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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2019 #30 **September 6, 2019**

INSIDE:

New Computer Model Could Provide Insights into Medicines that Prevent the Development of Sickled Cells

An abnormality in hemoglobin, the oxygen-transporting protein in red blood cells (RBC), causes sickle cell disease (SCD). Under certain conditions, this abnormality leads RBCs to assume crescent shapes and become more "sticky," causing them to become stuck in the small blood vessels and interrupt healthy blood flow. This process damages the organs and causes severe pain. People with SCD have two copies of an altered gene that produces sickle hemoglobin instead of normal adult hemoglobin. A recent paper published in *Science Advances* describes the potential for a new computer model to identify medicines that may prove valuable in preventing the development of sickled cells. "[T]he proposed kinetic model is capable of predicting RBC sickling based on patient- and organ-specific data and thus can be used to guide the prognosis for SCD patients with various degrees of severity." Researchers took existing computer models and combined them into a single model that completes the sickling process. "There are currently only two drugs approved by the [U.S. Food and Drug Administration] for treating sickle cell disease, and they don't work for everyone," said Lu Lu, a Ph.D. student in the Division of Applied Mathematics at Brown and the study's co-lead author in a news release. "We wanted to build a model that considers the entire sickling process and could be used to quickly and inexpensively pre-screen new drug candidates."

The new model not only allows individuals to identify specific organs for simulation, but also inputs the "degree of severity of SCD" for individual patients. "To test the potential effectiveness of drugs, the model allows users to input the mode of action by which a drug is presumed to work, information is often gathered during preliminary lab studies," noted the release. Researchers were able to validate the model by "reproducing" previous outcomes both in the lab and in individuals.

"Sometimes a drug can be designed to work on one parameter but ends up having a different effect on other parameters," said the paper's Senior Author George Karniadakis, a professor of applied mathematics at Brown. "The model can tell if those effects are synergistic or whether they may negate each other. So the model can give us an idea of the overall effect of the drug. Clinical drug trials are very expensive and the vast majority of them are unsuccessful. The hope here is that we can do in silico trials to screen potential medications before proceeding to a clinical trial."

(Source: Brown University News Release, 8/22/19)

Citation: Lu, L., Li, Z., Li, H., Li, X. Vekilov, P. and Em Karniadakis, G. Quantitative prediction of erythrocyte sickling for the development of advanced sickle cell therapies. *Science Advances*. 2019. Doi: 10.1126/sciadv.aax3905. ♦

REGULATORY NEWS

A report from the *Washington Post* this week disclosed that current Acting FDA Commissioner Norman Sharpless, MD received the endorsement of four former FDA commissioners to be appointed Commissioner of the agency. The letter stated that he "has gained the respect of the agency staff and a broad spectrum of the public in support of the FDA's mission." Former commissioners Mark McClellan, MD, PhD, Andrew von Eschenbach, MD, Robert Califf, MD, and Margaret Hamburg, MD signed the letter that was sent to both President Trump and U.S. Department of Health and Human Services (HHS) Secretary Alex Azar. Acting Commissioner Sharpless replaced Scott Gottlieb, MD who resigned earlier this year. Dr. Gottlieb also supports the appoint of Acting Commissioner Sharpless according to the *Washington Post*, which reported that the Administration is also considering MD Anderson Cancer Center's Stephen Hahn, MD, a chief medical executive, and Alexa Boer Kimball, MD president and chief executive officer of the Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center in Boston.

(Source: *Washington Post*, MD Anderson cancer doctor emerges as a top candidate for FDA job, 9/5/19)

The U.S. Food and Drug Administration (FDA) issued a warning letter to California-based Stemell, Inc. for the manufacturing and distribution of unapproved cord blood-derived products on August 28th. The agency noted Stemell had deviated from current good tissue practice (CGTP) and current good manufacturing practice (CGMP) requirements that could potentially compromise patient safety. The products in question were deemed by the agency to be subject to both drugs and biologics regulations. Stemell, Inc. did not have a biologics license application, which is needed to market the product in a "lawful" manner, and the products were being used in humans without an investigational new drug application in place.

