the state and be predominantly committed to supplying blood to hospitals within the state. It also authorizes enforcement by the Department of Health to ensure that no unregulated entity engages in blood collection. The bills’ sponsors say the need for this legislation arose because another blood center in New England that is part of a large national chain has begun to collect blood in Rhode Island, even though this out-of-state center provides no blood products or services to hospitals in Rhode Island. If enacted, the provisions of the legislation will take immediate effect. (Source: Narragansett-SouthKingstownPatch, 7/8/13)
INFECTIOUS DISEASE UPDATES

BABESIOSIS

The Food and Drug Administration warned in a recent consumer update that babesiosis, which can be severe or fatal among seniors, newborns, and people with weakened immune systems, is becoming more common in certain parts of the US. “Public awareness is critical, because most cases can be prevented by avoiding tick bites,” Mark Walderhaug, PhD, associate director for risk assessment at the FDA’s Center for Biologics Evaluation and Research. Dr. Walderhaug was an author of a study on babesiosis published last year, which found that seniors in Connecticut, Massachusetts, New York, and Rhode Island had the highest rates of babesiosis, and that the disease also appears to be on the rise in Maryland, Virginia, and the District of Columbia. Most people who develop babesiosis are infected by tick bites, although rare cases of transmission from mother to baby during pregnancy or delivery have been reported, and it can be transmitted through blood transfusion. To prevent babesiosis, FDA recommends being aware of ticks when spending time outdoors in wooded or grassy areas, by using insecticide and doing a full body tick check once a day after being outdoors in a tick-prone area. More information is available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm358486.htm (Source: FDA consumer update, 6/28/13)

BORRELIA MIYAMOTOI

A recently identified tick-borne illness has been detected in two patients in the northeastern US, according to case reports published on July 1 in the Annals of Internal Medicine. The pathogen that causes this illness, a new species of Borrelia bacteria called Borrelia miyamotoi, was first identified by Japanese researchers in 1995, which subsequently led to the identification of B. miyamotoi in ticks in Eurasia and North America, according to an accompanying editorial by John A. Branda, MD, and Eric S. Rosenberg, MD. By 2011, human cases of illness associated with B. miyamotoi infection have been documented in Russia. The first reports of cases in US patients, documented earlier this year and described in the Annals of Internal Medicine report, suggest that some cases of B. miyamotoi may be misdiagnosed as human granulocyte anaplasmosis (HGA), a tick-borne disease caused by bacteria Anaplasma phagocytophilum. Hanumara Ram Chowdri, MD, and colleagues used a polymerase chain reaction assay and DNA sequencing to identify B. miyamotoi in the blood of two patients with presumed HGA who exhibited a delayed response to therapy with doxycycline. The cases were detected in a 61-year-old man from Massachusetts and an 87-year-old man from New Jersey. They conclude that physicians should be aware that B. miyamotoi infection is a possible cause of HGA-like symptoms, especially in individuals who do not respond quickly to doxycycline. The editorial authors caution that much remains to be learned about B. miyamotoi infections, noting that the range of illness from this infection and its prevalence are unknown. Its prevalence may actually be quite low because studies have suggested far fewer ticks carry B. miyamotoi than the bacterium that causes Lyme disease, said the editorial authors.


Correction

In the June 28th ABC Newsletter, we published an item in the “Calendar” section on page 19 advertising the 11th Annual Canadian Blood Services International Symposium – Utilization of Blood Products: A Focus on Platelets. However, we mistakenly published the incorrect website for the symposium. The correct website is http://bit.ly/ZTj8mf. We apologize for any confusion caused by this error.
STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

