

# A B C N E W S L E T T E R

# URRENT EVENTS AND TRENDS IN BLOOD SERVICES

**ABC Releases Whitepaper on Blood Donor Reactions in Teens** 

Visit ABC's Web site at: www.americasblood.org

#### 2019 #28

#### August 23, 2019

#### INSIDE:

REGULATORY NEWS3
RECENT REVIEWS3
Upcoming ABC Webinars - Don't Miss Out!4
A Case of Hemolysis4
WORD IN WASHINGTON
PEOPLE6
MEMBER NEWS7
GLOBAL NEWS7
INFECTIOUS DISEASE UPDATES8
ADRP Webinar: Understanding, Managing, and Preventing Vasovagal Blood9
Donor Reactions in Teenagers9
Updated Disaster Response Plan9
ABC 2020 Meetings & Workshops9
CALENDAR10
POSITIONS10

High school blood donors can oftentimes account for a significant proportion of a blood center's collections during the school year. These young donors also tend to be more susceptible to an increased rate of adverse reactions, which are generally mild and consist primarily of hematomas and vasovagal reactions (VVRs). To help mitigate the risk of such reactions, America's Blood Centers (ABC) has published the Understanding. Managing, and Preventing Blood Donor Reactions in Teenagers whitepaper to serve as a resource for donor center operations including donor recruitment, communications, marketing, collections, medical, and additional blood center staff and leadership.

Understanding, Managing, and Preventing

Blood Donor Reactions in Teenagers



OF THE ABC SCIENCE, MEDICAL, AND TECHNICAL COMMITTEE				
Jerry Gottschall, MI	D			
Chris Gresens, MD	(			
Lou Katz, MD				
Todd Straus, MD				
Mary Townsend, M	1D			



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Development of the whitepaper and the accompanying summary sheet was led by members of a working group of ABC's Science, Medical, and Technical Committee (SMT) that envisioned these resources being used as education tools and a reliable reference for providing background information, research, and recommendations as a means of informing readers on the frequency of VVRs in teen donors and strategies to limit their occurrence. Specifically, this paper examines the various forms of reactions among teenage donors and provides recommendations that cover both pre-donation education, environment setup as well as donation, and post-donation strategies.

The working group included:

- Jerry Gottschall, MD;
- Chris Gresens, MD;
- Louis Katz, MD;
- Todd Straus, MD; and
- Mary Townsend, MD.



Teen Donor Whitepaper Published (continued from page 1)

The authors used research that identifies psychological and physiological factors that contributes to VVRs to inform their mitigation strategies which are evidence-based. Additionally, they focused on two intervention categories that consist of:

- Reducing the emotional stressors (especially fear) of donation, and
- Preventing/counteracting the responsible physiologic changes.

Both the <u>whitepaper</u> and <u>summary sheet</u> are available for download on ABC's website. We encourage blood centers to use both resources with their staff. For questions or feedback, please contact ABC's Director of Quality Services <u>Toni Mattoch</u>.

(Source: MCN <u>19-058</u>, 8/22/19)





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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.

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# **REGULATORY NEWS**

ABC Newsletter

The U.S. Food and Drug Administration (FDA) has issued a request for nominations for voting members to serve on the Blood Products Advisory Committee (BPAC) in the Center for Biologics Evaluation and Research (CBER). The announcement in the Federal Register states that first consideration will be granted to nominations received prior to October 21st. Interested individuals may nominate one or more qualified persons or themselves. Nominations must be submitted through the online portal and require a current, complete résumé or curriculum vitae for all nominees in addition to a business address, phone number, email address, and signed Acknowledgement and Consent Form. More information on becoming a committee member can be found on the FDA's website. Further questions can be directed to Christina Vert. BPAC "reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum, or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which FDA has regulatory responsibility, and advises the Commissioner of Food and Drugs (the Commissioner) of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents." The committee is made up of 17 voting members chosen by the FDA "Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions."

