

# ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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#### 2019 #41

#### **December 6, 2019**

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# **BPAC Discusses Considerations for Cold Stored Platelet Products Intended for Transfusion**

The U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) met recently to discuss the various roles, available characterization, and functional studies of cold stored platelets (CSP). The committee also learned about future studies, while hearing the results from clinical studies and the potential role of CSP in both the military and civilian populations. The purpose of the meeting was to discuss the scientific implications and not recommend any actions or clinical trials.

The meeting began with a presentation from FDA's Carlos Villa, MD, PhD who provided an overview of CSP and room temperature platelets (RTP). He reviewed the physiological and biochemical changes, known as storage lesions, which occur in platelets during storage and noted the design of clinical studies to evaluate the safety and efficacy of CSP stored for more than 3 days, along with the regulatory issues and other points to consider such as the risk profile of CSP in terms of potential adverse events. He was followed by Darrell Triulzi, MD of the University of Pittsburgh who provided an overview of the general clinical standards by which platelets are used. His presentation examined national statistics on platelet collection and distribution, noting the continued decline in platelet transfusion, which he attributes to patient blood management and additional attention surrounding the appropriate use of platelets, the risks of platelet transfusion, and explained the difference between apheresis and whole blood pooled platelets.

Monique Gelderman, PhD of FDA discussed changes in platelet storage in addition to the approaches to the evaluation of novel platelet products such as pathogen reduced platelets or new storage containers. The experience of Bloodworks Northwest followed with a presentation by Moritz Stolla, MD. It focused on preclinical *in vitro* and *in vivo* recovery and survival studies that compared platelets stored in 100 percent plasma versus a combination of plasma and an additive solution and examined mitochondrial function, glucose levels, and platelet yield. Next Geir Strandenes, MD provided results from a clinical study of cold stored platelets in Norway. Results from the pilot suggested that platelets stored cold for up to 14 days contribute to hemostasis in patients with clinical bleeding. James Stubbs, MD provided the Mayo Clinic experience since they began transfusing CSP in 2015. The Mayo Clinic Medical Transport would prefer the ability to transport CSP on air ambulances, but do like many ABC members, not intend to proceed with any plan until they can extend the shelf life of CSP (with a goal of 14-day CSP). His presentation was followed by Donald Jenkins, MD examining the role of CSP in clinical care in the







#### BPAC Discusses Cold Stored Platelets (continued from page 1)

general population. Col. Andrew Cap, MD, PhD then evaluated CSP function within the context of the military experience. The Department of Defense would like to see the shelf-life extended to 21 days to dramatically increase inventory and the ability to ship fully tested products from the U.S., though they are appreciative of the 14-day variance that FDA has given them which increased the platelet supply from civilian sources to support contingencies. Phillip Spinella, MD closed the scheduled presentation portion of the meeting by describing a proposed clinical trial to evaluate the efficacy of CSP in surgical platelets and potential endpoints for CSP clinical studies. His presentation highlighted the importance of platelets to stop bleeding and the need to increase efficacy and storage duration linking both to the potential to improve patient outcomes in bleeding patients.

The committee then discussed the need for more data before recommending policy changes. In the interim, they recognized that the FDA was in a position to act quickly in the form of variances, which can even be fast tracked, with the aim of approving them in a reasonable amount of time. This will help with situations that currently exist in which patients in need of platelets are unable to get them. Members of the committee stated that they did want the variance process to be viewed as helpful rather than a hinderance in making both the safest and best use of platelet products. Variances could prove to be a useful compromise solution, especially if they are based on ones that have already been passed to get some type of protocol in place to meet a more urgent need as has been done with the military.