People

David Wellis, PhD, has been named San Diego Blood Bank’s (SDBB) new CEO, the center announced in a press release in June. Dr. Wellis succeeds Ms. Ramona Walker, who is retiring in July. “We greatly appreciate the long service and leadership of Ms. Walker, who oversaw the SDBB’s extraordinary growth to where we now service some 50 medical centers throughout Southern California, and have helped institutions in our region and around the country quickly and reliably meet their blood needs in times of urgent crises,” said SDBB Board President Shawn Hagerty. “Her extraordinary legacy is one of making possible the saving of thousands of lives, and helping create a highly respected organization.” Dr. Wellis joins the SDBB following his tenure as president of San Diego-based BioAtla, LLC, a protein therapeutics service provider. Previously, Dr. Wellis headed Product Marketing at Illumina, Inc., one of the world’s largest developers and marketers of genomic research and clinical analysis instruments. He was also previously president and CEO of San Diego-based GenVault Corporation. The company was one of the world’s leaders in biosample transport and banking, and was instrumental in helping medical research, agriculture, and other fields advance genomic analysis and sample preservation. Dr. Wellis began his commercial career at Axon Instruments, Inc., which developed novel instrumentation for biomedical research, diagnostic and applied markets. “Dr. Wellis brings an extraordinary, and unique, background in life sciences including

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PEOPLE (continued from page 16)

scientific research, strategic leadership and management acumen, much grown here in the San Diego and California community, over his more than 25 years of experience,” said Mr. Hagerty. “We are fortunate to have someone of his strong vision, energy, successful experience in the commercial marketplace, and track record in managing complex organizations here in the San Diego area join us and help us realize even greater levels of service for the community’s blood supply while moving the organization into emerging clinical and scientific areas of excellence.” (Source: San Diego Blood Bank press release, 6/20/13)

James Jeter was recently hired at the Community Blood Center of the Carolinas as the developer for York, Chester, and Lancaster Counties. Mr. Jeter is responsible for managing relationships with businesses, high schools, colleges, and the faith-based community to help increase blood donations through sponsored blood drives. He brings three years of blood donor recruitment experience to his role. He also was an in-home treatment services intern for the South Carolina Department of Social Services and served as president of Advocates for Progress while attending Winthrop University. He graduated with a Bachelor of Arts in Social Work. (Source: Community Blood Center of the Carolinas press release, 7/8/13)
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 Purchase. Bloodmobile Needed! Community Blood Services of NJ/NY is seeking to immediately lease or purchase a four- or five-bed bloodmobile for its community blood drives. Contact Tom Koester, Chief Financial Officer, tomk@cbsblood.org or (201) 389-0456.

POSITIONS AVAILABLE:

Clinical Education Consultant (LZR00004). Fenwal, Inc., a Fresenius Kabi company, is a global blood technology company dedicated to supporting transfusion medicine and cell therapies. We currently have an opportunity for a Clinical Education Consultant based out of Dallas, Chicago or St. Louis to work collaboratively with the customers and the sales teams providing clinical support for Fenwal product’s supporting the US. Requirements include: MT(ASCP) certification. SBB and/or CQA(ASQ) preferred; Bachelor’s degree preferred; five plus years progressive working experience in clinical laboratory operations (preferably blood banking) in quality and compliance activities; knowledge of AABB Standards and regulatory requirements (FDA, CMS) preferred; experience presenting QC data findings, root cause analysis, and recommended solutions to staff, QA, and Sr. Management; ability to travel 70 percent across the US. For more information to apply, please visit our website at www.fenwalinc.com and click on the Careers tab and search for job: LZR00004. Fenwal is an Equal Opportunity Employer.

Laboratory Technologist. The Main Lab at the Rhode Island Blood Center has a part time Laboratory Technologist position available on 2nd shift with rotating weekends and holidays. Responsibilities include: Routine testing of donor blood samples with proper technique and documentation, labeling of blood components, performing and documenting quality control procedures, and generating client reports for donor testing. Lab Tech I: MLT (ASCP) certification. Lab Tech II: BB(ASCP), MT, OR SBB (ASCP) certification. RI license as a Clinical Laboratory Scientist or Technician is required and can be obtained within six months of hire. Please apply online at www.ribc.org. Only applicants who are selected for interviews will be contacted directly. JOIN THE TEAM THAT GIVES THE GIFT OF LIFE!!! As a blood center employee, you’ll truly make a difference in the lives of Rhode Island residents. We are an Equal Opportunity Employer and participate in E-Verify to confirm work authorization.

