

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2018 #15

May 4, 2018

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Please Note: The *ABC Newsletter* will not be published on May 11th due to the 2018 ADRP Annual Conference. We will resume regular publication on May 18th. Thank you for your continued interest.

FDA Updates to Zika Guidance

This week, the U.S. Food and Drug Administration published an <u>updated</u> Zika Guidance document regarding human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance is entitled "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika virus by Human Cells, Tissues, and Cellular and Tissue-Based Products." It updates the March 2016 guidance by: providing findings from more recent epidemiological studies including impact on public health, reporting new data that informs the potential for transmission of Zika virus (ZIKV), discussing the current status of availability of ZIKV tests, updating sexual contact risk factors, updating when an area is considered to have an increased risk for ZIKV transmission, and providing additional scientific references. The guidance identifies ZIKV as being associated with neurological complications such as Guillain-Barré syndrome and notes that mosquito-borne transmissions are "actively occurring" or have been "recently reported" in Puerto Rico, the U.S. Virgin Islands, American Samoa, and other specific areas in the continental U.S.

It recommends that living donors be considered ineligible for HCT/Ps donations if any of the following apply: the donor has been diagnosed with ZIKV infection in the past six months, resided in, or traveled to, an area with active ZIKV transmission in the past six months, or had sex in past six months with a male who was diagnosed with or resided/traveled to an area of active transmission. Birth mother donors of umbilical cord blood, placenta, or other gestational tissues should be considered ineligible if any of the following apply: they have been diagnosed with ZIKV infection at any point during the pregnancy, resided in, or traveled to an area with active ZIKV transmission at any point during the pregnancy, or had sex at any point during the pregnancy with a male who was diagnosed with or resided/traveled to an area of active transmission in the preceding six months. Cadaveric donors should be considered ineligible for HCT/Ps donations if the donor had a medical diagnosis of ZIKV infection in the previous 6 months.

Limited Instances for which use of HCT/Ps recovered from an ineligible donor is not prohibited, or in which a donor eligibility determination is not required, are described in 21 CFR 1271.65(b) and 21 CFR 1271.90 respectively.

(Source: FDA Guidance, 5/2/18) •





OUR SPACE Louis Katz, MD, Chief Medical Officer Whither Minipool (MP) Testing for Zika Virus?

In August 2016, as a public health imperative, the U.S. food and Drug Administration (FDA) mandated our emergent implementation of individual donation (ID) Zika nucleic acid testing (NAT) via direct final

guidance (i.e. issued for rapid implementation without a draft or comment periods). ABC and others in the blood community were unconvinced of its medical, epidemiologic, and risk-benefit justifications, and FDA committed to a timely review of the requirement using evidence accrued with testing and from the evolution of the epidemic. What have we learned, where will we go and when? FDA acted on that commitment in December 2017. After hearing data from a year of ID testing, the Blood Products Advisory Committee (BPAC) recommended (overwhelmingly) nationwide conversion to MP-NAT with local triggering back to ID-NAT using Zika activity criteria to be agreed upon—analogous to what evolved (and has worked) during 15 years of West Nile (WNV) testing. Follow-up of ID positive donors estimated that MP-Zika NAT might miss 6.8-10 percent of potentially infectious donations. Given that:

- 1. ...we accept risks of this magnitude for the greater transfusion safety threat, WNV;
- 2. transfusion-transmitted Zika is rarely recognized; and...
- ...when recognized has not been associated with recipient morbidity;
- 4. transfusion of the patients at greatest risk (in early and mid-pregnancy) is rare;
- 5. Zika has virtually disappeared in the Americas,
- 6. CDC estimates the cost of ID Zika screening at \$137,000,000 annually; and
- maintaining ID-Zika during unpredictable WNV seasons is burdensome. The sheer volume of testing places
 unneeded stress on testing laboratories, especially staffing and the throughput required when ID-WNV testing is triggered due to local donor infections.

