

A B C N E W S L E T T E R CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #7

February 21, 2020

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CDC Reports Latest Figures on Dengue Cases

The Centers for Disease Control and Prevention (CDC) <u>published</u> in its February 14th *Morbidity and Mortality Weekly Report* an update on travel-associated and locally acquired dengue cases in the U.S. from 2010-17. Dengue is a mosquito-borne illness that can be potentially fatal as the virus can be transmitted by *Aedes spp*. mosquitoes. During that period, a total of 5,387 dengue cases were reported with 93 percent of the cases resulting from travel. CDC analyzed data from the national arboviral surveillance system (ArboNET), which includes cases reported by all 50 states and the District of Columbia. Of the nearly 400 locally acquired cases in the U.S., 250 were from the state of Hawaii with 103 in Florida, 24 in Texas, and one in New York.

The authors noted that "[c]ases were equally distributed between males and females, and median age was 41 years. Eighteen (three per 1,000) fatal cases were reported, all among travelers. [Individuals traveling] should review country-specific recommendations for reducing their risk for dengue virus infection, including using insect repellent and staying in residences with air conditioning or screens on windows and doors." More than 50 percent of the travel-associated cases were concentrated in New York, California, Florida, and Texas, while regions with the highest incidence with regard to travel-associated cases in the U.S. were "the Caribbean (33 percent) and Asia (29 percent), followed by Central America (14 percent), North America (10 percent), and South America (7 percent). Additionally, the authors stress the importance of individuals that are traveling being "vigilant and reviewing current dengue trends" prior to departing. They conclude that "[t]he number of travel-associated dengue cases peaked at approximately 900 in 2016 and could increase if large dengue epidemics occur in the Region of the Americas. Dengue surveillance is a critical public health task because of the presence of Aedes aegypti in many jurisdictions and the risk for virus introduction. Although dengue incidence in travelers is low, health agencies must remain vigilant because most cases are asymptomatic and reported cases represent a small percentage of all infections." Furthermore, they stated that the increasing frequency of travel by U.S. residents could lead to potential local outbreaks of dengue even in parts of the country that have not experienced dengue activity recently.

(Source: CDC <u>MMWR</u>, 2/14/20) •





REGULATORY NEWS

ABC Newsletter

The U.S. Food and Drug Administration (FDA) issued an updated Broad Agency Announcement (BAA) for the Advanced Research and Development of Regulatory Science. The BAA solicits research proposals for funding to "advance the state of the art and achieve improvements in technology, materials, processes, methods, devices, or techniques" regarding specific topics. The FDA states that it is seeking the development and facilitation of "innovative technologies toward universal pathogen reduction of the blood supply." According to the BAA the projects should:

- identify and evaluate innovative treatments and technologies that inactivate known and emerging blood-borne pathogens in ex vivo stored whole blood, while preserving the quality and functions of the individual blood components for transfusion;
- develop new and improved technologies to expand the range of whole blood pathogen inactivation (e.g., demonstrate inactivation of parvoviruses, bacterial spores or prions); and
- develop novel reagents and methods that can mitigate adverse effects associated with pathogen inactivation treatments to improve the quality of blood components for transfusion compared to existing licensed methods.

Additional information including the submission process and guidelines can be found on the FDA <u>website</u>. In 2018, FDA held a public workshop entitled "Pathogen Reduction Technologies for Blood Safety," during which Office of Blood Research and Review Director Nicole Verdun, MD stated, "FDA is committed to moving pathogen reduction technology forward and moving the needle forward will require collaboration among everyone here."

(Source: FDA Announcement, 2/18/20)

(continued on page 3)

Upcoming ABC Webinars – Don't Miss Out!

- ADRP Webinar: How NHS Blood and Transplant Solved the O- Problem February 27th from 1 2 p.m. (E.T.) <u>Register</u> today.
- ABC SMT Journal Club Webinar March 30th from 2 3 p.m. (E.T.) More information coming soon.
- ABC QA Education Webinar: FDA and the 356h Application Process May 19th from 3 4:30 p.m. (E.T.) More information coming soon.