(Source: Federal Register <u>Announcement</u>, 8/20/19)

## **RECENT REVIEWS**

Authors of a recent "Viewpoint" appearing in the Journal of the American Medical Association (JAMA) believe the U.S. Food and Drug Administration (FDA) should increase regulation of the 510(k) pathway for medical devices. They suggest that new medical devices entering the marketplace should be required to meet a higher standard than that of "substantial equivalence" for an existing, previously FDA-cleared device in the U.S. for the same intended use. The piece proposes that "legislation should mandate that 510(k) devices show improved safety and effectiveness compared with marketed devices for the same clinical purpose, using meaningful clinical criteria to gain clearance. Although these criteria will differ based on the intended use of the device, all criteria should be based on patient-oriented clinical outcomes... Because many safety issues only emerge once a product is in clinical use, postmarket surveillance for all medical devices must be strengthened." Additionally, the authors feel the agency should capitalize on the heightened scrutiny of the medical device industry to further ensure both device safety and effectiveness by "mandating postmarket data from clinical practice based on objective criteria for safety and effectiveness could improve the care of the millions of patients in whom a medical device may be used."

**Citation:** Redberg, R., Dhruva, S. Moving from substantial equivalence to substantial improvement for 510(k) devices. *JAMA*. 2019. *Doi:* <u>10.1001/jama.2019.10191</u>.

A commentary published in *Lancet Haematology* suggests that additional resources should be devoted to the treatment of sickle cell disease (SCD). The author describes current and future interventions as a "new era" in treating the disease and emphasizes that the positive results associated with low-cost financial investments as intervention strategies to combat SCD "in the middle income Americas" can be extrapolated to hypothesize that similar techniques (e.g. "screening, caregiver education, and pneumococcal prophylaxis



#### <u>RECENT REVIEWS</u> (continued from page 3)

have reduced child mortality attributable to [SCD] by at least 90 percent)" will result in comparable outcomes for individuals in sub-Saharan Africa. Additionally, she discusses the importance of screening for SCD and the need for equal access to treatments regardless of geographic or socioeconomic barriers as she concludes that "[a] future in which the [SCD] community can survive and thrive is within reach. All children with this disease must share that bright future by being equal beneficiaries of these medical and systems innovations. For this to happen ,these children must first be screened... Technological, medical, and systems innovation has made sickle cell disease more detectable, treatable, and curable than ever before. In the leadup to realization of the Sustainable Development Goals, African children with sickle cell disease and their families will be left behind if this disease remains neglected."

Citation: Simpson, S. Sickle cell disease: a new era. Lancet Haematology. 2019.

#### Upcoming ABC Webinars – Don't Miss Out!

• ADRP Understanding, Managing, and Preventing Vasovagal Blood Donor Reactions in Teenagers Webinar – September 12 at 2 pm EDT. Register <u>here</u>!

# A Case of Hemolysis

Contributed by Richard Gammon, MD, Medical Director at OneBlood

\*\*Please note: 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.\*\*

*The New England Journal of Medicine* recently explored warm autoimmune hemolytic anemia (WAHA) by first describing the case of a 61-yearold woman suffering from fatigue, increasing dyspnea, and dark urine with a respiratory rate of 30 (normal 12-20) breaths per minute, pulse 116 (normal 60-100) beats per minute, and the oxygen saturation 90 percent (normal 90-100). Her hemoglobin (Hb) was 5.4 g/dL (normal 12.0-15.5) and mean corpuscular volume was 103 fL (normal 80-96). Reticulocytes were 15.7 percent (normal 0.5-2.5 percent) and total bilirubin was 9.7 mg/dL (normal 0.1-1.2). Numerous microspherocytes (Figure A) and agglutination (Figure B) were discovered through a peripheral blood smear. A direct antiglobulin test (DAT) was positive for IgG and weakly positive for C3d, as laboratory tests displayed a panagglutinin. She had taken no regular medication. A diagnosis of WAHA was made.

This condition causes accelerated red blood cell (RBC) destruction due to warm agglutinins (almost always IgG antibodies) that bind to antigens on RBCs at 37°C. Annual incidence is 1-3 cases per 100,000 persons, median age of onset is 52 years with a slight female predominance. Up to 70 percent of patients have a chronic, relapsing course.