ABC Board President Mike Parejko, chief executive officer of Mississippi Valley Regional Blood Center (Davenport, Iowa) offered the view of ABC members. He focused on the three-day expiration date, while mentioning the constraints the blood centers are currently operating under with the short-shelf life of platelets and how long it takes to get a variance approved by the FDA. "The 30,000 deaths that happen each year are preventable. Doing some quick math that is 82 a day. That's nearly 3.5 an hour. We've been here [in this meeting] for about 7 hours. Since we've had this discussion, 24 deaths have happened that may be preventable. I think when we look at big numbers we forget about the small sometimes. So, in the period of time that we've been here, 24 to 25 deaths could have been prevented," he told the committee. Additionally, ABC voiced the views of the membership to the committee and FDA asking both entities to:

- seek data that would support use of cold stored platelets in these and other settings and not limit it only to trauma situations; and
- to think broadly in their consideration of cold stored platelets and to seek data that would support expeditious decision making by the agency once the data is available.

Also, during the public hearing portion of the meeting, representatives from ABC member blood centers Hoxworth Blood Center, New York Blood Center (on behalf of the ABC and AABB membership), and South Texas Blood and Tissue Center delivered comments to the committee. A webcast of the meeting is available along with other meeting materials on the FDA's website.

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

#### **America's Blood Centers**

Chief Executive Officer: Kate Fry Chief Medical Officer: Rita Reik Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$390

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#### Estimates of the Total Number of Eligible Blood Donors in the U.S. Revisited

For years, many U.S. blood centers have used the statistic that estimated a little less than 40 percent of the U.S. population was eligible to donate blood, yet less than 10 percent of individuals do. A new study published recently in *Transfusion* updates the aforementioned 2007 study using a revised epidemiologic model that accounts for and identifies donor exclusionary factors and "epidemiologic databases selected to enumerate the population prevalence of the donor exclusion factors."

The researchers distinguished between donor "deferrals" (those who present to donate but are ineligible) and donor "exclusions" (total number of individuals in the population that are not viewed as "suitable" donors based on established risk. Using a six-step method that accounted for donor exclusion factors both short- and long-term, as well as permanent, the authors calculated an estimate of the number of excluded donors, using 2018 AABB standards, from which "the population of eligible blood donors can be approximated." They adjusted for age, the length of the exclusion, and comorbidities. Their model suggested that 204.9 million individuals are eligible to donate blood (62.6 percent) with 122.2 million (37.4 percent) a part of the excluded set. "This indicates that of the total US population, 62.6 percent were eligible to donate blood. This is a much larger number of potential donors than the 111 million we reported in 2007. This larger number is predominantly due to our inclusion in this study of the 65 years and older age segment. The exclusion of older individuals in our previous study was due to practice patterns, rather than AABB standards or U.S. Food and Drug Administration guidance. However, this exclusion now seems unnecessary since older individuals in good health donate at significant rates and can do so safely." The authors further acknowledge that "dissonance" exists between their findings of an increased eligible donor population in the U.S. and any shortages, as less than 5 percent of eligible donors give when applying their model to the 12 million units of blood collected from 9 million donors in 2017.

**Citation:** To, L., Dunnington, T, Thomas, C., Love, K, McCullough, J., Riley, W United States' potential blood donor pool: updating the prevalence of donor-exclusion factors on the pool of potential donors. *Transfusion*. 2019. Doi:10.1111/trf.15573. ◆

#### **REGULATORY NEWS**

The U.S. Food and Drug Administration (FDA) announced that it has approved an exception to the collection and distribution of whole blood (WB) from otherwise eligible donors who would have been deferred for vCJD risk due to spending time abroad. The exception under 21 Code of Federal Regulations (CFR) 630.10(a), 630.10(e), 630.10 (h), 630.30(b), Alternatives and Exceptions, is commonly known as a variance. It reads, "To collect and distribute Whole Blood from otherwise-eligible donors who would have been deferred for vCJD risk due to time spent in countries or on military bases, other than the UK, France and Ireland, use of prescription Finasteride in the past month or Dutasteride in the past 6 months, or travel to a malaria-endemic area in the past one year prior to the donation attempt. The Whole Blood collected from these donors will only be further manufactured into non-injectable reagent red blood cells. The approval can be found here.