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

America's Blood Centers

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

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<u>REGULATORY NEWS</u> (continued from page 2)

The FDA published a notice of "Important Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the 2019 Novel Coronavirus Outbreak." The agency states that it remains in continuous contact with the Centers for Disease Control and Prevention (CDC) in addition to other federal agencies regarding the ongoing outbreak of the novel coronavirus (COVID-19). As with blood products, the FDA indicates that "while respiratory viruses are not generally known to be transmitted by HCT/Ps, the actual potential for transmission of COVID-19 is unknown. To date, there are no known reported cases of transmission of COVID-19 by HCT/P and routine screening of donors already in place evaluates for clinical evidence of infection. The FDA is aware that some HCT/P establishments, like some blood establishments, are considering implementing additional screening measures as a result of the COVID-19 outbreak. HCT/P establishment medical directors are responsible for determining donor eligibility. If an establishment is considering taking additional action, the agency states that based on the limited information available at this time, a 28-day deferral for travel to areas with COVID-19 outbreaks, diagnosis or suspected diagnosis of COVID-19 infection, or living with such a person may be considered adequate at this time. The FDA continues to monitor the outbreak and issue updates as new information becomes available.

(Source: FDA Notice, 2/14/20)



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!



RECENT REVIEWS

ABC Newsletter

A review appearing recently in *Vox Sanguinis* reviewed the efficacy of using incentives to increase blood donations. The authors "focus[ed] on randomized controlled trials (RCTs) to obtain comparable treatment and control groups that minimize the risk of selection bias. The primary aim of this study was to compare incentive-and non-incentive-based interventions for increasing blood donation utilizing data from all identified trials simultaneously in a network meta-analysis. The secondary aim was to determine whether the level of intrinsic versus extrinsic motivation affects treatment." They conducted a network meta-analysis that looked at the "complete set of interventions" rather than providing a summary of evidence with regards to a single intervention category or failing to "simultaneously" synthesize all evidence that had been identified. The review only used trials "with donation as the only outcome, and that compare two types of interventions...The outcome of interest was whole blood donation, or an attempt to donate. These were considered to be equivalent as to not exclude donors deferred for medical reasons." The researchers categorized the studies based on the following interventions: monetary, non-monetary, and non-incentive and "trials were split into donor and non-donor populations based on the enrolled participants. Donors were those who had previously donated or taken steps towards their first donation. Nondonors were individuals with no prior donation history or evidence of an intent to donate." Their findings from their "network metaanalysis of 27 trials from 25 studies" showed that "the combination of a letter and telephone call or a telephone call-only was the most effective. Our findings were consistent when considering our pre-specified subgroups of donors and nondonors and when we repeated the analysis excluding trials at high risk of bias in at least one domain or trials performed outside of developed economies. They acknowledged the primary limitation of the review was the "generalizability of the pooled results from our network meta-analysis." The researchers conclude that the combination of a letter and a telephone call or a telephone call-only were the "best performing interventions. While non-monetary incentives are only effective in the donor subgroup, the effectiveness of monetary incentives remains unclear with limited, disparate evidence identified."

Citation: Irving, A., Harris, A., Petrie, D., *et al.* A systematic review and network meta-analysis of incentive- and non-incentive-based interventions for increasing blood donations. *Vox Sanguinis.* 2020. Doi: 10.1111/vox.12881. ♦

RESEARCH IN BRIEF

What is in an MTP? A report published in Transfusion suggests that confusion continues to exist regarding how components "should be used during a massive transfusion protocol (MTP) for traumatically injured bleeding patients." It details the case of a male admitted to the emergency department (ED) after sustaining injuries in a motor vehicle accident. He received six units of red blood cells (RBCs) and four units of plasma, which resulted from Tier one activation of the MTP. This was "designed to achieve a 1:1 ratio of plasma: RBCs by the end of tier three." Medical personnel continuously observed the patient's laboratory values throughout resuscitation efforts. Surgery was performed for liver lacerations, open fractures, and vascular injuries. Within 2.5 hours, the patient's bleeding was controlled, and he was moved to the intensive care unit. He had been administered "10 RBCs, six plasmas, two apheresis



Fig. 1. Graphic representation of the MTP tiers and contents. Tier 1 is sent to the bedside upon MTP activation. Subsequent Tiers 2 and 3 are provided sequentially as needed.