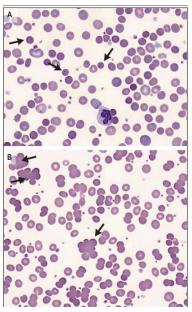


Photo courtesy of NEJM

(continued on page 5)

Case of Hemolysis (continued from page 4)

RBC clearance is through the spleen and liver with phagocytosis of the entire RBC membrane or a portion resulting in microspherocytes. Virtually all warm autoantibodies are polyclonal and react with all reagent RBCs (i.e. panagglutinins). Close to 50 percent of cases of WAHA are considered primary and idiopathic, while the rest are secondary to other disorders. "WAHA is often considered benign; however, mortality from vascular events (pulmonary emboli, myocardial infarction, and stroke) or from infection or sepsis may approach 5 percent."

Fatigue, dyspnea, and palpitations are all considered common symptoms of WAHA and are proportional to the degree of anemia. "It should be suspected in a patient who presents with anemia and laboratory evidence of hemolysis (i.e., an elevated lactate dehydrogenase level, an elevated indirect bilirubin level, and a low haptoglobin level). The diagnostic workup should include a complete blood count, a reticulocyte count, a peripheral-blood smear, and a DAT."

"WAHA with severe anemia (hemoglobin level <6 g/dL), hypoxia, confusion, or hemodynamic instability is a medical emergency, and urgent blood transfusion is indicated to reduce the likelihood of death from pulmonary edema, myocardial infarction, or arrhythmia." The crossmatch will be "incompatible," in practically all cases, as the autoantibodies recognize blood group antigens and will react with virtually all donor RBCs; in such cases, ABO- and Rh matched blood should be administered. The risk of a transfusion reaction with ABO and Rh-matched blood is close to zero "among patients who have not been sensitized to foreign RBC antigens, and low (<10 percent), in patients with a history of pregnancy or previous transfusion. The benefits of RBC transfusion outweigh the risks, even in patients with a predisposition to sensitization who have severe anemia due to WAHA. Blood should be infused slowly (over 2-3 hours). Extended phenotype matching should be performed with nonurgent cases where there is a high risk of alloimmunization. First-line therapy involves glucocorticoids and rituximab."

In conclusion, the author notes that the woman described in the vignette had severe anemia. After her condition stabilized, a workup for secondary causes of WAHA would be appropriate, as medical staff explain "that WAHA is often a chronic, relapsing condition, and additional therapies may be needed to achieve or maintain remission."

Citation: Brodsky, R.A. Warm Autoimmune Hemolytic Anemia. *N Engl J Med.* 2019. Doi: 10.1056/NEJMcp1900554. ♦

## WORD IN WASHINGTON

The U.S. Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) recently announced that it will provide \$23 million in funding to Merck & Co. for continued manufacturing of an investigational Ebola vaccine. The funding will be provided by the Biomedical Advanced Research and Development Authority (BARDA), whose ongoing support of development efforts of the investigational vaccine have totaled approximately \$176 million. "The best way to protect people at home from Ebola is to stop the virus from spreading abroad, and effective vaccine is an essential tool in that effort," said BARDA Director Rick Bright, PhD in a news release. "By ensuring that investigational vaccines continue to be available, we aid the global response and, simultaneously, help improve domestic preparedness." Additional support for both pre-clinical and clinical research projects has been contributed by the National Institutes of Health and the Department of Defense.

(Source: HHS News <u>Release</u>, 8/21/19)



#### WORD IN WASHINGTON (continued from page 5)

A report from *Bloomberg* examined the need and progress for U.S. to develop an integrated national surveillance and public health communications system to monitor infectious disease outbreaks and biological threats per the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPA). HHS has been tasked with developing and implementing this system by 2023. The U.S. Government Accountability Office (GAO) highlighted the importance of creating a nationally integrated surveillance and public health communications system that connected federal agencies to further foster improved information-sharing, preparedness, and response efforts to bioterror and infectious disease outbreaks. "What we're lacking here is a comprehensive almost one-stop-shop-like system where in an emergency you could go and have comprehensive information available," said Nicole Jarvis, an assistant director in the GAO's Information Technology and Cybersecurity division, to Bloomberg. "They have to start with having people in place that are going to take responsibility for taking the lead. Even though they said they were putting bodies in place, we didn't see them assigning responsibilities to the folks that needed to have responsibility." HHS Assistant Secretary for Preparedness and Response Robert Kadlec, MD acknowledged that the agency is "making incremental progress, but certainly more work needs to be done." He explained the complexity involved in developing the system and getting buy-in from all stakeholders while prioritizing data security by "protecting what would be personal information, private information, health information, and also proprietary information."