The BPAC recommendation was welcomed and is a priority for the blood community—a salutary outcome. We went home happily to craft triggering criteria with relevant stakeholders, including FDA. ABC supported the recommendation of BPAC and has since worked with others in the blood community to prepare for the conversion to MP-NAT.

Can it be accomplished before the 2018 WNV season with another direct, final guidance? That would avoid the delays baked into the draft guidance/comment period/final guidance paradigm. Backing off ID-NAT, unlike its implementation, may not be an urgent public health intervention, but are there stakeholders, beyond those represented on BPAC, needing the opportunity to comment. As I understand the good guidance regulations, there are at least three circumstances permitting a direct final guidance: public health urgency; a legal requirement (e.g. statute or a court or executive order); and for guidance that both serves public health and establishes a less burdensome policy. Our contention that ID-Zika is burdensome is transparent.

ABC has urged FDA (and continues urging) to issue direct final guidance and apprised the FDA commissioner and the Assistant Secretary for Health (the country's designated blood safety officer) of our concerns. Time is short—we need movement immediately—as WNV season approaches and days count given many operational challenges in converting Zika testing to MP. We, including the test manufacturers, need to prepare for a positive outcome, he said, (perhaps with irrational exuberance).

Louis Katz, MD

ABC Chief Medical Officer

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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 thoughtleader in the advancement of evidence-based medical and scientific solutions related to health and safety.

America's Blood Centers

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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 2018 Meetings & Workshops at a Glance

Meeting/Workshop	Dates	Location	Hotel	More Information
Human Resources & Training/Development Workshop	May 8-10	Dallas, Texas	Fairmont Dallas	Register Here
ADRP Annual Conference	May 9-11	Dallas, Texas	Fairmont Dallas	Register here
Medical Directors Work- shop*	July 31 (precedes Summer Mtg)	Montreal, Québec*	Hotel Omni Mont- Royal, <u>\$234 CAD</u> /night	Registration Opening Soon
Summer Meeting*	August 1-2	Montreal, Québec*	Hotel Omni Mont- Royal, <u>\$234 CAD</u> /night	Registration Opening 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.

* Non-Canadian residents will require passport for travel

ABC Has Moved

ABC moved on April 1st. Our new mailing address is, 1717 K Street NW, Suite 900, Washington, DC 20006. All telephone numbers will remain the same except the fax line which changed to (202) 899-2621. Please update your records accordingly and contact <u>ABC Member Services</u> with any questions.



We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to 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.

ABC Newsletter -4- May 4, 2018

RESEARCH IN BRIEF

Fibrinogen concentrates and red blood cell (RBC) transfusions are compared to frozen plasma (FFP) with RBCs in trauma. Ninety Iranian patients with severe blunt trauma, deemed in need of RBC transfusion, with fibrinogen levels <200 mg/dL were randomized to receive fibrinogen concentrates, FFP, or control (RBCs only). Injury severity scores were statistically higher in the fibrinogen cohort compared to FFP and control (19.3 vs. 17.2 vs 19.0 respectively, p=.009). Recipients of fibrinogen had lower RBC and fluid requirements in the first 24 hours. Mortality, ICU admission, and length of stay were also statistically lower with fibrinogen. Sepsis was less frequent in fibrinogen and control groups compared to FFP. The study was not blinded and relatively small, so its generalizability is unknown.

Citation: Akbari, E., Safari, S., Hanmabadi, H. The effect of fibrinogen concentrate and fresh frozen plasma on the outcome of patients with acute traumatic coagulopathy: A quasi-experimental study. *American J. Emerg. Med.* 2018. https://doi.org/10.1016/j.ajem.2018.02.018.