(Source: FDA Announcement, 12/3/19)

The U.S. Department of Health and Human Services has unveiled an initiative entitled "Ready, Set, PrEP." The program would make pre-exposure prophylaxis (PrEP) available to individuals at no cost without prescription drug insurance coverage. "Ready, Set, PrEP is a historic expansion of access to HIV prevention medication and a major step forward in President Trump's plan to end the HIV epidemic in America," said HHS Secretary Alex Azar in an agency news release. "Thanks to Ready, Set, PrEP, thousands of Americans

#### REGULATORY NEWS (continued from page 3)

who are at risk for HIV will now be able to protect themselves and their communities. The Trump Administration recognizes the vital role of prevention in ending the HIV epidemic in America, and connecting members of vulnerable communities to prevention services and medication is an important part of the President's initiative." In order to qualify for the initiative, present a valid prescription for the medication, test negative for HIV, and not have prescription drug insurance. "PrEP is highly effective in preventing HIV infection when taken as directed," added HHS Assistant Secretary for Health Adm. Brett Giroir, M.D. "It is a critical tool for ending the HIV epidemic, but to make an impact it has to be available for people who need it most. Ready, Set, PrEP will increase access to this effective and preventive drug for people at risk."

(Source: HHS News Release, 12/3/19) •

#### INFECTIOUS DISEASE UPDATES

#### **MALARIA**

The World Health Organization (WHO) published its World Malaria Report 2019. Malaria cases fell from 231 million in 2017 to 228 million in 2018, though there is still much work to be done to eliminate its prevalence in endemic areas. "The world has shown that progress can be made," said the WHO's malaria expert, Pedro Alonso, to a group of reporters that included <u>Reuters</u>. "But progress has slowed down," he said. "And we have stabilized at ... an unacceptably high level." The WHO also calls for further funding efforts in fighting the disease from countries around the world to help the organization reach its \$5 billion funding target, which is the amount that WHO estimates is needed worldwide in the fight against Malaria. The report also highlighted that 19 countries in sub-Saharan Africa and India make up 85 percent of the "global malaria burden, while six countries accounted for more than half of all malaria cases worldwide.

(Sources: WHO World malaria report 2019, 12/3/19, Reuters, Malaria fight stalling at 'unacceptably high level' of deaths: WHO, 12/419) •

#### WORD IN WASHINGTON

The Senate Health, Education, Labor and Pensions Committee voted in favor of approving the nomination of Stephen Hahn, MD as commissioner of the U.S. Food and Drug Administration (FDA). This paves the way for an upcoming confirmation vote on the Senate floor. Dr. Hahn would be the fulltime replacement for Scott Gottlieb, MD, who resigned earlier this year. "Dr. Hahn has extensive medical and research experience and is a proven leader in large health systems—all around, he is exactly the type of nominee we want to lead an agency as important as the FDA," said Committee Chairman Lamar Alexander (R-Tenn.) during the committee vote. "Now it's time for him to be confirmed because there is a lot the FDA needs to do-approve new life-saving drugs and devices, regulate tobacco and e-cigarettes, address the opioid crisis and ensure pain patients can receive the medications they need, and protect our nation's food supply." Ned Sharpless, MD, current director of the National Cancer Institute ran the organization on an interim basis as Acting Commissioner until last month when his term ended.

(Sources: Sen. Lamar Alexander News Release, 12/3/19) •

#### **RESEARCH BRIEFS**

America's Blood Centers welcomes contributions or briefs from guest authors for scientific/medical peerreviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing a brief for potential publication please contact us here.

#### A Look at the Use of Freeze-Dried Plasma in the Field

Hemorrhage after injury is the leading cause of potentially preventable death on the battlefield. Early transfusion of plasma, as part of damage control resuscitation, in a prehospital environment, has the potential to reduce downstream complications and is therefore an important component in ensuring optimal survival of patients with traumatic hemorrhage. In 2013, the Israel Defense Forces (IDF) approved Lyo-Plas N freezedried plasma (FDP) for use by advanced life support (ALS) providers in prehospital settings. According to the manufacturer, FDP should be stored at 2°to 25°C, allowing for 15-month shelf life. Based on these characteristics, FDP was approved as an alternative to fresh frozen plasma (FFP) for treating the same coagulopathies and factor deficiencies. For most drugs, manufacturers guarantee a potency of 90 to 110 percent for a specified period, when stored as recommended. Israeli ALS providers in the IDF carry their medical supplies, including FDP, in their personal supply vest where temperatures can reach as high as 50°C, for short periods. It is unknown to what extent field-stored medications are affected by exposure to extreme temperature ranges. A study recently published in *Transfusion* evaluated the effect of routine field storage conditions in the IDF on the stability and efficacy of FDP.

