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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2014 #37 **October 10, 2014**

INSIDE:

Expanded Analysis Shows no Association Between RBC Age and in-Hospital Mortality

Several observational studies in recent years have suggested that older, stored red blood cells (RBCs) are harmful for transfused patients when compared with fresher RBCs, while others have found no association. Multiple randomized trials are being conducted or analyzed to clarify this issue. Updated research by Canadian investigators adds further observational evidence suggesting that there is no association between RBC age and in-hospital mortality.

Nancy M. Heddle, FCSMLS, MSc, of McMaster University in Ontario, Canada, and colleagues analyzed data from a large group of cardiovascular patients transfused between 2002 and 2011 at Hamilton Health Sciences. Contrary to their earlier findings among a smaller group of cardiovascular patients, published in *American Heart Journal*, the researchers found no association between RBC age and in-hospital mortality.

The investigators evaluated data from the Transfusion Registry for Utilization, Surveillance and Tracking (TRUST) database, which reported clinical, laboratory, and transfusion data from 2002 to 2011 on all patients admitted to three acute hospital sites in Hamilton, Canada. To explore any association between RBC age and in-hospital mortality, they analyzed the transfusion data of cardiovascular patients during this period.

During the study period, 9,669 patients received 46,868 RBC transfusions. The median number of RBC units transfused was three and the median age of RBCs was 17 days. "Our previously reported findings of an increase in risk of in-hospital mortality with transfusion of older blood using TRUST data from 2002 and 2006 was not seen when the larger cohort was analyzed," reported the authors. Based on a pre-specified analysis of the expanded cohort, the researchers reported there was no association between RBC age and in-hospital mortality. While significant differences were observed between the two study periods, it was no longer significant when the investigators stratified the data by fiscal year of admission.

The investigators note that their findings highlight the inability of retrospective, observational studies to provide reliable conclusions regarding transfusion outcomes and RBC age. "Like all retrospective studies that have looked for this association, it is important to emphasize that there is potential for confounding

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OUR SPACE

ABC Chief Medical Officer Louis Katz, MD

It's the Vaccine Stupid!

The time is approaching for seasonal flu shots. In the US, uptake of flu vaccine on an annual basis remains disappointing. The Centers for Disease Control and Prevention estimates that only 42 percent of adults and 59 percent of kids were immunized during the last flu season. (I always remember the last time I missed my shot, in 1976 when I was an intern, and got influenza A while assigned to a Department of Veterans Affairs medical ward. I was afraid I was not going to die.) The best thing I ever did in health care was to push for – and finally see – implementation of mandatory flu immunization in the hospital where I worked for 30 years. This came after it became clear that rational, evidence-based appeals to patient and personal safety were met with unacceptable vaccine uptake.

If you take seriously our rhetoric that the blood community is a critical healthcare infrastructure, you have the opportunity, and really a moral responsibility, to protect your donors, your co-workers, your family, and yourself from the flu. Getting vaccinated ensures that we will all be there to do our work, even during a bad flu season. A center's ability to supply critical blood products and clinical services during flu season is dependent upon your good health, and overwhelmingly the best and safest protection from influenza is immunization.

Be sure your center offers the flu vaccine and makes it available in a user-friendly manner to the staff. Ideally, you should be bringing the vaccine to their desks, benches, donor rooms, and mobile coaches – to minimize disruption of blood center staff's busy schedules – often used as an excuse not be vaccinated (sort of like "the dog ate my homework"). If you cannot get more than 90 percent of your staff to volunteer, you might want to consider more "creative" approaches to encourage your staff to be vaccinated. By the way, America's Blood Centers' staff are incentivized to be vaccinated.

While you're at it, think about immunizing your donors. At my old center, we offered the vaccine to donors, because keeping them healthy was further protection of the blood supply. What better way is there to demonstrate your commitment to the well-being of your most important resource? What could you possibly offer that would impact the commitment of your donor base to the responsibility we share with them to provide a safe and adequate blood supply?

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

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Age of Blood in Cardiovascular Patients (continued from page 1)

from unknown factors that could affect the age of transfused blood and the patient outcome. Only randomized controlled trials can address this limitation and reliably inform whether the age of blood impacts the patient's clinical outcome."

One such randomized controlled trial published in 2012 [the Age of Red Blood Cells in Premature Infants (ARIPI) trial] suggested no difference in outcomes among pediatric patients when comparing older with fresher stored blood. Several other randomized controlled trials are currently underway and results are expected in late 2014 or early 2015, note the authors.

Because in-hospital mortality was potentially affected by changes that Canadian Blood Services made to its whole blood separation methods in 2008, the authors also suggest that the methods of whole blood processing could affect the quality of stored RBCs, thus influencing patient outcomes. "This possibility warrants further investigation," they write.

Citations: Heddle NM, *et al*. Exploratory studies on the age of transfused blood and in-hospital mortality in patients with cardiovascular diagnoses. Transfusion. 2014 Sep 19. [Epub ahead of print]

Eikelboom JW, *et al*. Duration of red blood cell storage before transfusion and in-hospital mortality. Am Heart J. 2010 May;159(5):737-743.

Community Blood Center of Greater Kansas City Facilitates Plasma Donation to Help in Treatment of Ebola Patient

Kent Brantly, MD, an American doctor who returned to the US after contracting Ebola in Africa, underwent plasmapheresis for the second time on Tuesday to help treat another Ebola patient – an NBC News freelance cameraman who was recently diagnosed with the virus. Community Blood Center of Greater Kansas City (CBC), which recently combined operations with New York Blood Center (NYBC), managed the donation and shipped the blood to Omaha, Neb., where the patient, Ashoka Mukpo, is being treated.

While there is no proven treatment available for Ebola virus, whole blood collected from patients who have recovered from Ebola virus disease – in the "convalescent phase" of infection – has been used to treat a small number of patients, including Dr. Brantly and another infected American doctor, Rick Sacra, MD. While both patients recovered, they both also received experimental Ebola medications and were evacuated to the US where they received top-level care, making impossible to estimate any effect from transfusion.

While taking a road trip from Indiana to Texas on Tuesday, Dr. Brantly was contacted by Nebraska Medical Center, informing him that his blood type matches Mr. Mukpo. Mr. Brantley stopped off at CBC to donate blood, which was flown to Omaha and transfused to Mr. Mukpo on Wednesday.