Evidence-based medicine vs. machine learning. The mantra in transfusion medicine, at least since the Transfusion Requirements in Critical Care (TRICC) study, has been adherence to the precepts of evidencebased medicine (EBM), which involves the application of hypothesis driven, protocolized (e.g. randomized, controlled trials) experiments, conducted in defined populations, with prespecified outcome measures and appropriate statistical methods). During the last twenty or so years, an alternative or complementary approach known as machine learning (ML)has become technologically feasible. It uses advanced computational resources to process large data sets, from diverse sources, to find patterns among many unselected variables. An "Ideas and Opinions" submission to the *Annals of Internal Medicine* describes the putative advantages of ML vs. EBM, especially its ability to minimize cognitive biases and its use of already collected data that can mitigate some consent and ethical issues. Likewise, the limitations of ML are tabulated, including the incompleteness/inaccuracy of routine data collections which can reflect both available resources but also biases, its inability to adjudicate diagnostic disagreements, variable levels of accessibility of available datasets, and the limitations of natural language processing among many others. ML demonstrates associations, but cannot make causative inferences, in contrast to high-quality EBM. The manuscript concludes that "[D]espite their differences, EBM and ML can assist one another." ML seems best suited to hypothesis generation in support of designing trials that realize the promise of EBM. Given that transfusion is one of the most common procedures in modern medicine, the blood community can benefit from supporting, contributing to, and leveraging the large data sets available from electronic health records to promote more focused and effective transfusion practices.

Citation: Scott, I.A. Machine learning and evidence-based medicine. *Ann. Int. Med.* 2018. https://doi.org/10.7326/M18-0115.

The Resolving Infection in Neutropenia with Granulocytes (RING) study suggests alloimmunization to white cells (WBC) does not affect the clinical efficacy of granulocyte transfusions (GT). The RING study was intended to "answer" a decades old controversy about whether GT is clinically effective in infected, neutropenic patients, but failed to do so due to limited enrollment and other issues. The authors of the RING study have published a useful secondary analysis of the impact of both the prevalent and incident human leukocyte antigen (HLA) class I and II and granulocyte-specific antibodies. Their presence had "no demonstrable effect on any clinical aspect of granulocyte transfusion therapy." They conclude there is no need, in the population studied, for concern about recipient WBC alloimmunization. A reassuring conclusion for those within the blood community that continue to collect, process, and provide the product.

Citation: Price, T.H., McCullough, J., Strauss, R.G. *et al.* WBC alloimmunization: effects on the laboratory and clinical endpoints of therapeutic granulocyte transfusions. *Transfusion*. 2018. doi: 10.1111/trf.14551.



RESEARCH IN BRIEF (continued from page 4)

Japanese study explores the relationship of ABO blood type to mortality in trauma patients. This retrospective observational study included consecutive patients with complete data available who had injury severity scores (ISS) of >15. The primary outcome assessed was in-hospital, all-cause mortality. Secondary outcomes included cause-specific in-hospital mortality, ventilator-free days and U.S equivalent units of red blood cell (RBC) transfusion within 24 hours of admission to the emergency department. Of the potentially eligible patients, 901 out of 1,049 were included in the analysis. Thirty-two percent, 32 percent, 23 percent, and 13 percent were type O, A, B, and AB respectively. Baseline characteristics of the groups were similar, including ISS, except type O patients had slightly lower Revised Trauma Scores (RTS). In univariate analysis, in-hospital mortality was 28 percent in type O compared to 11.5 for non-type O (p<.001). Deaths due to exsanguination, traumatic brain injury, and other causes were likewise significantly higher in the type O cohort. Ventilator-free days were fewer for type O. The number of RBC units administered were similar in the two groups. Multivariate analysis to control for age, ISS, and RTS gave similar results. The authors are appropriately conservative in their interpretation of the study, and caution against generalization due to the study size, its retrospective design, and its restriction to Japanese patients. They recognize that the explanation for the observed differences is obscure and speculate about the role of the well-recognized lower levels of factor VIII and von Willebrand factor in O patients to suggest further studies.

Citation: Takayama, W., Endo, A., Koguchi, H. *et al.* The impact of blood type O on mortality of severe trauma patients: a retrospective observational study. *Critical Care*. 2018. https://doi.org/10.1186/s13054-018-2022-0.