"We know that there are manufacturers and clinics across the country that manufacture or market violative stem cell products to patients, claiming that they don't fall under the regulatory provisions for drugs and biological products. The FDA has consistently stated that this is not true," said Acting FDA Commissioner Ned Sharpless, MD in an agency news release. "This company failed to take appropriate measures to protect patient safety. The FDA will be increasing our oversight related to cell-based regenerative medicine as part of our comprehensive plan to promote beneficial innovation while protecting patients. Those who are manufacturing or marketing unapproved, potentially unsafe products must understand that there's a clear line between appropriate development of these products and those practices that sidestep important statutory and regulatory controls that are in place to protect patients." An inspection revealed:

- deficient donor eligibility practices;
- unvalidated manufacturing processes;
- deficient environmental monitoring; and
- inadequate aseptic processes.

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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 (continued from page 2)

"The FDA remains highly committed to facilitating the development and availability of safe and effective cellular therapy products. However, we will not hesitate to take appropriate action to protect people from being harmed by products with potential significant safety concerns," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research (CBER), in the news release. "In addition to the warning letter issued today, we sent another 20 letters to manufacturers and healthcare providers across the country who may be offering unapproved stem cell products, reiterating the FDA's compliance and enforcement policy. We remain very concerned that countless clinics across the country continue to market violative stem cell products to patients that have not been appropriately evaluated for safety or efficacy."

Stemell, Inc. has 15 days to respond to the letter outlining corrective actions.

(Sources: FDA News Release, 9/3/19; FDA Warning Letter, 8/26/19)

WORD IN WASHINGTON

Rep. Mike Gallagher (R-Wis.) and members of his staff recently visited The Community Blood Center (Appleton) to donate blood, while Congress was on recess in August. A longtime advocate for both the blood center and blood donation, Rep. Gallagher took time to chat with donors and enjoy an early look at facility renovations, while learning about the challenges facing blood centers across the country. America's Blood Centers encourages all member blood centers to invite members of Congress and their staff to visit your blood center when they are in their home districts and states. Also, please remember to join us in March as we head to Capitol Hill to advocate on behalf of independent community blood centers during the ABC Annual Meeting.

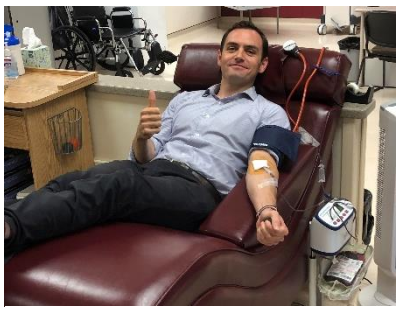

Photo courtesy of The Community Blood Center: Rep. Mike Gallagher makes a whole blood donation on August 26th.

(Source: The Community Blood Center (Appleton) Announcement, 9/3/19)

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 here!

Cold Platelets and Pathogen Reduction Technology

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Please note: America's Blood Centers welcomes regular contributions or briefs from guest authors for scientific/medical peer-reviewed 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 an article for potential publication please contact us here.

Conventional, room temperature (RT) storage of platelets (PLTs) limits shelf life to between four and seven days because of the risk of bacterial contamination and the decrease in PLT function. Cold-stored PLTs can offer a longer shelf-life, however an obstacle has been the significantly faster clearance from circulation compared to RT storage. This may be less relevant in acutely bleeding patients who require immediate hemostasis more than extended PLT circulation times. It limits their clinical applications. Cryopreservation can increase shelf life of PLTs to at least two years. Cryopreservation has a profound impact on PLT function *in vitro*, however, they retain hemostatic function particularly as procoagulants. Pathogen reduction technology (PRT) also impacts PLT function. For instance, the amotosalen photochemical treatment method significantly and irreversibly modifies PLT phospholipids within the PLT membrane. A shortening of the shelf life of PLT from seven to five days in Belgium, the authors' country of residence, spurred investigation to alternative storage methods of PRT treated PLTs.