"Coming to the aid of this Ebola patient represents just the kind of collaboration we anticipated when NYBC joined forces with CBC," said Rob Purvis, NYBC's vice president of Customer Service. He

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CBC, NYBC Aid Ebola Patient (continued from page 3)

explained that the call to come to the patient's aid came from Louis Katz, MD, chief medical officer at America's Blood Centers, at noon on Tuesday, and the frozen plasma was on the road to Omaha by around 7 p.m.

The plasma was collected, processed, and shipped under an emergency investigational new drug (IND) exemption granted to the University of Nebraska Medical Center by the Food and Drug Administration specifically for this patient.

"The staff at CBC in Kansas City did an amazing job in facilitating the plasma donation, assisted by Dr. Beth Shaz, chief medical director at NYBC. We're in the business of saving lives every day, but this was an extraordinary opportunity to help out," said Mr. Purvis.

This convalescent plasma donation comes shortly after the World Health Organization (WHO) published an interim guidance (available at http://bit.ly/1vBhcMf) for national health authorities and blood transfusion services, regarding the use of convalescent whole blood or plasma collected from patients recovered from Ebola virus. With experimental drugs or vaccines still months away and thousands of lives claimed by the largest Ebola outbreak in history, affecting multiple countries in West Africa, WHO sanctioned the use of convalescent blood therapies. The guidance outlined the steps to collect convalescent blood or plasma from Ebola recovered patients.

We are still accepting video submissions for ABC's Got Talent – America's Blood Centers' first-ever virtual talent show allowing ABC blood center employees, board members, volunteers, donors, and families to showcase their talents to raise money for the Foundation for America's Blood Centers. Contestants must submit a video of themselves on YouTube by Dec. 31. Those interested in submitting a video should contact Jodi Zand at jzand@americasblood.org for information on how to share your video on the special YouTube channel created just for ABC's Got Talent.

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INSIDE ABC

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

A Word About Ebola Virus

In response to the growing number of inquiries from its member blood centers regarding Ebola and the blood supply, we issued a member communication suggesting that America's Blood Centers' members consider a precautionary measure that will reassure staff, donors, and recipients that the blood community is proactive while events evolve.

Earlier this week, ABC's Scientific, Medical, and Technical (SMT) Committee discussed, and generally supported, promoting self-deferral by donors who may have had contact with Ebola virus disease infection. Our members can find a more detailed description of ABC's recommendations, as well as proposed messaging for blood centers to use at donor sites, in MCN 14-111 at http://bit.ly/1vUK3LD.

Transmission of Ebola virus by transfusion has never been observed. Donors potentially infected in West Africa must be deferred for a minimum of one year for potential malaria exposure. However, people in the US having recent contact with patients incubating and subsequently becoming ill with Ebola, such as the recent events surrounding an infected patient in Dallas, has raised concern that such contacts could be incubating the infection.

Asymptomatic Ebola viremia has not been described. That said, available evidence cannot prove the virus is never present in the bloodstream during a brief interval immediately before the onset of symptoms. Therefore, we consider it prudent for blood centers to provide background information regarding Ebola virus to donors throughout the US.

To address such concerns, we are asking our members to consider the straightforward intervention of having donors who have been identified by public health agencies to be at risk for infection from contact to refrain from blood donation.

Useful information for donors and staff can be found in *The Journal of the American Medical Association*, available for free at http://bit.ly/1t6fOmj. The European CDC published background information specifically addressing the transmission of Ebola virus through blood and other products of human origin, available at http://bit.ly/1BYbXWZ.

As always, you are welcome to contact me with any questions at lkatz@americasblood.org.

– ABC Chief Medical Officer Louis Katz, MD ♦

ABC Annual Report Now Available Online!

America's Blood Centers' Annual Report for fiscal year 2013-2014 is now available online at http://bit.ly/1vUk0T0. The report details ABC's accomplishments and initiatives over the past year within its four core values: Innovation, Data, Education, and Advocacy.

RESEARCH IN BRIEF

A recently published study in *The New England Journal of Medicine* found no difference in 90-day mortality among critically ill patients with septic shock when comparing a restrictive transfusion strategy with a liberal one. In 1999, the Transfusion Requirements in Critical Care (TRICC) trial found no significant differences in mortality among adult intensive care unit (ICU) patients when using a restrictive vs. a liberal transfusion strategy. Since then, several other studies have similarly found no difference in outcomes when using a restrictive transfusion strategy – lower hemoglobin or hematocrit transfusion triggers – as compared with a liberal strategy, while others have suggested more liberal blood use may harm the patient. In the current study, researchers from the Transfusion Requirements in Septic Shock (TRISS) trial group and the Scandinavian Critical Care Trials Group, conducted a multi-center, parallel-group, trial in which they randomly assigned patients in the ICU who had septic shock and a hemoglobin concentration of 9 g/dL to receive transfusion at 7 g/dL or less (lower threshold) or at 9 g/dL or less (higher threshold). They assessed the risk of death among 998 of 1,005 patients who underwent randomization. Patients in the lower-threshold group received a median of one unit of blood, while the higher-threshold group received a median of four units. At 90 days after randomization, 216 of 502 patients (43 percent) assigned to the lower hemoglobin threshold group, as compared with 223 of 496 (45 percent) assigned to the higher-threshold group, had died. "In this international, multicenter, partially blinded, randomized trial involving patients with septic shock who were in the ICU, we observed no significant differences in mortality at 90 days, in the numbers of patients with ischemic events or with severe adverse reactions, in the use of life support, or in the numbers of days alive and out of the hospital between the group of patients who underwent transfusion at a lower hemoglobin threshold and the group of those who underwent transfusion at a higher hemoglobin threshold," wrote the authors. Similar results were seen in various subgroup analyses. These results are consistent with those of the TRICC trial, note the authors. "We believe it has become abundantly clear that a transfusion threshold of 7 g/dL should become the new normal, recommended in all critically ill patients, including those with severe sepsis and septic shock," wrote Paul C. Hébert, MD, of Centre Hospitalier del' Université de Montréal, and Jeffrey L. Carson, MD, of Rutgers Robert Wood Johnson Medical School, in an accompanying editorial. They suggest that to speed the adoption of this strategy, clinical practice guidelines should be updated and implemented in healthcare facilities.