Clotting factor concentrations in FDP stored under various conditions were evaluated: 1) after six and 12 months' storage in a controlled environment at 40°C; 2) after six and 12 months' storage in a controlled environment at 25°C, representing room temperature storage; 3) after six and 12 months' storage in a controlled environment at four degrees Celsius, representing refrigerated storage; 4) FDP returned from the field units after uncontrolled storage for 15 months; and 5) freshly supplied FDP, sampled within one month after delivery, which served as a reference. Each sample was analyzed to evaluate the levels of clotting factors V, VIII, and XI; proteins C and S, VWF, fibringen, partial thromboplastin time (PTT), antithrombin III (ATIII), and international normalized ratio (INR). The study found that at four degrees Celsius after six months fibringen decreased significantly (p=0.04) and after 12 months factor V decreased significantly (p=0.006). At 25°C, average fibringen (p=0.01) and factor V (p=0.002) content were significantly lower at both periods, and INR was higher after 12 months (p=0.04). Average fibringen content (after six and 12 months) was significantly lower than in freshly supplied FDP units ( $p \le 0.001$ ). The same was true for PTT ( $p \le 0.001$ ), INR (p < 0.001), ATIII (p < 0.001), factor V (p < 0.001), factor VIII (p < 0.001), factor XI (p < 0.02), protein S (p < 0.005), and VWF (p < 0.04). After storage under field conditions for the manufacturer defined shelf life of 15 months, some samples were found to be out of normal range in almost all measured parameters. When compared to freshly supplied doses, fibringen, factor V, PTT, protein S, and factor XI were significantly decreased, whereas INR was increased (all p < 0.05).

The authors concluded that FDP was shown to be an appropriate alternative to FFP. It could be used for scenarios in which storing and thawing frozen plasma is of limited feasibility and rapid plasma transfusion is required, such as battlefield conditions even after many months of storage under uncontrolled conditions in Israel. Under controlled storage conditions at 40 °C, it was felt that shelf life could possibly be extended, although further study would be required.

**Citations:** Zur, M., Glassberg, E., Gorenbein, P., *et al.* Freeze-dried plasma stability under prehospital field conditions. Transfusion. 2019;.Doi: 10.1111/trf.15533.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

#### **Upcoming ABC Webinars - Don't Miss Out!**

- **ADRP Webinar: Community Outreach and Engagement** December 19<sup>th</sup> from 1 p.m. 2(ET). Additional details available here.
- **Irradiator Replacement at Blood Centers Webinar** January 21<sup>st</sup> from 3 4:30 p.m. (ET). Additional details coming soon.

### BC Newsletter

#### **PEOPLE**

The Rock River Valley Blood Center Board of Directors has named **Lisa Entrikin** Chief Executive Officer (CEO). She had been serving as acting Interim CEO since August. Ms. Entrikin has more than 20 years of blood center leadership experience and is also the current president of ADRP's, an International Division of America's Blood Centers, Advisory Board. She previously served as the Rock River Valley Blood Center's Director of Operations and has lead their collection, recruitment, marketing, cellular therapy, hospital services, and component operations during her career at the blood center. Ms. Entrikin holds a B.S. in Communications and Marketing from Northern Illinois University.



(Source: Rock River Valley Blood Center Announcement, 11/26/19)

**Heidi Ognibene** has become Rock River Valley Blood Center's Director of Operations after serving in that role in an interim capacity since August. Ms. Ognibene has more than 30 years of leadership and blood center experience and previously held the director of operations, community resources role at Rock River Valley Blood Center.