Standard PLTs were prepared by pooling of six buffy coats in 65 percent additive solution derived from whole blood donations. These products were compared to PRT using amotosalen photochemical treatment when stored at room (RT, 220C), cold (40C, n = 6), or cryopreservation (−800C, n = 8) using 6 percent dimethyl sulfoxide (DMSO). The impact of alternative storage methods on both arms was studied by flow cytometry, light transmittance aggregometry, and hemostasis in collagen-coated microfluidic flow chambers. The study found that platelet aggregation of cold-stored PRT PLTs was 44 percent + 11 percent compared to 57 percent + 14 percent for cold stored standard PLTs and 58 percent + 21 percent for RT-stored PRT PLTs. Integrin activation of cold-stored PRT PLTs was significantly lower for PRT PLTs stored at 40C (53 percent + 9 percent) compared to RT (69 percent + 13 percent, p=0.0124). The decrease was smaller for standard PLTs stored at stored at 40C (77 percent + 6 percent) compared to RT (85 percent + 4 percent, p = 0.3429). Comparable results were found for PLT aggregation with collagen. No visible aggregates were detected in any PLTs over the course of the study. Coagulation of cold-stored PRT PLTs started faster under flow (836 + 140 sec) compared to cold-stored standard PLTs (960 + 192 sec) and RT-stored PRT PLTs (1134 + 220 sec). Fibrin formation rate under flow was also highest for cold-stored PRT PLTs. This was in line with thrombin generation in static conditions because cold-stored PRT PLTs generated 297 + 47 nmol/L thrombin compared to 159 + 33 nmol/L for cold-stored standard PLTs and 83 + 25 nmol/L for PRT PLTs stored at RT. PLT aggregation of cryopreserved PRT PLTs (23 percent + 10 percent) was not significantly different from cryopreserved standard PLTs (25 percent+8 percent).

The authors conclude that cold storage of PRT affected PLTs in activation and aggregation studies but promoted coagulation in static and flow conditions *in vitro*. They emphasized that investigation of PLT circulation times and clinical efficacy are essential before considering implementation of these PRT cold and cryopreserved PLTs into routine blood banking practice.

Citations: Six, K.R., Devloo, R., Compernolle, V., *et al*. Impact of cold storage on platelets treated with Intercept pathogen inactivation. *Transfusion*. 2019.; Doi: 10.1111/trf.15398. ♦

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 newsletter@americasblood.org 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.

Direct Anticoagulants – The Cost of Reversal

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Please note: America's Blood Centers welcomes regular contributions or briefs from guest authors for scientific/medical peer-reviewed 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 an article for potential publication please contact us here.

The daily cost of warfarin is about $7, while the daily cost of the direct anticoagulants (DOACs) is around $16 per day. Of interest is the cost of the reversal agents. For warfarin it is either four-factor prothrombin complex concentrate or many doses of plasma, while for the DOACs it can approach $50,000.

Mech	Name	Approved	Cost	Reversal agent	Reversal cost
Vit K Ant	Warfarin (Coumadin)	1954	$7 qd ($2,500)	Kcentra	$5,000
DTI	Dabigatran (Pradaxa)	2010	$17 bid ($6,200)	Praxbind	$3,500 *
Xa inhib	Rivaroxaban (Xarelto)	2011	$18 qd ($6,600)	Andexxa	$49,500 *
Xa inhib	Apixaban (Eliquis)	2012	$16 bid ($5,800)	Andexxa	$49,500 *
Xa inhib	Edoxaban (Savaysa)	2015	$13 qd ($4,700)	[PER977]	?