Citations: Holst LB, *et al*. Lower versus higher hemoglobin threshold for transfusion in septic shock. N Engl J Med. 2014 Oct 9;371(15):1381-1391.

Hébert PC, Carson JL. Transfusion threshold of 7 g per deciliter – the new normal. N Engl J Med. 2014 Oct 9;371(15):1459-1461.

Research recently published in *Transfusion* suggests that the risk of developing post-transfusion purpura (PTP) is significantly higher with platelet containing transfusions, and suggests a number of other risk-factors among an elderly study population. PTP is a rare but serious transfusion complication resulting in sudden and severe thrombocytopenia. The risk-factors for PTP are not well understood, although prior alloimmunization to foreign platelets, especially through pregnancies, has been considered important. Because previous studies have suggested higher blood use among the elderly, Mikhail Menis, PharmD, MS, of the Food and Drug Administration's Center for Biologics Evaluation & Research, and colleagues, assessed PTP occurrence and potential transfusion and recipient risk factors among inpatient elderly US Medicare beneficiaries during 2011 and 2012. Using a Centers for Medicare and Medicaid Services (CMS) database, they identified blood transfusions using ICD-9-CM and revenue codes and identified PTP occurrence via ICD-9-CM diagnosis codes. They evaluated PTP rates per 100,000 inpatient transfusion stays, among elderly Medicare beneficiaries overall, and by age,

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RESEARCH IN BRIEF (continued from page 6)

sex, race, number of units and blood components transfused; they analyzed potential risk factors. In over 4.3 million inpatient transfusion stays for elderly beneficiaries during the study period, 78 had a PTP diagnosis code recorded, an overall rate of 1.8 per 100,000 stays. They found substantially increased risk of PTP occurrence with platelets transfused either alone or in combination with red blood cells (RBCs) and/or plasma, compared with RBC-only transfusion. The results also showed an overall increase in PTP occurrence with greater number of units transfused and suggest larger impact of transfused units among elderly patients 80 years and older. Consistent with previous findings, this study found "increased PTP risk among persons with prior alloimmunization (e.g., pregnancies, transfusions, transplants), as well as the importance of underlying comorbidities. Specifically our study suggests an increased risk of PTP among elderly persons with prior blood transfusions or transplantations of organs, tissues, or stem cells. The study also shows increased risk among younger elderly females compared to males, thus suggesting importance of prior pregnancies," write the authors. They suggest that physicians must be aware of PTP occurrence and highlight the need for development of specific prevention strategies, like antigen-matched or cross-matched compatible platelet transfusions, in the elderly population. "Without validation of the diagnosis in at least a subset of the patients, given the great difficulty in making a diagnosis of PTP, the meaning of these data is unclear. There are interesting hypotheses generated, but there is much more work to be done before understanding the meaning of these observations," said America's Blood Centers Chief Medical Officer Louis Katz, MD, who was not involved in the study.

Citation: Menis M, *et al*. Posttransfusion purpura occurrence and potential risk factors among the inpatient US elderly, as recorded in large Medicare databases during 2011 through 2012. Transfusion. 2014 Jul 28. [Epub ahead of print] ♦

BRIEFLY NOTED

A series of articles recently published in *JAMA Internal Medicine* highlights efforts by the Food and Drug Administration over the last several years to improve premarket device review and postmarket device surveillance, as well as challenges still facing the agency. "The past five years have ushered in major, much-needed changes in the oversight of medical devices in the US," write Elisabeth M. Dietrich, MPH, of the University of California, San Francisco, School of Medicine, and Joshua M. Sharfstein, MD, of the Maryland Department of Health and Mental Hygiene (and a former Principal Deputy Commissioner of the FDA), in a *JAMA Internal Medicine* editorial. They explain that FDA's responsibility to ensure a level of oversight sufficient to provide reasonable assurance that each device is safe and effective but not so burdensome as to stifle innovation, has long been a challenging balancing act. FDA's 510(k) approval process, an approval pathway for low-risk devices that requires manufacturers to prove the device is substantially equivalent to an already-approved device, has often been the subject of criticism for lack of transparency and clear requirements. In 2009, FDA began a comprehensive review of the program and in 2011 a new draft guidance was published outlining the steps of 510(k) decision-making process, as well as the type and quality of scientific information manufacturers should provide to support each step. Diana Zuckerman, PhD, and colleagues of the National Center for Health Research in Washington, D.C., detail some of the concerns that have been raised about the 510(k) pathway. Using FDA databases, they assessed the types of scientific evidence used to determine substantial equivalence, safety, or effectiveness for a sampling of implanted medical devices, the number of predicates for each implant, and whether this evidence was publicly available. They found that scientific data to support the claim of "substantial equivalence" were publicly available for eight of 50 newly cleared implants (16 percent) and 31 of their 1,105 listed predicates (3 percent). They found that certain issues

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BRIEFLY NOTED (continued from page 7)

persist, including the practice of citing more than one predicate device to make a claim of substantial equivalence and lack of sufficient scientific information in publicly available 510(k) summaries. Post-marketing surveillance is another way that FDA gathers and provides safety and efficacy information regarding medical devices, which typically enter the market with less clinical data than pharmaceuticals. In another piece published in this series, Ian S. Reynolds, MPH, of the Pew Charitable Trusts in Washington, D.C., and colleagues, show that while much information is available online, there is significant room to improve the transparency, efficacy, and effectiveness of postmarket oversight. In their review of post-market data available online, the authors found delays in launching and completing studies are common. "The FDA should develop and implement a more rigorous process to ensure completion of important post-approval studies," write the editorial authors. Another element of FDA medical device review discussed FDA's recently developed unique device identification system, in which every device on the market will be labeled with a standardized, traceable code. John Rising, MD, MPH, and Ben Moscovitch, MA, of the Pew Charitable Trusts, write in a viewpoint piece that "FDA's unique identification system for medical devices has remarkable potential to improve the data about devices available to physicians and to improve clinical care." Ms. Dietrich and Dr. Sharfstein commended FDA's Center for Devices and Radiological Health for actively working to improve the quality and availability of safety and efficacy data available for approved medical devices, while streamlining the regulatory process and eliminating unnecessary barriers to innovation.