FDA scientists explore the chemistry of hemoglobin-based oxygen carriers (HBOCs) to characterize those tested in human in comparison to their toxicity profiles. HBOCs are a diverse group of chemical entities intended to provide an alternative to red cell transfusion in a variety of clinical settings. Those in clinical development have mainly foundered prior to clearance from the U.S. Food and Drug Administration (FDA) due to a variety of toxicities. Investigators at the Center for Biologics Evaluation and Research (CBER) have published their evaluation of oxygen binding, ligand binding and oxidation kinetics, heme release, interactions with nitric oxide, and other parameters to better understand their function and provide a dataset that might allow rational selection of agents with optimal properties to further develop safe and effective red cell substitutes.

Citations: Meng, F., Kassa, T., Jana, S. *et al.* Comprehensive biochemical and biophysical characterization of hemoglobin-based oxygen carrier therapeutics: all HBOCs are not created equally. *Bioconjugate Chemistry*. 2018. https://doi.org/10.1021/acs.bioconjchem.8b00093. ◆

RECENT REVIEWS

A primer on chronic infection with hepatitis B virus (HBV). Blood center physicians and donor counselors provide much information to donors with reactive tests for HBV. A review in *JAMA* covers the epidemiology, viral life cycle and natural history, clinical sequelae, and diagnostic testing patterns seen in chronic HBV. It also discusses current treatment regimens and the impact on outcomes using contemporary antiviral options.

Citation: Tang, L.S., Covert, E., Wilson, E., and Kottill, S. Chronic hepatitis B infection, a review. *JAMA*. 2018. doi:10.1001/jama.2018.3795. ♦

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REGULATORY NEWS

The Centers for Disease Control and Prevention (CDC) reported that flea, tick, mosquito-borne illnesses have tripled in the past 13 years. "The data show that we're seeing a steady increase and spread of tickborne diseases, and an accelerating trend of mosquito-borne diseases introduced from other parts of the world," said Lyle Petersen, MD, MPH, director of the Division of Vector-Borne Diseases in the CDC's National Center for Emerging and Zoonotic Infectious Diseases. "We need to support state and local health agencies responsible for detecting and responding to these diseases and controlling the mosquitoes, ticks, and fleas that spread them." More than 642,000 cases of disease occurred in the U.S. from 2004–2016, with more than 60 percent of the reported cases being tick-borne diseases. "Zika, West Nile, Lyme, and chikungunya—a growing list of diseases caused by the bite of an infected mosquito, tick, or flea—have confronted the U.S. in recent years, making a lot of people sick. And we don't know what will threaten Americans next," said CDC Director Robert R. Redfield, MD in an agency news release. "Our Nation's first lines of defense are state and local health departments and vector control organizations, and we must continue to enhance our investment in their ability to fight against these diseases." To date babesiosis and anaplasmosis transmitted by ticks, and West Nile, from mosquitoes, have been relevant to transfusion medicine.

(CDC News Release, 5/1/18)

The National Institutes of Health (NIH) has officially announced May 6th as the enrollment date for the All of Us Research Program. ABC members BloodCenter of Wisconsin and San Diego Blood Bank were among the pilot participants. San Diego Blood Bank will act as a community-based clinic site for direct volunteers and providing collection services for healthcare provider organization participants. "For over 60 years, San Diego Blood Bank has worked to ensure local hospitals and patient needs are met. All of Us is a wonderful opportunity for us to continue to lead the way to better health and wellness for our community and beyond," said David Wellis, CEO of the San Diego Blood Bank in blood center news release. "We are pleased to expand the scope of our efforts in alignment with our mission to save lives today and improve life tomorrow." The All of Us began in 2016 with \$130 million earmarked to NIH with the stated goal of bringing precision medicine to all in the U.S. by recruiting and examining health data from 1 million individuals to assist with disease prevention and treatment. "All of Us is an ambitious project that has the potential to revolutionize how we study disease and medicine," said Health and Human Services Secretary Alex Azar according to an NIH news release. "NIH's unprecedented effort will lay the scientific foundation for a new era of personalized, highly effective health care. We look forward to working with people of all backgrounds to take this major step forward for our nation's health." Enrollment is open to individuals age 18 or older and will feature community events in seven cities, along with an online event. "The All of Us Research Program is an opportunity for individuals from all walks of life to be represented in research and pioneer the next era of medicine," said NIH Director Francis S. Collins, MD, PhD. "The time is now to transform how we conduct research—with participants as partners—to shed new light on how to stay healthy and manage disease in more personalized ways. This is what we can accomplish through All of Us."