Courtesy of Transfusion

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RESEARCH IN BRIEF (continued from page 4)

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platelets, and five cryoprecipitate pools." The international normalized ratio (INR) was 1.2. The trauma surgeon requested four additional plasma units because "the patient was not resuscitated with a 1:1 ratio of RBCs to plasma." The transfusion physician chose not to fill the request due to the INR being normal. Additionally, bleeding had ceased in the patient, as the transfusion physician believed that "transfusion conferred risk without hemostatic benefit." The ratio was nearly 1:1 when the plasma from the platelets was included. The patient was discharged 53 days later. Every apheresis or whole blood-derived platelet pool is suspended in one unit of plasma. The activity of most coagulation factors even at expiration is adequate for hemostasis. Each "dose could also be considered an additional plasma when calculating total plasma to RBC ratio." This concept has not been described in studies with civilian trauma patients. In this case, during certain parts of the MTP, the INR decreased, and the fibrinogen increased even though no plasma was administered. Cryoprecipitate was not used in the MTP, as there is approximately 700 mg of fibringen in a unit of plasma. However, the authors state that cryoprecipitate should be transfused when the MTP patient's "fibrinogen concentration is <150 to 200 mg/dL" and not corrected by plasma. They emphasized that laboratory testing should be performed throughout the MTP "to detect an evolving coagulopathy and identify situations in which patients may benefit from transfusion of additional components" beyond MTP.

Citation: Dunbar, N.M., Yazer, M.H. Confusion surrounding trauma resuscitation and opportunities for clarification. *Transfusion*. 2020. Doi:<u>10.1111/trf.15710</u>.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 🌢

We'll be ready when you're ready.

With the release of the FDA's bacterial risk control strategies guidance; we're ready to help blood centers and hospitals evaluate and implement the strategies that best meet their business needs.

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WORD IN WASHINGTON

ABC Newsletter

The Office of the Assistant Secretary for Preparedness (ASPR) within the U.S. Department of Health and Human Services (HHS) has announced the formation of a consortium of government agencies and private sector to combat health security threats, while improving medical care and the nation's bioeconomy known as the Foundry for American Biotechnology. "As the outbreak of the novel coronavirus reminds us, protecting the health and security of the American people requires constantly investing in biotechnology innovation and partnering with the private sector," said HHS Secretary Alex Azar in an agency news release. "The creation of the first Foundry for American Biotechnology in New Hampshire is a milestone achievement in the innovative work that ASPR has done to support America's development and manufacturing of medical countermeasures. Every year, America faces natural disasters and other public health emergencies, and some day, Americans will be able to recover faster from these emergencies and stay healthier because of products that come out of this Foundry." Based in Manchester, N.H., the foundry will be managed by the Advanced Regenerative Manufacturing Institute (ARMI) and led by DEKA Research Corp. "The Foundry for American Biotechnology represents a game-changer in driving technologies critical to saving lives in disaster response," said ASPR Robert Kadlec, MD in the news release. "By providing essential services that move biotechnology from bench to bedside, the foundry not only solves problems the nation faces in health security, but also boosts the U.S. bioeconomy."