Citations: Dietrich EM, Sharfstein JM, *et al*. Improving medical device regulation: a work in progress. JAMA Intern Med. 2014 Sep 29. [Epub ahead of print]

Zuckerman D, *et al*. Lack of publicly available scientific evidence on the safety and effectiveness of implanted medical devices. JAMA Intern Med. 2014 Sep 29. [Epub ahead of print]

Reynolds IS, *et al*. Assessing the safety and effectiveness of devices after US Food and Drug Administration approval: FDA-mandated postapproval studies. JAMA Intern Med. 2014 Sep 29. [Epub ahead of print]

Rising J, Moscovitch B. The Food and Drug Administration's unique device identification system: better postmarket data on the safety and effectiveness of medical devices. JAMA Intern Med. 2014 Sep 29. [Epub ahead of print] ♦

REGULATORY NEWS

AABB published Association Bulletin #14-07 last week to announce a new requirement that expands transfusion-related acute lung injury (TRALI) risk-reduction measures to include apheresis platelets. The bulletin also provides an extended two-year implementation period for this requirement. The new requirement modifies Standard 5.4.1.2 in the 29th edition of Standards for Blood Banks and Transfusion Services. The revised Standards now read:

- **5.4.1.2** Plasma, Apheresis Platelets, and Whole Blood for allogeneic transfusion shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
    - **5.4.1.2.1** For apheresis platelet components, Standard 5.4.1.2 shall be implemented by Oct. 1, 2016.

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REGULATORY NEWS (continued from page 8)

The association bulletin can be viewed at http://bit.ly/1EAnVu8. (Source: Association Bulletin #14-07, 10/3/14)

The International Council for Commonality in Blood Banking Automation (ICCBBA) recently announced that later this month, it will release the newly restructured ISBT Product Description Code Database. As the use of ISBT 128 expands, ICCBBA foresees that the original database design will not continue to be adequate. ICCBBA noted in a recent e-mail update that the limitations of the database will be reached in the not-too-distant future. Therefore, a new database design was created to replace the original database. The new database has many more tables that are described in the document, "ISBT 128 Standard Product Description Code Database v6.0.0 (ST-010)," available at http://bit.ly/1smpEOT. ICCBBA notes that it will continue providing the original tables (e.g., Attribute, Class, and Product Description) during the transition period to allow time for software developers to adapt their software to the new tables of the database. The original tables can be found among the new tables. Importantly, while the structure of the database has changed, the product description codes themselves have not changed. (Source: ICCBBA e-mail update, 10/3/14)

The Food and Drug Administration released last week a draft guidance and framework for Laboratory Developed Tests (LDTs). The Draft Guidance for Industry, FDA Staff, and Clinical Laboratories is titled "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)." The release of these documents was announced in the Federal Register on Oct. 3, which included specific questions and areas in which FDA seeks comments from the industry. LDTs are *in vitro* diagnostic devices that are intended for clinical use and are designed, manufactured, and used within a single lab. This guidance describes the process for clinical labs to notify the FDA of LDTs they manufacture, as well as describes the medical device reporting requirements for clinical labs manufacturing LDTs. America's Blood Centers' staff has already begun preparing comments requesting a prospective exemption of internally validated tests using immunohematology reagents derived from individual patients and donors with unusual and rare red blood cell antibodies and antigens. ABC is concerned that the proposed regulatory scheme would be unacceptably burdensome in this venue, where FDA licensed reagents either do not exist or are only intermittently available. The demand for any such individual reagent is frequently far too small for the major vendors of immunohematology reagents to consider submissions to CBER for FDA approval, given the current complexity and cost of clearance. Licensed blood centers are extensively evaluated by FDA and other regulatory and accrediting organizations, which assures appropriate validation and ongoing quality assurance while maintaining the flexibility to perform critical low volume clinical testing. Due to this already high-level of regulation, ABC feels that further FDA oversight laid out in this draft guidance would not enhance the safety of transfusion but rather would consume resources better used for other activities. ABC asks member blood centers to review the draft guidance (http://1.usa.gov/1ouX1ts) and framework (http://1.usa.gov/YHCISQ) and designate an individual to provide a single response to ABC as it prepares comments for submission to FDA. ABC requests all input be submitted by Dec. 1 to Ruth Sylvester at rsylvester@americasblood.org.

The Food and Drug Administration has approved Cerus Corporation's clinical protocol to make the Intercept Blood System for platelets available under an Expanded Investigational Device Exemption (IDE) to regions in the US with outbreaks of chikungunya and dengue virus. Cerus submitted the protocol to FDA in September in response to the risk for the establishment of autochthonous transmission of chikungunya and dengue virus in the US (see *ABC Newsletter*, 9/26/14 at http://bit.ly/1v8P7gM). "We are pleased to provide US blood centers and hospitals early access to Intercept for the treatment of platelet components in light of the escalating threat of chikungunya and dengue

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REGULATORY NEWS (continued from page 9)

transfusion-transmitted infections," said Carol Moore, Cerus' senior vice president of Regulatory Affairs Quality and Clinical. "With this expeditious approval of our IDE, we hope to initiate our first study site before year end." Under the IDE, Intercept treatment can be performed in place of bacterial detection gamma irradiation and CMV testing, stated Cerus in a press release. Cerus added that the reviews of Cerus' Premarket Approval (PMA) submission for Intercept plasma and platelets will continue in parallel with the Treatment Use IDE study. Approval decisions for both PMA submissions are expected in 2015. More information can be found in the Cerus press release at http://bit.ly/1rjU6Ug. (Source: Cerus press release, 10/7/14)

GLOBAL NEWS

Ministers of Health from throughout the Americas recently agreed upon a series of actions to ensure safe and sufficient supplies of blood and blood products through voluntary altruistic donations, reported the Pan American Health Organization (PAHO) in an Oct. 1 press release. The new Plan of Action for Universal Access to Safe Blood 2014-2019 was approved during the 53rd Directing Council of PAHO, which was held in Washington, D.C. from Sept. 29 to Oct. 3. Over the past few years, the number of blood units collected in the region has increased – in 2012, more than 9 million units were collected. However, the increase was not shared evenly across countries and came largely from family or replacement donation, rather than voluntary, non-remunerated donors, which is the safest form of blood collection. The plan of action calls on countries to achieve self-sufficiency in blood products through 100 percent voluntary altruistic donations. It also urges

- Strong leadership on this issue by national health authorities;
- Integration of national blood programs and services into national health systems;
- Screening of 100 percent of blood units for transfusion-transmissible infections;
- Appropriate use of blood and blood products; and
- Strengthened surveillance, risk management, monitoring, and evaluation.