(Source: Rock River Valley Blood Center Announcement, 11/26/19)

#### **MEMBER NEWS**

**Versiti, Inc.** announced this week that it has developed a new P-Selectin Expression Assay (PEA) for patients suspected of having Heparin-Induced Thrombocytopenia (HIT), an immune-mediated drug interaction. This test can detect more patients with HIT antibodies in less than 24 hours. "When compared to [Serotonin Release Assay] (SRA), the PEA test has improved sensitivity and is less demanding to run—it doesn't require any radioactive elements, has a quicker run time, and allows us to provide results in less than 24 hours compared to SRA's projected 1-3 day timeframe," said Brian Curtis, PhD, senior director, diagnostic laboratories who leads the laboratory testing for the PEA at Versiti's diagnostic laboratories. "The PEA test offers new hope for stopping the deadly conditions associated with HIT and thrombosis," said Richard Aster, MD, a senior investigator who has worked in the development of HIT diagnostics at Versiti Blood Research Institute for almost 40 years.

(Source: Versiti News Release, 12/2/19)

Northwest Oklahoma Blood Institute received a \$50,000 donation from the Northwest Oklahoma Osteopathic Foundation as part of a \$1.4 million fundraising effort to renovate the Northwest Oklahoma Blood Institute's Enid Donor Center. "We are very pleased to have the \$50,000 donation from the Northwest Oklahoma Osteopathic Foundation to kick-start our campaign," said Jessy Dershem, executive director of Northwest Oklahoma Blood Institute Enid Donor Center, to the *Enid News & Eagle*. "It will greatly improve our efficiency, help us grow, and improve quality of life for our front-line staff." Anita Luetkemeyer, executive director of the Northwest Oklahoma Osteopathic Foundation added, "[w]e believe in the mission of the Northwest Oklahoma Blood Institute, and we know how important a successful blood bank is to the community and the hospitals. We thought this gift would be a good opportunity to jump in, to kick it off, and to challenge other businesses to do the same." The facility upgrades are also seen as potentially positioning Northwest Oklahoma Blood Institute to contribute to the development of research and technological







#### MEMBER NEWS (continued from page 6)

opportunities in regenerative medicine and cellular therapy. "We want to make sure this community is well up on the list of places that get the benefit of those cures and therapies when they become available — earlier, rather than later," Oklahoma Blood Institute President and CEO John Armitage, MD said to the *Enid News & Eagle*. "We want to bring that kind of clinical therapy to our communities as early as possible."

(Source: Enid News & Eagle, OBI receives \$50K donation to kick-start Enid Donor Center upgrades, 11/27/19)

Steve Harrell, a Florida veteran on a mission to donate blood in every <u>state</u> recently visited **The Blood Connection's** (TBC) Arden Donation Center in North Carolina on Veteran's Day. His mission to save lives has inspired Mr. Harrell to travel across the nation, donating blood in every state. "If you want to be a hero...you can do that right here at home," Mr. Harrell told TBC. "People that give blood are heroes too, they're saving lives every time they donate." His stop at TBC was the 10th state on his list. He will be donating with TBC again in South Carolina to check another state off his list. The Jacksonville, Florida native plans to donate blood every 2 months until he's donated in every state, the last two being Alaska and Hawaii. The entire journey will take him about 7 years. Mr. Harrell says this mission is driven by his passion to give back to communities. For every blood do-



nor who presented to donate at a TBC donor center on Veteran's Day, TBC pledged to give \$10 to the Wounded Warrior Program. TBC will be donating \$3,380 to the Wounded Warrior Program as a result of the donors that showed their support on Veterans Day.

(Source: The Blood Connection Announcement, 11/25/19)

**Kentucky Blood Center** and **MEDIC Regional Blood Center** held their annual friendly <u>competition</u> to see which center would have the most donors leading up to the University of Kentucky versus the University of Tennessee annual football game. Kentucky Blood Center won this year's battle with 2,894 donors winning the title back from MEDIC for this year. "Thanks to our generous blood donors who gave us a really strong finish, we're bringing the trophy back to Kentucky," said Martha Osborne, vice president of marketing for Kentucky Blood Center in a news release. "Thank you to everyone who came out to donate this week. Countless lives will be saved this holiday season." This was the 32<sup>nd</sup> competition between the two blood centers with Kentucky Blood Center holding an 18-13-1 record thanks to an 8-year winning streak that was snapped last year.