Courtesy of The Trauma Pro

**Clinical effectiveness not supported by current studies.*

Citation: Barnes, G.D., Ageno, W., Ansell, J., *et al*. Recommendation on the nomenclature for oral anti-coagulants: communication from the SSC of the ISTH. *J Thromb Haemost* 2015. Doi: 10.1111/jth.12969.

(Source: The Trauma Pro, What should we call them? NOAC VS DOAC, 8/29/19)

INFECTIOUS DISEASE UPDATES

EBOLA

The World Health Organization (WHO) has asked for all partners to increase their presence and help "full force" in their response efforts to the Ebola outbreak in the Democratic Republic of the Congo (DRC). "Our commitment to the people of the Democratic Republic of the Congo is that we will work alongside them to stop the Ebola outbreak," said WHO Director-General Tedros Adhanom Ghebreyesus, PhD in a WHO news release. "Our commitment also means strengthening health systems to give them all the other things they need. Building strong systems is what will protect people, communities and the world." The outbreak continues to spread to new areas in the DRC. The Centers for Disease Control and Prevention (CDC) issued a statement Director Robert R. Redfield, MD, "[f]ar too many lives have been lost in this Ebola outbreak. The DRC, U.S. government, and international partners are working hard to overcome the significant challenges to stopping the spread of this disease in DRC. CDC is prepared for a long-term public health response in DRC and its neighboring countries, and we agree with our World Health Organization colleagues about the need for a change in the response to bring this outbreak to an end." 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).

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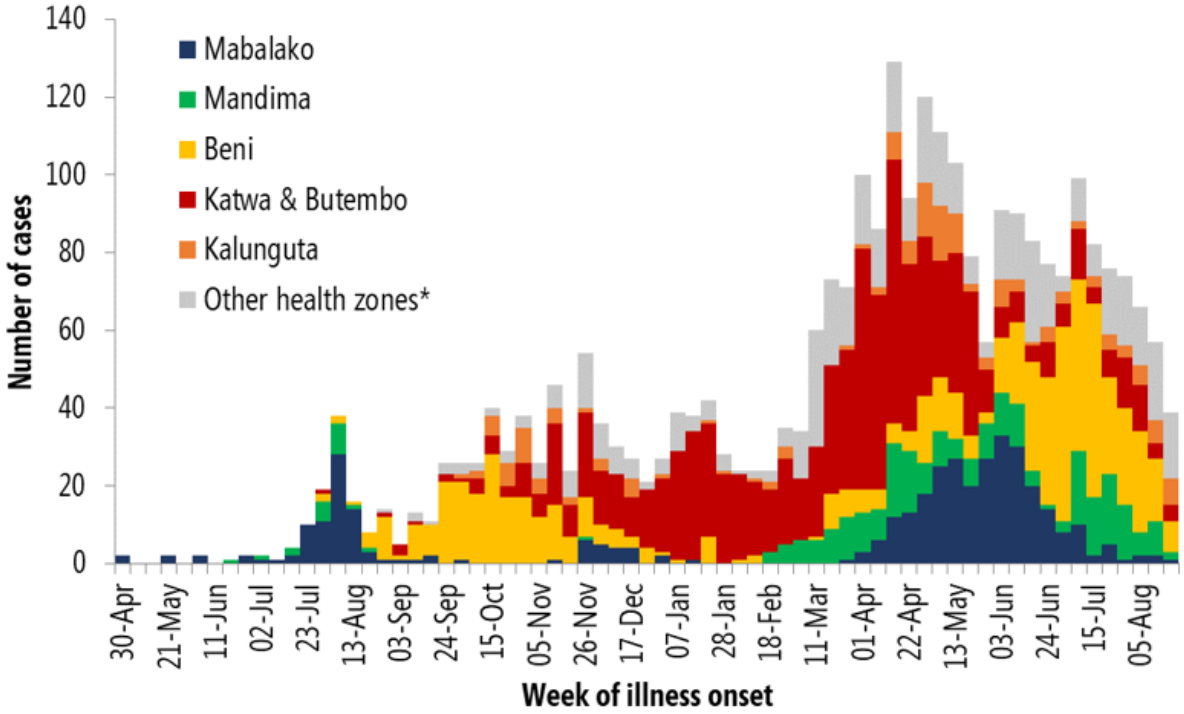
INFECTIOUS DISEASE UPDATES (continued from page 5)