PAHO's plan can be accessed at http://bit.ly/1q8ePLo. (Source: PAHO press release, 10/1/14)

Life sciences officials from the Asia-Pacific Economic Cooperation (APEC) economies have developed a new framework of collaborative measures to improve safety and sustainability of the blood supply chain, reported APEC in an Oct. 2 press release. The 2020 Blood Supply Chain Roadmap was formulated during a recently concluded policy dialogue and workshop in Manila, Philippines. The roadmap is the first of its kind for the region. It emphasizes building the capacity of blood services, infrastructure and governance, and promoting of international blood safety and quality standards in APEC economies in coordination with the private sector. "The world is now seeing just how important a safe and adequate blood supply chain is critical to global health security," declared Enrique Ona, MD, secretary of Health of the Philippines and executive board chair of the APEC Life Sciences Innovation Forum. "Ensuring the safety and availability of blood has become the cornerstone of developing health systems and public health in Asia-Pacific economies." The roadmap provides guidance on implementing and harmonizing international standards; optimizing blood processing, testing, and distribution systems; improving clinical transfusion practices and patient blood management; and boosting capacity to develop and export plasma to help sustain blood systems in APEC economies. More information can be found in the APEC press release at http://bit.ly/1vRgidU. (Source: APEC press release, 10/2/14)

INFECTIOUS DISEASE UPDATES

MALARIA

A study published in *Malaria Journal* found an association between the number of pediatric malaria outpatient visits and admissions to a Zambia hospital with the number of blood transfusions, suggesting that malaria control measures lead to a reduction in pediatric blood transfusions. Malaria is a leading cause of child mortality in sub-Saharan Africa, accounting for about 627,000 deaths in 2012, according to the World Health Organization's 2013 World Malaria Report. Malarial anemia is a major cause for blood transfusion in sub-Saharan Africa, especially among pediatric patients, with malaria accounting for up to 70 percent of all transfusions. Alison B. Comfort, of Abt Associates, and colleagues, conducted a retrospective analysis of data from 2000 to 2008 from one hospital in Zambia to quantify the extent to which the use of pediatric blood transfusions was associated with the number of pediatric malaria outpatient visits, pediatric malaria admissions, and pediatric admissions for severe malarial anemia. They also investigated whether the use of pediatric blood transfusions was associated with the scale-up of malaria control efforts in the hospital's service area over time. "In this study, the results show that the number of pediatric admissions for severe malarial anemia largely explain the number of pediatric blood transfusions used. This finding highlights that reducing pediatric admissions for severe malarial anemia lowers the use of pediatric blood transfusions," write the authors. "The results show a one-to-one relationship between pediatric admissions for severe malarial anemia and pediatric blood transfusions use during the 2000 to 2003 period," and that this relationship appears to be affected by malaria control scale-up. There were 19.1 fewer pediatric blood transfusions per month during 2004 to 2008 when increased malaria control efforts were implemented, representing a 72 percent decline compared to the period with limited malaria control. The authors highlight that malaria control efforts that reduce the use of blood transfusions could benefit other areas of the health system by increasing blood availability, particularly in areas where the supply is limited.

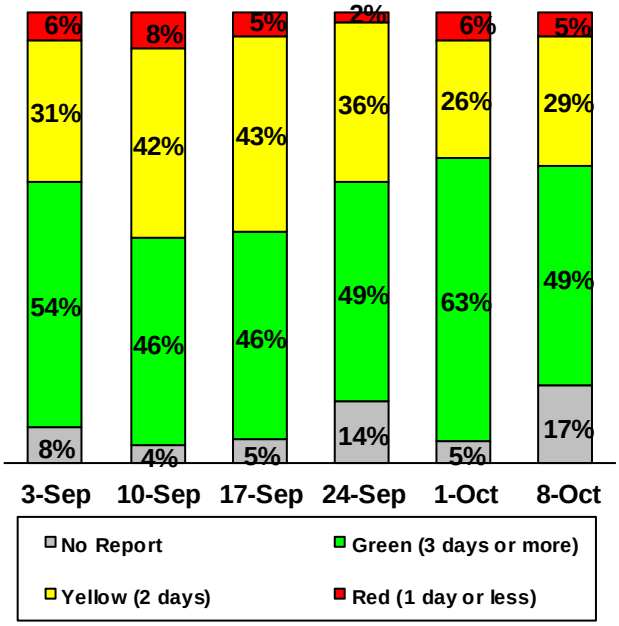
Citation: Comfort AB, *et al*. Association between malaria control and pediatric blood transfusions in rural Zambia: an interrupted time-series analysis. Malar J. 2014 Sep 26;13:383.

We Welcome Your Articles

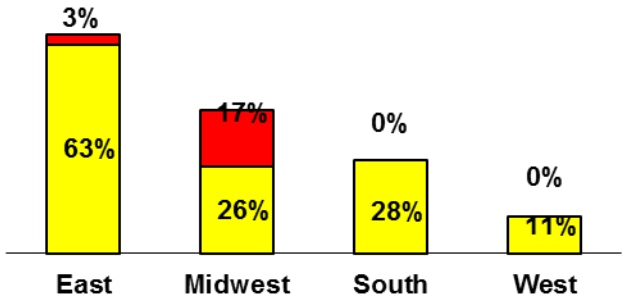
We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer's name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Editor Betty Klinck at newsletter@americasblood.org. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, October 8, 2014



Percent of Total ABC Blood Supply Contributed by Each Region
East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:
www.AmericasBlood.org