(Source: *Bloomberg*, <u>Overdue outbreak detection system leaves patchwork defense</u>, 7/30/19)

## PEOPLE

ABC Newsletter

Houchin Community Blood Bank has named **Brad Bryan, PhD, MBA** president and chief executive officer (CEO). He previously held the role of interim CEO since May. "It is an honor and a privilege to be placed at the helm of Houchin Community Blood Bank, a long standing organization that has helped the Kern County community save over three million lives since 1952," <u>said</u> Dr. Bryan according to *The Bakersfield Californian*. "I look forward to the opportunity to lead this amazing organization into the future and to continue serving this great community." He received his PhD in medical science from Texas A&M University and his MBA from the University of Massachusetts, Amherst. "We are extremely fortunate to have Dr. Brad Bryan join our Houchin Family," said Houchin Community Blood Bank Chair Joseph Engle. "He has brought a new perspective with innovative ideas to our organization." Additionally, Dr. Bryan holds a Bachelor of Science degree in biological sciences from Stephen F. Austin State University and a Master of Science degree in biochemistry from Texas A&M. He has served in the U.S.



Coast Guard Reserve and joined Houchin Community Blood Bank in March as the director of Laboratory and Technical Services before being promoted to the role of chief operating officer, a position he held while serving as interim CEO.

(Source: *The Bakersfield Californian*, <u>Houchin Community Blood Bank appoints new president and CEO</u>, 8/21/19) ●

#### We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at <u>newsletter@americasblood.org</u> or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.



# MEMBER NEWS

ABC Newsletter

**Versiti Blood Center of Indiana** and the Indianapolis Colts of the National Football League partnered for the 2019 Colts Leadership Challenge this summer. The initiative began in 2012 and is designed to create leadership skills in high schoolers by encouraging high school football teams to organize and host blood drives as way of saving lives and giving back to the community. According to a report in *Patch*, "[s]ince June, 53 teams [have] an-



swered the call, collecting 1,467 total blood donations across the state." Last year's challenge resulted in 44 participating high schools with more than 1,400 participating donors. High schools honored for hosting the largest blood drives were North Vermillion High School, Delphi Community High School Noblesville High School, and Eastern Hancock Jr.-Sr. High School.

(Source: Patch, 4 high school football teams win 2019 Colts Leadership Challenge, 8/19/19)

## **GLOBAL NEWS**

The Irish Blood Transfusion Service (IBTS) is ramping up its inventory of supplies used in the collection of blood and blood products as part of contingency planning efforts given the uncertainty of a withdrawal agreement being approved by members of Parliament in the United Kingdom (UK) before the UK leaves the European Union (EU). "Brexit", as the UK's exit from the EU has been named, is set to take place on October 31<sup>st</sup>. "Stocks of blood [supplies] will be increased prior to October 31<sup>st</sup> to ensure supply into 2020," said a spokeswoman from the IBTS to Irish Independent. "We will still be able to access these consumables used in the production of blood - this can also include kits used for testing. Neither the EU, UK nor Irish Government can say with any certainty what will happen on November 1<sup>st</sup>, 2019 in a no-deal Brexit. The IBTS has reviewed risks such as delays at ports, and has in place a plan to build contingency stock that will be held in Ireland. In the event of any delays into or from UK ports, this will allow access to critical consumables so that blood can be collected, processed, and distributed to hospitals...The IBTS has also contacted Irish suppliers and distributors to ensure they are holding contingency stock. In the event of a disorderly Brexit, this allows for certainty in the supply chain." The IBTS anticipates such contingencies being an interim solution for a couple months as the fallout for failure to reach a withdrawal deal are better understood, "It is envisaged that after approximately two months we will understand the impact of a no-deal, including potential delays at ports. At that stage contingency stocks can be run down. So really the cost is being front-loaded, but will not impact adversely on IBTS funding as stocks will be used," added an IBTS spokesperson to the Irish Independent.