Associate Director of Validation/Equipment. The Rhode Island Blood Center is seeking an Associate Director of Validation/Equipment for the QA dept. Responsibilities include: Ensure all regulated areas achieve and maintain compliance with the FDA, AABB and any other accrediting agency that inspects/audits Rhode Island Blood Center. Lead company-wide validations and maintenance activities of critical equipment. Mentor staff in achieving quality outcomes in everyday activities and during audit/inspections. Bachelor’s degree required and MT (ASCP), BB(ASCP), or SBB(ASCP) certification required. Significant experience in a related field lieu of educational and certification requirements will be taken into consideration. Please apply online at www.ribc.org. Only applicants who are selected for interviews will be contacted directly. JOIN THE TEAM THAT GIVES THE GIFT OF LIFE!!! As a blood center employee, you’ll truly make a difference in the lives of Rhode Island residents. We are an Equal Opportunity Employer and participate in E-Verify to confirm work authorization.

Manufacturing Processes Specialist. Blood Systems is searching for a Manufacturing Processes Specialist to join its team in Phoenix, AZ. Under minimal supervision, the successful candidate will be responsible for providing project management for the evaluation, development and implementation of quality operational systems, process improvement, and customer satisfaction initiatives. The successful candidate will be responsible for being the expert and primary source in assigned manufacturing areas. Knowledge /Education: Bachelor’s degree in related area required. Current understanding of federal and AABB standards governing blood industry mfg. activities preferred. Licenses/Certifications: MT (ASCP), RN, SBB, or equivalent certification/licensure required. Experience: five years

POSITIONS (continued on page 19)
**POSITIONS (continued from page 18)**

related experience required. Skills Preferred: development of system-wide procedures, process validations, and training materials in assigned manufacturing areas. Current understanding of FDA, CLIA, and other applicable regulations governing blood center operations. Minimum three years of experience in blood center/blood bank. Mainframe and/or personal computer experience. Strong project management and communication experience. Blood Systems offers a comprehensive benefits package that includes: affordable medical/dental coverage, matched 401(k), relocation and much more! For consideration please submit resume by 07/19/2013 to: jobs@bloodsystems.org ATTN: HR/2013/81. Visit our website at: www.bloodsystems.org. Pre-employment background check and drug testing is required. EOE M/F/D/V.

**Manufacturing Processes Specialist.** Blood Systems is searching for a Manufacturing Processes Specialist to join its team in Phoenix, AZ. Under minimal supervision, this candidate will be responsible for providing project management for the evaluation, development and implementation of quality operational systems, process improvement, and customer satisfaction initiatives. The candidate will be responsible for being the expert and primary source in assigned manufacturing areas. Knowledge/Education: Bachelor’s degree in related area required. Current understanding of federal and AABB standards governing blood industry mfg. activities preferred. Licenses/Certifications: MT (ASCP), RN, SBB, or equivalent certification/licensure required. Experience: five years related experience required. Skills Preferred: development of system-wide procedures, process validations, and training materials in the areas of whole blood and apheresis collections and therapeutic apheresis. Current understanding of FDA, CLIA, and other applicable regulations governing blood center collections/manufacturing/processes and broad knowledge base of blood center functions. Experience in the area of Whole Blood (WB) and apheresis collections. Mainframe and/or PC experience. Strong project management and communication experience. Blood Systems offers a comprehensive benefits package that includes: medical/dental coverage, matched 401(k), and much more! For consideration please submit resume by 07/19/2013 to: jobs@bloodsystems.org ATTN: HR/2013/81. Visit our website at: www.bloodsystems.org. Pre-employment background check and drug testing is required. EOE M/F/D/V.

**Quality Director (UBS-Reno).** Blood Systems is searching for a highly motivated Quality professional to fill its Quality Director position. This individual will be responsible for providing oversight of the quality system at a blood center in Reno, NV. This position is responsible for review of quality and compliance in all areas of technical and clinical operations. Additional responsibilities include serving as a resource to operations on quality issues, and providing oversight of staff participation, and participating in performance initiatives through data and process analysis. Knowledge/Education: Bachelor’s degree required. Licenses/Certifications: Certification as a Medical Technologist or SBB is preferred. Experience: Five years related experience in a regulated industry required. To include: three years in a quality, regulatory, and/or auditing environment. Two years supervisory experience. For consideration, please submit resume via e-mail by 07/19/2013 to: jobs@bloodsystems.org ATTN: HR/2013/80. We offer a competitive benefits package including: affordable medical/dental insurance, relocation, matched 401(k), and much more! Pre-employment background check and drug testing is required. Visit our website at: www.bloodsystems.org. EOE M/F/D/V.