(Sources: NIH News Release, 5/1/18; San Diego Blood Bank News Release, 5/1/18)

The U.S. Food and Drug Administration (FDA) published a draft working model of the software precertification program. The model outlines processes for "the precertification of companies, the premarket review process, and postmarket surveillance" of their software as medical devices to both streamline the review process and hasten their availability within the market. "Given the benefits from empowering consumers, we believe the FDA must encourage the development of tools that can help people be more informed about their health," said FDA Commissioner Scott Gottlieb, MD in an agency announcement. The model is a part of the agency's Digital Health Innovation Action Plan.

(Source: FDA Announcement, 4/26/18) •







WORD IN WASHINGTON

Members of the Senate Health, Education, Labor, and Pensions (HELP) Committee announced a bipartisan discussion draft to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). The draft Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAI) bill contains a section that would require the office of the Assistant Secretary for Preparedness and Response (ASPR), in consultation with other Federal agencies, to develop guidelines for regional systems of hospitals, healthcare facilities, and public health facilities with varying levels of capabilities to treat patients affected by chemical, biological, radiological, or nuclear (CBRN) threats, including emerging infectious diseases, and improve medical surge capabilities and capacity. Notably, the draft bill also requires ASPR to consult and engage with "appropriate healthcare providers and professionals" including "blood banks." Sens. Lamar Alexander (R-Tenn.), Richard Burr (R-N.C.), Robert Casey (D-Penn.), and Patty Murray (D-Wash.) released the draft that aims to improve the preparedness and response tools to pandemics and bioterrorism within the PAHPA framework. "After a deadly hurricane season, Americans want to know we are better prepared to face public health threats - whether that's natural disasters, flu outbreaks, or bioterror attacks," said Senator Alexander in a committee news release. "This bipartisan proposal, led by Senators Burr and Casey, takes the next step toward ensuring we are able to protect Americans from 21st century threats by strengthening our capabilities to be prepared for and able to respond to the full range of public health threats." America's Blood Centers, AABB, and the American Red Cross submitted joint comments to the committee. "Protecting our families against the health threats of tomorrow means taking steps to be prepared today, which is why this legislation is so important," said Senator Murray. "I'm glad we could put together a bipartisan bill that reinforces our vigilance against emerging disease outbreaks, pandemics, and other threats—including by bolstering critical work to combat antimicrobial resistance, and focusing on the diverse needs of everyone jeopardized by a public health threat. I will keep working with my colleagues to build on this discussion draft and get this bill signed into law, to make sure we are always preparing for crises with foresight rather than simply learning from tragedies in hindsight."

(Source: Senate HELP Committee News Release, 4/26/18)



56 SUMMER MEETING July 30 – August 2, 2018 Montréal, QC

2018 SUMMER MEETING SCHEDULE

Monday, July 30 ABC Board Meeting
Tuesday, July 31 Medical Directors Workshop

Wednesday, August 1 SMT Forum Business Forum

Host Event by Héma-Québec (off-site)

Thursday, August 2 ABC Members Meeting

All of us at Héma-Québec look forward to hosting our ABC colleagues, family and friends at the 2018 ABC Summer Meeting in Montréal. A striking union of European charm and North American attitude, Montréal seduces visitors with a harmonious pairing of the historic and the new, from exquisite architecture to fine dining. We hope you can take the opportunity to see what Montréal has to offer and discover its many colorful and vibrant neighborhoods which overflow with markets, museums, boutiques, restaurants and local cafés—diverse expressions of the inhabitants "joie de vivre."