(Source: Irish Independent, Blood stocks to be hoarded ahead of Brexit deadline, 8/22/19)

## **ABC Calendar of Events**

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The <u>calendar of events</u> includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

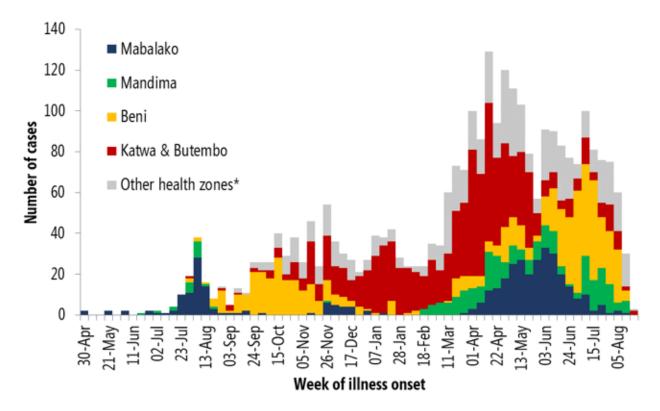
# INFECTIOUS DISEASE UPDATES

### **EBOLA**

The Ebola outbreak in the Democratic Republic of the Congo (DRC) continues to spread with four confirmed cases in the Mwenga Health Zone in the South Kivu province. This marks the 3<sup>rd</sup> province in the DRC with confirmed cases of Ebola joining North Kivu and Ituri. The WHO and CDC have not classified the affected areas as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that "in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2).

As of August 20<sup>th</sup>, there were 2,822 confirmed cases with 1,961 confirmed deaths in the DRC.

#### Confirmed and probable Ebola virus disease cases by week of illness onset, data as of August 20th\*



\*Data in recent weeks are subject to delays in case confirmation and reporting, as well as ongoing data cleaning. Trends during this period should be interpreted cautiously.

(Source: Ebola virus disease – Democratic Republic of the Congo, 8/22/19)



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

# ADRP Webinar: Understanding, Managing, and Preventing Vasovagal Blood Donor Reactions in Teenagers

<u>Register</u> today for the Thursday, September 12<sup>th</sup> ADRP Webinar entitled "Understanding, Managing, and Preventing Vasovagal Blood Donor Reactions in Teenagers." This webinar will take place at 1 p.m. eastern and feature Mary Townsend, MD senior medical director at Vitalant. Attendees will receive information on research regarding vasovagal reactions and be presented with recommendations to prevent and manage these reactions in teenage donors. This webinar is designed for recruitment, collections, and medical personnel. ADRP subscribers may register for free and non-subscribers can participate for \$25.

(ADRP Announcement, 8/12/19)

ABC Newsletter

## **Updated Disaster Response Plan**

ABC and Blood Centers of America, Inc. (BCA) have reviewed and updated disaster plans and documents. Version 2.0 of the ABC/BCA Disaster Plan is <u>available</u> and has been amended to reflect industry changes over the past decade. The previous Disaster Plan depended on the use of the ABC Hub and Spoke system which no longer fits the current need due to mergers and consolidations within the industry. In lieu of the Hub and Spoke system, operational responses to disasters will continue to be coordinated by BCA with regulatory and communication support provided by ABC. The <u>ABC/BCA Disaster Plan Version 2.0</u> reflects these changes. We strongly encourage members to review the plan with your internal teams to acquaint yourself to the process and incorporate into your own disaster plans. The <u>disaster page</u> on the ABC Member site contains links to various documents that have been updated as appropriate to assist members in disaster planning and response.

(Source: MCN <u>19-052</u>, 7/19/19) •

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 19th-21st	Phoenix, Ariz.	Hyatt Regency	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 <u>Public Site</u>.

-9-

August 23, 2019

# CALENDAR



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

#### 2019

Sept. 13. **Carter BloodCare 2019 Enrichment Lab, Euless, Texas.** A continuing education program designed for medical technologists and clinical laboratory specialists, interested in transfusion medicine. Attendees can earn up to 6 hours of P.A.C.E.® credit. More details available <u>here</u>.

Sept. 19. National Institutes of Health Clinical Center Immunohematology and Blood Transfusion 38<sup>th</sup> Annual Symposium, Bethesda, Md. More details available <u>here</u>.

Sept. 20. **Red Cell Genotyping 2019: Patients First, Bethesda, Md.** This 9th annual symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. More details available <u>here</u>.