**IRL Clinical Lab Manager.** Blood Systems Laboratories is searching for a Clinical Lab Manager to assist its busy Immunohematology Reference laboratory (IRL) in Phoenix, AZ! The successful candidate must be highly organized, able to multi-task in a busy office environment, as well as work successfully in a team environment. Responsibilities will include managing the overall activities and providing skilled technical oversight in the laboratory. This position will work with other team members to ensure timely, quality, test results. Education/Knowledge: Bachelor’s degree required. Master’s degree preferred. Must satisfy CLIA requirements for High Complexity Testing required. Licenses/Certifications: SBB or CHS certification required. Experience: Seven years clinical laboratory experience required. To include: three years supervisory experience. Previous experience in molecular techniques, immunohematology techniques, automated testing and computerization preferred. For consideration, please submit resume via e-mail by 08/02/2013 to: jobs@bloodsystems.org ATTN: HR/2013/82. We offer a competitive benefits package as well as matched 401(k), education assistance, relocation and much more! Pre-employment drug testing is required. Visit our website at: www.bloodsystems.org. EOE M/F/D/V.

**Medical Technologist – Immunohematology.** The Community Blood Center (Kansas City) provides blood for the majority of the hospitals in the region and is home to one of 56 AABB certified Immunohematology Reference Labs worldwide. The staff provides consultation to area hospitals, resolution of complex serological problems and supplies antigen-negative blood or other special units for transfusion recipients. The lab performs a variety of serologic procedures, and molecular phenotyping. Our career ladder allows individuals to continue to grow in their knowledge base and contribution to our lab. The Community Blood Center employs seven (7) SBB’s who teach and mentor our new employees. Requirements: BS degree in medical

**POSITIONS (continued on page 20)**
Sr. Medical Director – Corporate. Blood Systems is seeking a Sr. Medical Director to provide medical and operational direction to our clinical services division. This position will provide primary supervision and expertise for corporate program and service initiatives; assist with the development of our product portfolio and clinical services associated with programs (stem/progenitor cell laboratory, transfusion service and HLA laboratory); and a primary role in participating in medical policy meetings and collaborating with our customers. Requirements: MD or DO currently licensed (or within six months) in AZ; and Board Certification in Clinical Pathology or Internal Medicine and in Blood Bank/Transfusion Medicine or eight years experience in Transfusion Medicine. Preferences: American Society of Histocompatibility and Immunogenetics certificate; five years stem cell processing experience and experience at a blood center and knowledge of blood manufacturing practices. For consideration please submit resume by 07/19/2013 to: jobs@bloodsystems.org
ATTN: HR/2013/51. www.bloodsystems.org. Pre-employment drug testing is required EOE M/F/D/V.

Training Supervisor. LifeShare Community Blood Services is located 40 miles west of Cleveland, Ohio and is seeking a Training Supervisor for our Lab. This position trains all lab employees and ensures that competencies are maintained. Coordinates the activities for all new laboratory personnel and provide practical training to include steps involved in accessioning, component production, the labeling function, testing, distribution, QC tech, data entry, etc. Additionally, the training supervisor will ensure all regulatory guidelines and compliance issues are communicated and enforced throughout all departments. This position is responsible for maintaining accurate records relating to the training process and other duties and projects assigned. This position requires a bachelor’s degree in a chemical, physical or biological science or medical technology from an accredited institution with a minimum of two years laboratory experience. The successful candidate will have a thorough knowledge of FDA, cGMP, AABB, CLEA, and OSHA standards and regulations. Must have demonstrated presentation, organization, verbal, and written communication skills. Prior experience in training or adult education is desirable. The schedule may include evenings, weekends, holidays and overtime as needed. Background check and drug test required. Please submit resume and cover letter to: shyster@lifeshare.cc. EOE