Luc Vermeersch,
 Acting Chief Executive Officer
 and Vice-President, Finance
 and Strategic Project Management

Hotel Information

Hotel Omni Mont-Royal Hotel room rate: \$234 (CAD) + tax

For registration information, visit http://bit.ly/abc_summer_meeting.

For sponsorship opportunities, please contact Leslie Maundy at Imaundy@americasblood.org









MEMBER NEWS



Michael Lees (right), Terumo BCT, Vice President, Commercial, North America, presents check to John Armitage, MD, CEO of Oklahoma Blood Institute and Chair of the Global Blood Fund.

The Global Blood Fund (GBF) recently received a \$25,000 contribution from Terumo BCT to assist with efforts to improve transfusion practices and safety in emergent nations. "We are very grateful to Terumo BCT for its leadership in supporting better transfusion care for the majority of people across the globe who cannot be assured that blood will be available for them when it is needed," said Oklahoma Blood Institute CEO and Chair of GBF John Armitage, MD in a news release. "This gift will help fight the annual deaths of hundreds of thousands of women hemorrhaging during childbirth

and young children under age five succumbing to malaria, injuries, other afflictions." GBF is a 501(c)(3) charity established by Oklahoma Blood Institute in 2008 that has supported more than 40 global transfusion-related initiatives in Africa, Latin America, and

Asia. "Terumo BCT and the Global Blood Fund share a commitment to serving patients by unlocking the potential of blood across the globe," said Michael Lees, Terumo BCT Vice President of Commercial in North America. "We are honored to support GBF's work serving those patients most in need, in parts of the world that are still developing their blood transfusion capabilities across Africa, Latin America and Asia. Terumo BCT is proud to support GBF's work to directly improve patient's access to safe blood around the world."

(Source: GBF News Release, 5/3/18)



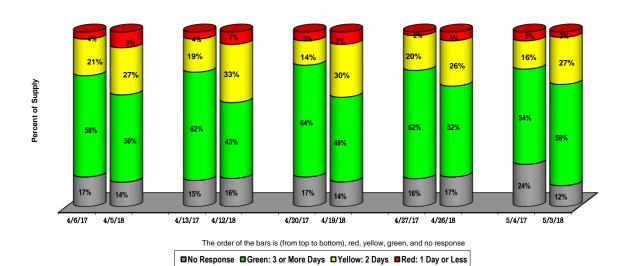
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COMPANY NEWS

Terumo BCT has announced the enrollment of the first person in the U.S. clinical trial of the Mirasol® System. The PRAISE study is a randomized, crossover trial that will assess the safety and efficacy of Mirasol® RBCs in chronically transfused thalassemia patients. "Terumo BCT is committed to advancing a safe global blood supply, which includes bringing Mirasol® to the U.S. market," said Palani Palaniappan, executive vice president of Innovation and Development at Terumo BCT according to the news release. "A safe blood supply is central to our mission of preparedness and security for the entire nation," said Army Col. Audra Taylor, director of the Army Blood Program. "FDA approval of Mirasol® will further enhance the safety of blood transfused to our Warfighters in combat as well as U.S. civilians."

(Source: Terumo BCT News Release, 4/30/18)

STOPLIGHT®: Status of the ABC Blood Supply



Daily updates are available at:

www.AmericasBlood.org

GLOBAL NEWS

Facebook recently announced the launch of new features to preexisting tools for blood donation available to individuals in India, Pakistan, and Bangladesh that will allow them to register as blood donors on the social media platform. "We know that donors want to step up to help their community, but often don't know when or where to donate. So today, we're announcing Blood Donations on Facebook to make it easier for people who want to donate to find opportunities nearby. [P]eople in India, Bangladesh and Pakistan will be able to view nearby blood donation camps, requests for blood donations and blood banks from one place on Facebook," stated a blogpost on Facebook's website. The tools are designed to combat blood shortages that occur in these areas, by making it easier and more accessible for individuals to donate blood.