MEMBER NEWS

Flights for Life, a group of volunteer pilots in Arizona who help United Blood Services (UBS) deliver blood throughout the state, was recently featured in the aircraft owners and pilots magazine *Flight Training*'s October issue. The Flights for Life pilots volunteer their time, planes, and fuel to provide both routine and urgent transportation for blood and blood products for UBS. The group was awarded the 2012 Outstanding Humanitarian Service Award by America's Blood Centers to recognize its efforts and support of voluntary blood donation. UBS operates six donor centers and more than 10 mobile blood drives every day. Flights for Life pilots help to transport blood from outlying areas in the state into Scottsdale and Tempe labs, as well as out of the Phoenix area to hospitals the organization serves. In 2013, Flights for Life pilots flew 1,884 boxes of blood on 1,039 missions, reported UBS in a recent press release. The *Flight Training* article can be viewed at http://bit.ly/1rjert1. "We are the only blood center in the US that has the support of this kind of volunteer group," said Audrey Jennings, regional center director for UBS/Arizona. "Their dedication allows us to collect more blood and to deliver it to patients in need across Arizona, no matter where they live. They are true heroes to us." (Source: UBS press release, 10/7/14)

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BloodSource, headquartered in Mather, Calif., recently announced that Mike Gorton, a dedicated donor and volunteer at BloodSource's Roseville center, was inducted into the 2014 Fenwal Blood Donation Hall of Fame on Sept. 22. For more than a decade, Fenwal, a manufacturer of products to improve blood safety and availability, has partnered with blood centers through the Donation Hall of Fame to recognize commitment and dedication of extraordinary donors and volunteers, such as Mr. Gorton. Across the nation, only 12 donors per year are inducted into the Blood Donation Hall of Fame. A donor of nearly 300 units of blood, Mr. Gorton was deeply honored to receive the award, which was presented by Carolyn Brown, a Fenwal account manager, according to a BloodSource press release. "Mike's passionate dedication to blood donation and our community is remarkable. Blood donation is only one of the ways he helps others in Roseville and beyond," said Becky Cheshire, the Roseville donor center manager, who nominated Mr. Gorton for this recognition. Mr. Gorton donates plasma and volunteers regularly at BloodSource blood drives. He has also been recognized for other efforts benefiting the community. In 2013, Mr. Gorton was honored as California Department of Forestry and Fire Protection's Firefighter of the Year and he also volunteers for Special Olympics and Shriners Hospital. (Source: BloodSource press release, 9/25/14)

Celebrating the induction of Mike Gorton (5th from left) into the Fenwal Donation Hall of Fame at BloodSource's Roseville center are (from left to right) Candace Judson, BloodSource VP of collections; Carolyn Brown, of Fenwal; Becky Cheshire, BloodSource Roseville manager; Sheryl Lanzi, blood center recruiter; Mr. Gorton; Debi Crabill, BloodSource phlebotomist; Heather Corbett, BloodSource's director of Sacramento Collections; and Steve Ferraiuolo, BloodSource senior VP.

BioBridge Global (BBG), a nonprofit holding company offering services in regenerative medicine, blood banking, and biological testing, and StemBioSys Inc. (SBS), a developmental-stage biomedical company in stem cell and regenerative medicine, announced on Tuesday the grand opening of a new pilot manufacturing lab on the BBG campus. BBG's subsidiaries include the South Texas Blood & Tissue Center, QualTex Laboratories, The Blood & Tissue Center Foundation, and GenCure. In a collaborative agreement, BBG built a lab space in its headquarters building for use by StemBioSys, which will conduct research and product development activities using its patented procedures, involving various types of adult stem cells. StemBioSys was founded in 2010 to develop technology, first created at the University of Texas Health Science Center (UTHSC) that enables the isolation and expansion of stem cells for medical research, diagnostic, and therapeutic applications. "It's very unusual for a nonprofit organization to carve out space for a for-profit entity, but for all the right reasons. It made sense not only for us and StemBioSys but also for the city of San Antonio and UTHSC," said Linda Myers, BBG CEO. "It truly is a government-nonprofit-private, entity-university, mutually beneficial arrangement. It's a synergistic relationship that focuses on regenerative medicine, which is part of the future for BBG as well as the San Antonio biomedical community." In 2013, the City Council voted to invest $200,000 in StemBioSys through a grant to the San Antonio Economic Development Corporation. "Once StemBioSys expands and outgrows the space, BBG will be left with a world-class facility in which to continue our own research or manufacturing," said Ms. Myers. In the partnership, BBG builds on an already-established relationship with StemBioSys that began in 2012. At that time, BBG's founding affiliate, the

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South Texas Blood & Tissue Center – which houses the Texas Cord Blood Bank – established an agreement to provide SBS researchers with cord blood cells. Cord blood units that are ineligible for the public cord blood bank registry are used for research. StemBioSys plans to begin operations on BBG's campus on or about Oct. 18 and locate there for the next several years as the company continues to grow and mature. The new laboratory is approximately 1,000 sq. ft. and will be current Good Manufacturing Practices (cGMP) compliant, said the press release. (Source: BBG press release, 10/7/14) ♦

PEOPLE

Tracy Bridges was recently named vice president of Business and Development and chief technical officer at The Blood Connection (TBC) headquartered in Piedmont, S.C. Since 2006, Ms. Bridges has served as TBC's director of Technical Services, overseeing the organization's state-of-the-art reference lab and hospital services. In her new role, Ms. Bridges will oversee business development, marketing, and technical operations. "It is with great pleasure that I announce Tracy's new appointment and expanded leadership focus," said TBC President and CEO Delisa English. "Her broad understanding of business operations and excellent relationships with customers positions Tracy for her new, expanded role." Ms. Bridges joined TBC as a laboratory technician in 1988. In 2000, she became the director of Biologics Processing and Distribution responsible for the manufacturing of blood products and hospital services. Through the years, Ms. Bridges has consistently supported the implementation of policies that ensure safe blood transfusions, said a TBC press release. She has also forged new connections with hospitals that have allowed TBC to reach a broader number of patients. Ms. Bridges received a Bachelor of Science in business management followed by a Master of Business Administration from Western Governors University. She also received an Associate of Science in medical laboratory technology from Greenville Technical College. "I accept this new responsibility with honor and gratitude," said Ms. Bridges. "I look forward to working with stakeholders throughout our service areas, as well as in new areas, to support TBC's mission." (Source: The Blood Connection press release, 9/29/14) ♦