Sept. 23-25. The MedTech Conference, powered by AdvaMed, Boston, Mass. More details available here.

#### 2020

Jan. 15-16. IPFA/EBA Workshop on Plasma Collection, Location to be announced. More details available here.

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

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

May 13-14. IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal. More details available <u>here</u>.

May 19-21. 2020 ADRP Conference, Phoenix, Ariz. 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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: <u>lmaundy@americasblood.org</u>.

## POSITIONS

Donor Services Director. Stanford Blood Center, a subsidiary of Stanford Health Care, is focused on connecting our communities to provide hope for healing. We lead the fields of transfusion and transplantation medicine by advancing science and technology. For more information, visit http://bloodcenter.stanford.edu/. We are seeking a Donor Services Director. Under the general operational direction of the Chief Operating Officer and the technical direction of the Medical Director, the Donor Services Director will set the strategy, goals, objectives and structure of Donor Services. Core Duties: Responsible and accountable for management, supervision, and coordination of day-to-day operations of departments involving donor collections and donor recruitment at a number of fixed sites and mobile locations. Responsible for using frequently changing customer utilization patterns to make

decisions regarding staffing, center hours, and expenditures for areas of responsibility, coordinating with upper management for other operational areas. Oversee implementation of policies and procedures and assure that employees understand and adhere to established policies and procedures. Qualifications: Four-year college degree required; RN license, medical technologist license or MBA preferred. Five years of progressively responsible management experience and demonstrated ability to effectively manage several functions required. For complete job description and to apply visit <u>https://www.stanfordhealthcarecareers.com/</u> and reference job #53086.

(continued on page 11)

#### **<u>POSITIONS</u>** (continued from page 10)

Chief Operating Officer. Stanford Blood Center (SBC), a subsidiary of Stanford Health Care, is focused on connecting our communities to provide hope for healing. We lead the fields of transfusion and transplantation medicine by advancing science and technology. For more information, visit http://bloodcenter.stanford.edu/. We are seeking a Chief Operating Officer. Under the general direction of the SBC Executive Director, and technical direction of the Medical Director, is responsible for the administrative and technical management of Blood Center operational departments. Core Duties: Lead annual operations planning to establish goals and metrics for blood collection, testing, manufacturing and distribution. Manage department heads and supervisors to develop, evaluate and adjust organizational structures and systems to assure accomplishment of Blood Center mission(s) in the most effective and economical manner. Perform long range policy, personnel and fiscal planning for blood operations. Participate in, and analyze, budget preparation for the Blood Center. Authorize expenditures of approved funds. Recommend reallocation of funds based on spending trends and projections and program requirements. Qualifications: Bachelor's degree in Business Administration, public health or related field required. Minimum of five years blood bank or health care experience required. For a complete job description and to apply please visit https://www.stanfordhealthcarecareers.com/, and reference job #52722.

Director of Donor Services. Houchin Community Blood Bank (HCBB) is seeking a highly motivated individual who is responsible for management and operations of Donor Services department. The department is responsible for blood donor registration, eligibility screening, and phlebotomy for whole blood and apheresis donations. Director will lead a team of 30 plus staff at two blood donation centers in Bakersfield and blood drives covering over 8,000 square miles of Kern County. Director will coordinate with HCBB's Quality and Process Improvement department to ensure that Donor Services operations are in compliance with regulations set by the Food and Drug Administration, State of California, and American Association of Blood Banks. Director will coordinate closely with HCBBs Community Relations team who are responsible for organizing mobile blood drives and events. This ideal candidate will have a bachelor's degree in science, medicine, or operations management related fields. Ten plus years supervisory experience in operations management, preferably blood bank or hospital setting. Exceptional customer service, multi-task, work independently, excellent written and oral communication skills, extremely organized, and creatively and effectively solve problems. Send resumes to careers@hcbb.com.