(Source: Kentucky Blood Center News Release, 11/21/19)





## **INSIDE ABC**

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

#### ABC Awards of Excellence Call for Nominations Extended to December 13th

ABC members are encouraged to nominate blood donation sponsors, corporations, and advocates for the 23<sup>rd</sup> Annual *Awards of Excellence*. This year's ceremony on Tuesday, March 10<sup>th</sup> will be in Washington, D.C. during ABC's 58th Annual Meeting at the Ritz-Carlton (Pentagon City). Nominations are currently open until Friday, December 13th. Additional details are available in MCN 19-072 for ABC member blood centers. The online submission form is available here. ABC members are permitted to submit up to three nominations per category. The following awards will be presented during the awards ceremony and are currently open for nominations:

- ABC Outstanding Blood Drive of the Year
- Outstanding Public Relations Campaign
- Corporation of the Year Award
- Larry Frederick Award (jointly presented by ABC and ADRP)
- William Coenen President's Award
- Blood Community Advocate of the Year Award
- Thomas F. Zuck Lifetime Achievement Award

A complete description of each award is available <u>here</u>. Please direct any questions about nominations or the awards ceremony to <u>memberservices@americasblood.org</u>.

(Source: MCN <u>19-072</u>, 10/30/19)

#### **2020 ADRP Award Nominations Available**

Each year, ADRP honors individuals and organizations that have demonstrated outstanding service, accomplishments or leadership in blood banking. Blood centers are encouraged to nominate individuals and

organizations. In addition to a complimentary conference registration, winners receive a commemorative award and recognition in the ADRP newsletter and website. The nomination deadline is December 31, 2019. This year's award categories are:

#### **Individual Awards**

- Donor Recruiter of the Year
- Collections Team Member (Recruitment and Collections)
- Rolf Kovenetsky Leader of the Year
- Ron Franzmeier Lifetime Achievement
- Ronald O. Gilcher, MD

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#### **INSIDE ABC** (continued from page 8)

**Organization Awards** 

- Media Partner
- Humanitarian Service
- Blood Drive (Most Creative and Most Productive)
- School Blood Drive (HS or College)

Additional information on the ADRP awards is available on the ADRP website.

(Source: ADRP Awards Announcement, 10/29/19)

ABC 2020 Meetings & Workshops					
Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees	
2020 ABC Annual Meeting	March 9 <sup>th</sup> -11 <sup>th</sup>	Washington, D.C.	Ritz-Carlton (Pentagon City)	More details coming soon!	
ADRP 2020 Conference	May 19 <sup>th</sup> -21 <sup>st</sup>	Phoenix, Ariz.	Hyatt Regency	More details coming soon!	
2020 ABC Medical Directors Workshop and Summer Summit	July 21st-23rd	Cleveland, Ohio	Westin Downtown	More details coming soon!	

#### Notes:

For the most up-to-date information on all events, members of ABC may check the <u>calendar</u> on ABC's Member Site.

Non-members may attend all events; information will be updated on ABC's Public Site.

#### 2020 ADRP Annual Conference Now Accepting Abstracts

ADRP, an international division of America's Blood Centers, is encouraging donor collections, donor recruitment, marketing, and communications professionals to consider sharing their knowledge at the 2020 ADRP Annual Conference by being a presenter. The call for speaker abstracts is open until December 31<sup>st</sup>. Topics that have been the most requested by attendees include:

#### • Leadership and team development:

- Critical thinking
- o Time management
- Staff adequacy and talent level
- Managing change

#### • Blood Type Management:

- Collecting correct units based on blood type
- o Maintaining inventory during time of need
- o Rebooking donors and drives with emphasis on time of need

#### • Donor and sponsor communication strategies:

- Diversification of the donor base
- Addressing donor apathy
- o Communications strategies



#### <u>INSIDE ABC</u> (continued from page 9)

As the industry's leading conference for donor facing professionals in the areas of collections, communications, marketing, and recruitment, this year's focus, "Charting the Course to Excellence," will delve into each step of the donor journey and provide proven solutions for how staff from all aspects of the blood center can work together to achieve the best possible outcomes. Additional information about the conference is available on ADRP's website.