Correction

In the Sept. 5 *ABC Newsletter*, we reported on the Food and Drug Administration's Guidance for Industry: "Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis." On page 8, we wrote, with reference to donors screened using an FDA-cleared treponemal test, "The final guidance allows reentry only after completion of acceptable treatment for syphilis regardless of whether their physician or a public health clinic determines that the donor did not have syphilis." In fact, the guidance allows donors with a reactive treponemal screening test to be tested on the index or follow up sample with an "FDA-cleared treponemal screening test different from initial treponemal screening test on index donation or follow-up sample (emphasis added)." If the second treponemal test is negative, the donor may, in fact, be reentered without further evaluation or treatment. Please refer to the text of the guidance (http://1.usa.gov/1s0F3Ti) at section C.3 on page 9, and to Figure 2 on page 11. We apologize for any confusion caused by this error.

MEETINGS

Nov. 13-14 **HHS Advisory Committee on Blood and Tissue Safety and Availability Meeting, Arlington, Va.**

The Department of Health and Human Services' Advisory Committee on Blood and Tissue Safety and Availability will meet on Nov. 13 to 14 at the Veteran Health Administration National Conference Center in Arlington, Va. The meeting will focus on the implications of hemoglobin S testing in blood donors. The committee will also continue its discussion on blood donor policy for men who have sex with men and begin considering the potential impact of babesia on the blood supply and on patient safety. More information can be found in the Federal Register announcement at http://1.usa.gov/ZTqtnp. ♦

CLASSIFIED ADVERTISING

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

POSITIONS AVAILABLE

Mobile Operations Supervisor. Join our friendly, caring team of employees and help save lives! As our Mobile Operations Supervisor you will use your nursing and/or medical experience, your people management and organizational skills to supervise blood drives at local businesses, high schools, colleges and the University of Oregon to ensure that donor needs are met by delivering smooth operations and great customer service. Requirements include: RN license or other health-related professional education degree; excellent phlebotomy skills; three to five years of supervisory experience; and great leadership and customer service skills. Two years of blood banking experience preferred. Competitive pay and great benefits including medical, dental, life, long term disability and retirement plan. Go to www.laneblood.org and click on "About Us", "Employment Opportunities" for complete job description and how to apply. Lane Blood Center, 2211 Willamette St, Eugene, OR, 97408 (541) 484-9111.

Director of Human Resources. The Blood & Tissue Center of Central Texas in Austin is hiring an HR professional to lead, develop, and supervise all HR functions. As a member of the management team, this position guides the HR department and serves as the subject matter expert to all staff on recruitment and screening; compensation and benefits administration/planning; employee relations; HR policy/procedures development and monitoring; staff training and development. Qualified candidates must have at least five years HR experience and a college degree with no less than three years high-level HR management experience or at least 10 years HR experience, plus PHR/SPHR certification with no less than five years high-level HR management experience. Proficient understanding of benefit and compensation programs, investigation and resolution of employee relation issues, and employment and benefit laws/regulations including ERISA, DOL, EEOC, IRS and any other regulatory entities. Working knowledge of HRIS and electronic payroll systems desired - ADP proficiency a plus. Must be at least 21 years old, hold a valid driver's license, provide a copy of an acceptable driving record, and show proof of liability insurance. Applicants may send cover letter, resume, and salary requirements to resumes@tcms.com. Please include position title in subject line.

Reference Lab Supervisor. The Rhode Island Blood Center is looking for a Reference Lab Supervisor to supervise and manage staff, daily workload and compliance with applicable standards of the AABB and CLIA. This requires advanced technical knowledge of immunohematology techniques and knowledge of proper handling of biological materials and hazardous chemicals. Assign and supervise daily workload and activities of Reference staff. Review, interpret and report results prepared by staff. Perform immunohematological test procedures on patients and donors to resolve complex

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serologic problems. Write patient consultation reports including transfusion recommendations/suggestions sent to hospital blood bank supervisors and Vice President and Chief Medical Officer and coordinate with blood bank supervisors, Vice President and Chief Medical Officer and private physicians to provide the safest blood products for patients with red cell / antibody problems. Maintain adequate inventories of reagent antisera, reagent red blood cells, chemicals, equipment/instruments and laboratory supplies. Assist Director in budget planning and long-term Capital equipment needs(s). BS in Medical Technology or related field. Certified Specialist in Blood Banking (SBB). Rhode Island Clinical Laboratory Scientist License. Four years of blood banking or two years supervisory experience in a hospital or blood center laboratory. 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 directly.

Reference Laboratory Supervisor. LifeStream, a blood center located in Southern California, serving 80 hospitals with 200,000 blood products annually, is searching for a Reference Laboratory Supervisor. Performs and reports test results for all Reference Laboratory procedures in an accurate and timely manner in compliance with Federal and State Regulations, AABB Standards, manufacturer's recommendations, and internal operating procedures. Demonstrates proficiency, competency, and understanding of fundamental principles of Reference Laboratory procedures. Assists in the training of Reference Staff and provides technical direction on complicated cases. Provides excellent customer service to all of the department's customers. The candidate must have a four-year Bachelor's of Science Degree (BS) in Clinical Laboratory Science or related field (e.g,. Medical Technology), Specialist in Blood Banking, SBB (ASCP) is preferred. Two to three years' experience in high complexity testing to include antibody identification and transfusion service. Please visit www.LStream.org to view the full job description and position responsibilities. LifeStream has an excellent compensation & benefits plan. For further information and to apply online please visit: www.LStream.org, or fax cover letter, resume, and salary history to (909) 386-6813. Must pass pre-employment background check, drug screen and physical exam. LifeStream is an Equal Opportunity Employer, M/F/D/V. Job Number: IN-4189357936