Director, Blood Collection Operations (The Community Blood Center, Appleton, WI). Are you looking for a meaningful career creating a culture of highly engaged staff, collaborating to provide customers with exceptional service? Our organization is looking for a dynamic leader for our blood collection team. You will coach and engage a team of 60 staff, create and implement systems and processes to provide outstanding service and be part of a team of professionals united in the mission of Connecting Lives | Sharing Life. Responsible for oversight of the activities of Collections 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. Responsible for accomplishment of key department and organizational objectives including assigned goals, operational productivity targets, compliance measures and staff engagement metrics. Ensure compliance with quality control functions, documents and industry regulations. Develop plans to maintain or adjust operations as needed based on financial forecasting. Requires a bachelor's degree and 10 years management experience, ideally with increasing levels of responsibility. Medical background or blood center experience desired. Excellent leadership, staff development and team building skills. High level of data analysis skills. How apply: https://www.communito tyblood.org/careers.

Medical Apheresis RN/Nurse (Houston, Texas). Gulf Coast Regional Blood Center is looking for a Medical Apheresis RN/Nurse for its newly expanded, state-of-theart apheresis center. This person is responsible for patient/donor care during apheresis procedures and must be able to apply the nursing process with patients and donors. Duties include assisting in the development of new procedures, performing required equipment maintenance, evaluating and maintaining technical procedures, communicating with physicians regarding patient status, remaining current on national standards and trends in the area of apheresis and making appropriate suggestions as to necessary changes or updates, maintaining all records required by AABB, FDA and other accrediting agency or vendor standards, participating in management and coordination of clinical research studies if necessary. Qualifications for this position are: a graduate degree from an accredited School of Professional Nursing, a current RN license, three years of recent direct patient care nursing experience (preferably in an acute-care setting), demonstrated proficiency in peripheral intravenous access, certification in Basic Life Support or ACLS (Advanced Cardiovascular Life Support). For more information or to apply, click here. Contact name, address and telephone number: Tracy Reynolds Talent Acquisition Manager, 1400 La Concha Lane, Houston, Texas 77054-1802; Phone: (713) 791-6395.

#### POSITIONS (continued from page 11)

Medical Technologist II - San Francisco, CA (Reg:191052). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Founded in 1943, Vitalant is one of the nation's oldest and largest nonprofit transfusion medicine organizations. Bachelor's degree in a chemical, physical, biological, medical technology or clinical laboratory science required. Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. CA Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. SBB preferred. State licensure (as required by regulations). Three years' experience in a clinical laboratory setting required or SBB. Experience in developing and conducting formal training preferred. Please click here to apply.

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, earlyor mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. Service and teaching responsibilities will be shared with three other full and parttime staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ233, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Quality Assurance Director (Oklahoma City, OK). The Oklahoma Blood Institute, the nation's fifth largest blood center and Oklahoma's largest Bio-Tech company, has an immediate opening for a director for our quality assurance systems. This position will provide direct supervision for quality systems consultants, promote a quality culture within the organization and ensure that policies, procedures, processes, work instructions and training programs comply with industry standards and regulatory requirements. The position also ensures that the firm's quality plan and objectives are implemented throughout each phase of blood/tissue manufacturing and clinical services. Qualifications: Requires a Bachelor of



Science degree in medical technology or related field and eligible for registration with the ASCP; minimum of five years' experience in managing quality systems; strong written and verbal communication skills. Salary Range: Competitive salary, relocation package is possible, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, tuition reimbursement and holiday pay. How to Apply: http://obi.org/careers/.

Quality & Regulatory Affairs Specialist. The Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the general supervision of the Director of Quality and Regulatory Affairs, this position will perform the quality and regulatory affairs duties and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, validations, and assist with development, as necessary. Develop, perform and report departmental, system audits, and safety inspections. Perform Good Manufacturing Practice (GMP) and safety training, trend analysis of events and quality indicators, root cause analysis, process improvement, corrective and preventive actions; maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports, when required. Core Duties include: Review validation plans, procedures, training documents, PDIF records, product and equipment QC for regulatory compliance and assist with development and training as necessary. Develop, perform and generate departmental reports and system audits. Develop, revise, institutional QRA SOPs and training. Perform GMP, QRA and safety training. Perform trend analysis of events, complaints, and quality indicators with subsequent performance of root cause analysis, and process improvement. For comjob plete description and to apply, visit www.stanfordhealthcarecareers.com and reference job # 51343.

**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

(continued on page 13)

#### <u>POSITIONS</u> (continued from page 12)

free medical coverage with a competitive benefit 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 <u>www.oneblood.org</u> to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.