As of August 27th, there were 2,892 confirmed cases with 1,998 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.*

(Sources: Ebola virus disease – Democratic Republic of the Congo, 8/29/19; WHO News Release, 8/29/19; CDC Statement, 8/29/19) ♦

IN MEMORIAM

Dennis W. Mestrich, passed away on September 4th. He served as the chief executive officer of Heartland Blood Centers from 1997-2014. Mr. Mestrich was known to lead by example often assisting in setting up blood drives, greeting donors, and serving refreshments. He played an important role in forming an alliance with the then BloodCenter of Wisconsin that later became known as Versiti. After retiring from the blood center, the board of directors established the Dennis Mestrich Scholarship Fund to help local students and blood center employees with their educations. His career spanned 44 years and also included positions in healthcare administration positions at St. Anthony Medical Center and Children's Memorial Hospital. A funeral will be held on September 7th in St. John, Ind. In lieu of flowers, contributions can be made in his honor to the Joseph Maley Foundation.

(Source: Dennis Mestrich Obituary, 9/5/19) ♦

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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.

ABC Member Feedback Sought in Iron Deficiency Mitigation Survey

As member blood centers address the changing AABB Standards for donor iron depletion mitigation, programs are being developed to:

- enhance educational materials;
- facilitate access to iron; and
- test donors' ferritin levels and/or increase inter-donation intervals.

ABC seeks to better characterize what members are/will be doing in 2019 along with details about deferral periods and target donor groups. We are asking member blood centers to please take a few minutes to answer some high-level questions about what your center is doing now or will begin doing by year's end by completing a survey on Iron Deficiency Mitigation Strategy conducted by Drs. Ralph Vassallo, Samantha Ngamsuntikul and Suchi Pandi. The results will be used during an AABB webinar taking place on September 11th, so a quick turnaround is requested. Any additional submissions will be added in for another presentation at the AABB Annual Meeting in October. The survey is blinded, and no identifying information will be collected that would reveal respondents or their organizations. Please note that only one survey response for each license under which your center operates is sought. A link to the survey is available to ABC members in MCN 19-064.

(Source: MCN 19-064, 9/3/19)

ABC Seeks BPAC Nominations and Feedback on Committee Structure

America's Blood Centers (ABC) is seeking member input on the U.S. Food and Drug Administration's Blood Products Advisory Committee (BPAC). Specifically, we are looking for member suggestions on both the committee structure as well as the names of individuals you believe ABC should consider nominating for both the industry representative(s) and general committee positions. Please send any feedback by September 18th to ABC CEO Kate Fry, MBA. Additional details are available to ABC members in MCN 19-059.

(Source: MCN 19-059, 8/22/19)

August SMT Journal Club Webinar Recording Available

A recording of the ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar from August 19th is available to ABC members. The webinar explored:

- Financial impact of alternative approaches to reduce bacterial contamination of platelet transfusions (*Transfusion*);
- Response to random apheresis platelets versus HLA-selected platelets versus pooled platelets in HLA-sensitized patients (*Transfusion*); and
- Platelets stored in whole blood at 4 C: in vivo posttransfusion platelet recoveries and survivals and in vitro hemostatic function (*Transfusion*).

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INSIDE ABC (continued from page 7)

Additional details including the presentations and a playback of the webinar are available to ABC members in MCN 19-060.