Reference Laboratory Technologist. LifeStream, a blood center located in Southern California, serving 80 hospitals with 200,000 blood products annually, is searching for a Reference Technologist. The Reference Technologist performs and reports test results for all Reference Laboratory procedures in an accurate and timely manner in compliance with Federal and State Regulations, AABB Standards, Manufacturer's recommendations, and internal operating procedures. Demonstrates proficiency, competency, and understanding of fundamental principles of Reference Laboratory procedures with a minimal amount of supervision. The candidate must have a Bachelor's of Science Degree (BS) in Medical Technology or related field, California Clinical Laboratory Scientist License. One to two years' experience in a laboratory and hematology laboratory is preferred. Please visit www.LStream.org to view the full job description and position responsibilities. LifeStream has an excellent compensation & benefits plan. For further information and to apply online please visit: www.LStream.org, or fax cover letter, resume, and salary history to (909) 386-6813. Must pass pre-employment background check, drug screen and physical exam. LifeStream is an Equal Opportunity Employer, M/F/D/V. Job Number: IN-4189357552

Quality Assurance Assistant Director (BR004b) - San Antonio, TX. QualTex Laboratories a subsidiary of BioBridge Global is seeking a QA Assistant Director. The ideal person will have quality experience in blood banking, in particular the management and review of a CAPA system, working knowledge of laboratory techniques, ability to perform and/or facilitate corrective/preventive actions in response to audits and deviations, and will maintain knowledge of regulatory/quality requirements (national/ international, e.g., FDA, EU, GHM, ISO & cGMP). Bachelor's degree in Applied Science or equivalent required. Five years lab experience required. Two years supervisory experience required. Excellent management and computer skills required. Certified MT (CLS) or equivalent preferred. Categorical Specialty Certifications preferred. Visit our website at www.qualtexlabs.org. E-mail résumé to hr_dept2@biobridgeglobal.org. Call Human Resources (210) 757-9557. BioBridge Global and its subsidiaries are proud to be an EEO/AA-M/F/D/V/Genetic Data employer that maintains a Tobacco & Drug-Free Workplace. All qualified applicants will receive consideration for employment without regard to race, color, ethnicity, religion, sex, national origin, disability, veteran status, genetic data, or other legally protected status.

Histocompatibility Technologist. Stanford Blood Center is seeking two (2) Histocompatibility Technologists to perform human histocompatibility testing including molecular typing, HLA antibody identification, and crossmatch testing. Test specimens, analyze, interpret, and report results. Experience in HLA is a plus, but we will train. Must qualify for or hold current California Clinical Laboratory Scientist license. Qualifications: BA or BS degree, with current California clinical laboratory technologist license, training license pending examination, or ABHI CHS/CHT certification. State license must be obtained within six months of start

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date. After completion of training, regular work hours are 2:30 PM to 11:00 PM Monday through Friday, with occasional Saturday assignment. Employee must be able to take on-call evenings, weekends, and holidays on a rotating basis. Please visit our website and reference Job # 63313 to apply. http://stanfordcareers.stanford.edu/job-search. Stanford University is an affirmative action, equal opportunity employer.

Reference Laboratory Technologist. Kentucky Blood Center, located in Lexington, Ky., is seeking a medical technologist to perform and interpret serological procedures on specimens submitted for compatibility testing or problem resolution. Will resolve typing problems, antibody problems, and crossmatch problems, and communicate with hospitals as needed. MT(ASCP) with minimum two years' recent blood bank experience, MT(ASCP)SBB preferred. Strong written and oral communication skills, a do-what-it-takes work ethic, and a team player attitude required. Competitive salary, comprehensive benefits including health/dental/life, LTD, paid sick/vacations/holidays, EAP, 403(b) retirement savings plan, and pension plan. For more information or to apply online, please visit www.kybloodcenter.org. Drug-free and EOE/AAP

Director, Quality Assurance & Regulatory Affairs. Hoxworth Blood Center seeks Director, Quality Assurance & Regulatory Affairs to monitor comprehensive quality assurance plan for Hoxworth's Cellular Therapies Division, which produces novel cell-based products for phase I/II clinical trials. Assure compliance with applicable regulatory requirements and assure clinical trial investigators that all products produced are of clinical-grade. Direct incoming raw material inspections, vendor audits, batch release, equipment process, facility validation, controlled document review, employee training documentation, all with a focus on continuous quality improvement. Prepare batch records for clinical trials. Provide input for project teams, interface with management, establish and track quality system timelines, track processing outcomes relative to goals, mentor staff, and assist with student teaching objectives. Qualifications: Bachelor's degree in medical technology, biology, chemistry, or related field is required. At least three years clinical laboratory/blood center experience (e.g., hematology, immunohematology, etc.) is required. At least one-year supervisory experience is required. Apply for this position at https://www.jobsatuc.com.

Supervisor, Immunohematology Reference Laboratory. Make a life-saving difference by joining the dedicated staff of Michigan Blood. This management position will oversee all facets of the Immunohematology Reference Laboratory (IRL) in the southeastern Michigan/ suburban Detroit area including staffing, procedures, testing, clinician education and training, outcome data collection, and budgeting. This role is responsible for developing an AABB-accredited IRL, maintaining standard operating procedures (SOPs) to assure compliance with regulatory agencies, validating and monitoring procedures and equipment, serving as a liaison with hospitals, and supervising IRL staff. The ideal candidate will demonstrate remarkable technical, customer service and professional communication skills. Specialist in Blood Banking (SBB) or equivalent, bachelor's degree (BS) from a four-year college or university plus two years of blood bank experience, and MT(ASCP) or MLS(ASCP) certification required. Advanced level blood banking problem solving required. Prior management experience preferred. We offer a competitive salary and benefit plan. If you want to be part of our lifesaving organization please apply via our website: www.miblood.org. Interview opportunity available at the AABB Annual Meeting.

Medical Director. Provide oversight on all medical aspects of the regional blood center operations, including the reference laboratories, research, medical community relations and collections. Develop and implement medical policies and procedures for the blood region as needed; coordinate communications between the blood services region, the local and national medical community and National Headquarters; provide timely medical and technical consultation in transfusion medicine to operation units and customers. We offer excellent benefits including health/dental/vision insurance, 401(k) and 403(b). Positions available in several locations including Salt Lake City, UT (BIO46548) St. Louis, MO (BIO47188) and Columbus, OH (BIO42182) For more information or to apply visit: www.americanredcross.apply2jobs.com. EOE M/F/D/V