(Source: Facebook Announcement, 5/1/18)









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) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2018

- May 8-10. **ABC Human Resources & Training/Development Workshop, America's Blood Centers, Dallas, Texas.** More details available https://example.com/here/here/.
- May 9-11. ADRP Conference & Expo., Dallas, Texas. More details available here.
- May 15. **2018 NJABBP Spring Seminar & Annual Conference, Woodbridge, NJ.** Join NJABBP by March 15th to be eligible to receive benefits. More details available here.
- May 16-17. IPFA/PEI 25th Workshop on "Surveillance and Screening of Blood-borne Pathogens," Athens, Greece. More details available here.
- June 2-6. 35th International Congress of the ISBT, Toronto, Canada. More details available here.
- June 25-26. **FDA 2018 Center for Biologics Evaluation Research Science Symposium,** Silver Spring, MD More details available here.
- Sept. 5-7. **3rd European Conference on Donor Health and Management, Copenhagen, Denmark.** More details available here.
- Sept. 12. 8th Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD. More details available here.
- Sept. 28. 36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD. More details available <a href="https://doi.org/10.1007/jhen2.0007







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) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Executive Director. The European Blood Alliance (EBA) is seeking an Executive Director who will be based in/close to Brussels and whose key goals include building the organizational capability and capacity and supporting the membership; contributing to EBA strategy and policies and implement these in close collaboration with the President and Executive Board of EBA; representing the EBA in contact with other organizations and the EU institutions (Commission, Parliament, Council etc.) and to manage the EBA office/secretariat, and supervising staff. The successful candidate must be able to demonstrate achievements in leadership positions, in the ability to build organizational capacity for a membership organization, and in content knowledge of blood banking. A track record of networking and interacting with EU bodies is a bonus. The full job description and person specification can be read on the EBA-website: https://wp.me/p4l3nF-2aF. Applications should be received by 31 May 2018.

Systems Analyst (Department: Management Information Systems). Position reports to the MIS Project Manager and is responsible for performing software testing and validation of the enterprise software and computer systems. Duties include: Analyze software modsets and patches to develop comprehensive test cases; validate that the change is functioning properly and meet the requested user requirements. Analyze software modsets and patches to ensure (risk analysis) changes will not have a negative impact on company's software enhancements. Execute test cases and complete all required supporting documentation per SOP(s). Assist in reviewing, developing and training SOPs. Assist with new equipment installations and user training, as needed. Assist with keeping the Development and Test environment up to date and current Act as the primary Help Desk contact for SafeTrace. Act as primary contact with software vendor for software problems, updates and documentation. Education and Experience: Bachelor's degree from an accredited college or university in Computer Systems or Life Sciences. Minimum of three years works experience in Computer Support/Training preferably in a blood or tissue center or blood bank. Strongly prefer experience working with SafeTrace. MLS or MLT desirable, but not required. Valid Texas Driver's license and an acceptable driving record are required. Please apply at: apply at https://jobs.giveblood.org.

Compliance/Quality Assurance Director. The Community Blood Bank of NWPA & WNY is seeking a Compliance/Quality Assurance Director. He/she must be thoroughly knowledgeable in AABB, FDA, CLIA, OSHA, and State Health Department regulations and standards. Must be familiar with the principles of risk management, corporate compliance and quality assurance. The incumbent must be available during outside agency inspections and maintain a positive professional rapport with inspectors. Candidates should have a minimum of a bachelor's degree in Medical Technology, Clinical Laboratory Science, or related science field, master's or advanced certification (e.g.: SBB, ASQ) a plus; five years of blood bank quality and regulatory affairs experience preferred. Experience should include participation in FDA site inspections, experience with GMP requirements and application of quality assurance principles; three years of supervisory experience preexcellent ferred. Must possess conceptual, communication, and analytical skills, and be competent with Microsoft Office (Word, Excel, PowerPoint) and Crystal Reports. Office 365 knowledge a plus. To apply, please send a resume and any relevant documentation to: Deanna Renaud, Interim Executive Director, Community Blood Bank, 2646 Peach St., Erie, PA 16508; or email Deanna.renaud@fourhearts.org.