(Source: ADRP Abstract Submission Form, 10/10/19)

#### **CALENDAR**

**Note to subscribers:** Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a> or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

#### 2020

Jan. 14-15. IPFA/EBA Workshop on Plasma Collection, Amsterdam, the Netherlands. More details available here.

Mar. 9-11. 2020 ABC Annual Meeting, Washington, D.C. More details coming soon.

Mar. 25-26. IPFA 5<sup>th</sup> Asia Workshop on Plasma Quality and Supply, Chonburi, Thailand. More details available here.

May 19-21. 2020 ADRP Conference, Phoenix, Ariz. More details available here.

July 21-23. **2020 ABC Medical Directors Workshop and Summer Summit, Cleveland, Ohio.** More details coming soon.

#### **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, e-mail: <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a>

#### **POSITIONS**

Director, Plant Operations and Product Management. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for the position of Director, Plant Operations and Product Management. This position reports to the Vice President, Operations and oversees the management of preventive and corrective maintenance activities associated with the plant operations systems, medical device equipment, and fleet equipment. Directs and coordinates logistical functions of the organization including transportation, mobile staging, equipment and staff, supply chain management and warehouse. Ensures that compliance is achieved and maintained with all Federal, State, and local environmental rules and regulations. Oversees the management of the safety program in

compliance with Federal, Cal/OSHA, FDA, AABB guidelines and other regulatory agencies. Reviews and compiles pertinent financial information as needed for the Accounting department. Oversees product distribution, hospital services, transportation, fleet maintenance, facility, medical device management, mobile staging, and warehouse and EHSS functions. Provides unparalleled customer and employee responsiveness. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal government E-verify program to determine employment eligibility. Apply online at <a href="https://www.lstream.org/open-positions/">https://www.lstream.org/open-positions/</a>

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#### **POSITIONS** (continued from page 10)

Reference Lab Manager. OneBlood is currently recruiting for a Lab Manager in our AABB-Accredited Immunohematology Reference Laboratory. This position provides leadership and technical expertise, manages staff, and performs training and quality activities for the staff responsible for performing basic through advanced testing procedures on patient and/or donor samples. Applicants must have a bachelor's degree in medical technology, biological science or related scientific field from an accredited college or university. Five or more years in a clinical laboratory, preferably blood banking environment, or an equivalent combination of education, certification, training and/or experience. Applicants must have SBB certification, as well as a valid and current Florida Clinical Laboratory Supervisor license, or eligible, in Immunohematology or Blood Banking. To apply and view a complete Job Description of this position, go to www.oneblood.org and click on the Careers tab. One-Blood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Laboratory Manager (Appleton, Wisc.) The Community Blood Center is seeking a Manager for our Laboratory Operations. This individual will have a passion for leading others, and experience leading laboratory testing, component, and hospital service activities. The Community Blood Center currently provides 20+ Wisconsin and Michigan hospitals with a full range of blood components. Responsibilities for this individual will include planning, managing and supervising all laboratory testing, component, and hospital service activities. Responsible for oversight of the activities of Laboratory staff and ensuring all processes are compliant and safe. Oversight consists of allocation of resources, monitoring, correcting, improving and updating all technical, regulatory, administrative, and personnel functions. This individual will be responsible for accomplishment of key department and organizational objectives including assigned goals, operational productivity compliance measures and staff engagement metrics; ensuring compliance with quality control functions, documents and industry regulations; budget preparation and plan development to maintain or adjust operations as needed. The position requires a MT(ASCP) or equivalent and minimum two years lab experience, ideally with increasing levels of responsibility. Medical background or blood center experience with strong working knowledge of laboratory practices, equipment and regulations; excellent leadership, staff development and team building skills, in addition to budget preparation and monitoring skills, with a high level of data analysis skills. Apply at: https://www.communityblood.org/careers.