(Source: MCN 19-060, 8/26/19)

ADRP Webinar to Explore Vasovagal Donor Reactions in Teens

Register today for ADRP's webinar entitled "Understanding, Managing, and Preventing Vasovagal Blood Donor Reactions in Teenagers." This webinar will take place on Thursday, September 12th at 2 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)

MEMBER NEWS

Oklahoma Blood Institute recently held a groundbreaking ceremony for their Ardmore location. The facility's construction is expected to be completed by May 2020. "The people who are going to be coming here are going to be dedicated to giving," said Oklahoma Blood Institute President and CEO John Armitage, MD according to *The Daily Ardmoreite* as he addressed the audience at the ceremony. "This facility is going to be an amazing tribute to that human need to give, and we're here celebrating the creation of this facility dedicated to that wonderful impulse to help others. Anybody who has seen donors or been around donors knows that the act of giving blood is uplifting. It's a spiritual moment for many when they realize they're getting in touch with what they are intended to do. The good that is inside them literally comes out and is shared with someone else."

Photo courtesy of The Daily Ardmoreite.

(Source: *The Daily Ardmoreite*, The gift that keeps on giving: Oklahoma Blood Institute breaks ground on new facility, 8/30/19)

GLOBAL NEWS

The World Health Organization (WHO) announced approval of phase one in the formation of a global registry that will track human genome editing research. A committee of 18 experts made a formal recommendation to the organization, which will use the International Clinical Trials Registry Platform and include both somatic and germline clinical trials. "Since our last meeting, some scientists have announced their wish to edit the genome of embryos and bring them to term," said WHO Director-General Tedros Adhanom Ghebreyesus, PhD in a statement from the organization. "This illustrates how important

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GLOBAL NEWS (continued from page 8)

our work is, and how urgent. New genome editing technologies hold great promise and hope for those who suffer from diseases we once thought untreatable. But some uses of these technologies also pose unique and unprecedented challenges – ethical, social, regulatory and technical." The WHO created the committee to establish guidelines for human gene editing late last year following the controversy surrounding a scientist in China who edited the genes of human embryos in hopes of making them HIV-resistant resulting in the births of gene-edited twins. The committee will continue to formulate the human genome editing framework, considering stakeholder feedback from both online consultations and face-to-face meetings, and urged relevant research and development initiatives to register their trials.

(Source: WHO Statement, 8/29/19)

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 calendar of events 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!

ABC 2020 Meetings & Workshops

Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9th-11th	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 calendar on ABC's Member Site.

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

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 (lmaundy@americasblood.org) 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 here.

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

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 here.

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CALENDAR (continued from page 9)

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

Oct. 15-16. **Biomedical Advanced Research and Development Authority Industry Day 2019, Washington, D.C.** More details available here.

Nov. 12-14. **U.S. Food and Drug Administration Center for Drug Evaluation and Research Small Business and Industry Assistance Clinical Investigator Training Course, College Park, Md.** 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 here.

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: lmaundy@americasblood.org.

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 https://www.stanfordhealthcarecareers.com/ and reference job #53086.

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.

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POSITIONS (continued from page 10)

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.

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 complete job 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 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 www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.

Director, Marketing and Public Relations. Blood Assurance is currently seeking a Director of Marketing and Public Relations. As a member of the operations team, this role is responsible for strategically planning, communicating and executing Blood Assurance marketing and public relations efforts in multiple markets. Develops organizational strategies and executes departmental management plans that support all efforts of the organization as it pertains to marketing and communication needs. Prepares and manages marketing budgets, represents BA leadership internally and externally, and partners with all management levels to meet organizational Key Performance Indicators. Advanced leadership and management skills; advanced decision-making, judgment, negotiation and communications skills with ability to effectively collaborate, develop productive teams, manage complex responsibilities, plan and execute strategic operational initiatives and impact organizational KPI results/success; requires flexibility, customer/client service focus, analytical, budgeting, reporting, computer and organizational skills. Bachelor's degree required; master's degree preferred in business field. At least five to10 years prior related sales, marketing, or public relations experience required. Qualified candidates are encouraged to submit

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an online employment application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.