Manager, Transfusion Services. BloodCenter of Wisconsin seeks an experienced leader to manage our Transfusion Services team. This position is based with Children’s Hospital of Wisconsin, in Milwaukee, Wis. This key position is responsible for managing daily operations of pre-transfusion testing on patient samples and for providing blood and blood products to transfusion recipients in a timely and accurate manner. Also responsible for successful execution of business and strategic initiatives, managing the people and financial resources, and for ongoing and sustainable improvement in the areas of compliance, customer/employee satisfaction, and process control. Successful candidate will have strong leadership skills, effective communication skills, and strong technical skills. Position requires bachelor’s degree, ASCP certification, a minimum of five years experience working in a transfusion service, and at least three years management experience. SBB preferred. We offer a competitive salary and excellent benefits. The BloodCenter is a world-class institution due in part to the high caliber of its employees. Apply online at www.bcw.edu/careers. We embrace and encourage diversity in our workforce. EEO

Medical Director. LifeSouth Community Blood Centers is currently seeking a qualified and visionary Medical Director (MD, MD/PhD or DO) to expand the team of physicians in the medical office in Gainesville, Fla. Reporting directly to the CEO, the selected candidate will be expected to contribute significantly to LifeSouth’s strategic and operational goals. The selected candidate will be primarily responsible for medical direction of all cellular therapy activities, including the cord blood bank (LifeCord) and progenitor cell collection of donors and patients, with responsibilities including: Direct Cellular Therapy staff for determining marrow/PBSC donor eligibility, cord blood eligibility, and interaction with the National Marrow Donor Program; serve as Medical Director and Cord Blood Bank Director to meet FACT/HRSA/FDA requirements; oversee cord blood processing in compliance with GMPs, GTPs, FDA license and accreditation requirements; perform final review of all cord blood units prior to distribution for transplantation; engage in appropriate cellular therapy and/or blood banking and transfusion medicine research activities. Board certified in blood banking/transfusion medicine preferred. At least five years of experience in blood banking/transfusion medicine preferred. This is a full-time position. Background

POSITIONS (continued from page 19)
technology or related field; registered MT (ASCP), CLS, or BB(ASCP); SBB preferred. Education assistance and tuition reimbursement is available to obtain SBB certification; and two to five years laboratory experience; blood bank experience preferred. Skills and Knowledge: Advance problem-solving, good oral and written communication, detail oriented, excellent customer service and time management. Hours during training are Monday-Friday 8:30-5:00 with periodic weekends (training is approximately six (6) months). 2 Position Openings: (1) 2nd Shift and (1) 3rd Shift with some weekends required. Must apply online at: www.savealifenow.org. EOE M/F/D/V.

Director of LifeCord. LifeSouth Community Blood Centers is currently seeking an innovative and experienced professional as the director of LifeCord in Gainesville, Fla. This position is responsible for overseeing the cord blood collections and cellular therapy initiatives within the organization through the LifeCord program. LifeCord is a program of LifeSouth which performs community and donor education, cord blood collection and processing, distribution of the cord blood units and evaluation of transplant outcomes. Responsibilities include, but are not limited to: Develop, coordinate, and implement a long term strategic plan for LifeCord; provide vision and leadership to the development and growth of the LifeCord program; oversee manufacturing operations to ensure compliance with quality standards and industry regulations; recruit and hire qualified staff to ensure technical aspects and requirements of the program are met; serve as the primary representative of LifeCord to third parties. Bachelor’s degree required and background in healthcare or science-related field preferred; MBA/MHA/MPHA desired. Two years of management or supervisory experience required. Project management/strategic planning/business development/grant acquisition experience desired. Willingness and ability to travel at least 25 percent required. Ability to create and deliver relevant presentations. This is a full-time position. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Click on the link to apply: https://home.eease.adp.com/recruit/?id=537138.

Clinical Laboratory Scientist. QualTex Laboratories, an affiliate of the South Texas Blood & Tissue Center (STBTC), seeks several skilled individuals for the Immunohematology Reference Laboratories at our Norcross, Ga. and San Antonio, Texas locations. Duties include compatibility testing, receiving/processing orders and complex secondary procedures, such as antibody identification, antibody titration and RBC genotyping/phenotyping. Must be able to prioritize, reprioritize, and handle deadlines and emergency requests. QualTex Laboratories screens millions of whole blood and plasma donations for infectious agents each year for biotechnology companies locally and across the globe. Qualifications required include a Bachelor of Science degree and national certification such as MT/CLS or MLS (ASCP) or equivalent and prior BB experience. For further information, visit our website http://bit.ly/ZpLpir. Please include job code from website on all submissions.