**Donor Services Collections Operations Director.** (Ada, Okla. and Ardmore, Okla.) This position will provide leadership and direction over all aspects of the

Oklahoma Blood Institute Donor Services collection team for both mobile and fixed site operations. It is responsible for assessing, developing and implementing strategic plans to achieve donor services objectives and goals. Create a friendly competitive environment to motivate staff to achieve high system wide standings on all key performance metrics (loss rates, errors, 2RBC conversion, Global Blood Fund, etc.). Conduct routine meetings to communicate organizational vision, updates, and changes and recognize outstanding staff performance keeping morale high. Maintain adequate staffing levels. Make frequent visits to both fixed and mobile collection sites. Actively participate in internal and external assessments/inspections including corrective action plans and effectiveness checks as needed. Track and monitor inventory and collection goals, which include whole blood, automation rates, and WB conversion data. Analyze data and make adjustments to increase productivity. This includes working closely with recruitment to ensure projections are met. Prepare and manage department annual budgets. Bachelor's degree in management or medical field. Minimum of five years' leadership/management experience, and valid driver's license. Competitive salary and excellent benefits package. How to Apply: <a href="http://obi.org/careers/">http://obi.org/careers/</a>

Director of Quality and Regulatory Affairs (Grand Rapids, Mich.) Versiti was founded with the belief that together, our blood centers can better serve patients' urgent need for life-saving healthcare. We love what we do, and we're looking for passionate individuals to join the Versiti family. We foster a diverse environment that affirms each employee's dignity and worth, and we offer a chance to work with a team of compassionate people who provide lifesaving blood to our communities on a daily basis. Under the direction of the Chief Quality Officer provides leadership and direction for developing, implementing, and executing quality assurance processes and practices that support the manufacture of FDA-regulated biologics (blood and tissue). The primary responsibility is to lead the affiliate QA/RA/QMS function for these services and ensure that all activities meet regulatory requirements and result in high quality, safe, and effective products and services. Supports standardization of policies, processes, procedures, and practices across Versiti. Promotes culture of quality and compliance. Works effectively with other Quality Directors within Versiti to provide effective quality and compliance solutions and practices that advance Versiti Quality mission. Requirements: Bachelor 's degree in a scientific field from an accredited university; academic training or direct work experience in Master's degree in a scientific field, business, health care or other related field preferred; previous experience working in a blood bank required; minimum five years' experience in a regulated industry (biologics, pharma, or medical device), where change management,

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#### **POSITIONS** (continued from page 11)

validation, and creation of SOPs (standard operating procedures) has been required and successfully implemented; a minimum of 3 years of direct management experience or progressively more responsible project management experience is required; prior experience participating and/or managing FDA inspections is required. Additional experience working with accreditation bodies and third-party auditors preferred. You can find the job posting and apply <a href="here">here</a>. For further inquiries, please email Melissa Manley.

**Executive Director.** (Little Rock, Ark.) The Arkansas Blood Institute is seeking a "community spirited" professional to lead its Little Rock team in fulfilling the mission to recruit blood donors, drive sponsors, and volunteers and to store and deliver blood units for local hospitals. This public facing, "visible" position not only requires an outgoing, bright, and energetic personality to foster relationships, but also demands detailed attention to planning, communication, regulations, finances and personnel. Significant successes in project management and organizational expansion and entrepreneurship are desirable. Connectivity with regional leaders and access to key social networks would also be positives. The successful candidate will present and maintain a credible, positive image of the Arkansas Blood Institute in the local community. He or she will act as a liaison between the Institute and the community, organizations and residents. Applicants should be goal-driven self-starters who have strong interpersonal, organizational and analytic skills. They should be able to motivate and inspire diverse constituencies including donors, sponsors, staff, and volunteers. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Apply: http://arkbi.org/careers/.

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Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of free medical coverage with a competitive benefits package, 403(b) retirement plan with company contribution plus a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Ft. Lauderdale, Florida area, with some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our "Careers" page at www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.