(Source: HHS News Release, 2/10/20)

HHS has published its 2019 annual report highlighting the agency's accomplishments in fulfilling its five strategic goals. The report mentions the incorporation of blood centers as stakeholders in the nation's disaster response and preparedness efforts, which America's Blood Centers advocated for in multiple coalition letters, joining more than 60 organizations. The letters were sent to congressional leadership encouraging passage of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPA). Also, ABC members advocated for passage of PAHPA on Capitol Hill with their members of Congress during ABC's annual Advocacy Day in March 2019. Additionally, the report also notes progress on a promising National Institutes of Health (NIH)-supported gene therapy trial aimed at finding a cure for sickle cell disease by having patients produce "normal red blood cells and healthy hemoglobin." The full report is available on the HHS website. "The men and women of [HHS] can be proud of all they achieved in 2019," said Secretary Alex Azar in an agency news release. "This past year was marked by exceptional progress in accomplishing our mission: to enhance and protect the health and well-being of all Americans. We're a big department, but we're united by one strategic vision: a country where our HHS programs, and America's healthcare, human services, public health, and biomedical science institutions, work better for the people we serve."

(HHS News <u>Release</u>, 2/6/20; HHS Annual <u>Report</u>, 2/6/20) •

MEMBER NEWS

South Texas AirMed announced a partnership with **South Texas Blood and Tissue Center** (San Antonio, Texas) in which type O-positive blood is now being supplied onboard AirMed's air ambulances and used to treat trauma patients enroute to a hospital. "[I]f somebody's bleeding out and you can't control the bleeding, then, you need blood," <u>said</u> Louis Corbeil, director of air medical operations for South Texas Air Med to *The Monitor*. That's the only thing that's [going to] save you...Blood is what does everything," Corbeil said. "The sooner you get the blood, the more likely you are that you're going to survive." The AirMed helicopter takes two pints of blood on each call and is immediately restocked upon using them. "The minute that we use it, they will actually deliver it to us," added Mr. Corbeil. "By the time we get back from our call, it'll be here at the base already ready to restock us."

(The Monitor, Texas air ambulance service now carrying blood, 2/14/20)

INFECTIOUS DISEASE UPDATES

CORONAVIRUS

The U.S. Food and Drug Administration (FDA) issued a statement this week on the domestic response of the agency to the COVID-19 outbreak. We are keenly aware that the outbreak will likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products in the U.S.," said FDA Commissioner Stephen Hahn in the statement. "We are not waiting for drug and device manufacturers to report shortages to us—we are proactively reaching out to manufacturers as part of our vigilant and forward-leaning approach to identifying potential disruptions or shortages. The FDA has dedicated additional resources to review and coordinate data to better identify any potential vulnerabilities to the U.S. medical product sector, specifically from this outbreak." Additionally, Commissioner Hahn stated that FDA has, "been in contact with hundreds of manufacturers of human and animal drugs and medical devices, as well as syncing up with global regulators, like the European Medicines Agency, to assess and monitor for indications and early warning signs of potential manufacturing discontinuances or interruptions due to the outbreak. It's worth noting that there are no vaccines, gene therapies, or blood derivatives licensed by the FDA that are manufactured in China." He added that the agency will continue to collaborate with other agencies and external partners to advance treatment efforts to combat COVID-19.

The number of cases continue to rise globally, though no new cases were reported in the U.S. this week number of positive confirmed U.S. cases dropped to 13 (11 travel-related, 2 person-person) as it does not include people who returned to the U.S. via State Department chartered flights according to the Centers for Disease Control and Prevention (CDC) with more than 75,000 reported by the WHO with the vast majority in China. America's Blood Centers (ABC) issued a public <u>statement</u> on February 6th regarding the novel coronavirus outbreak as well. It emphasized that the blood donation process is safe and encouraged all donors and sponsors of blood drives to schedule appointments and keep commitments to donate blood. ABC will continue to monitor the outbreak and provide timely updates to member blood centers.



States with Confirmed COVID-19 Cases

(Sources: FDA Statement, 2/13/20; CDC Update 2/21/20; ABC Statement 2/6/20)

GLOBAL NEWS

Researchers in China have begun treating some COVID-19 patients with convalescent plasma infusions from individuals that have recovered from the virus according to a <u>report</u> in *Reuters***. An official from the World Health Organization stated that clinical trials exploring the effectiveness of such infusions**



<u>GLOBAL NEWS</u> (continued from page 7)

is an important area of research in hopes of eventually curing the ongoing coronavirus outbreak that originated in China's Hubei province. "It is a very important area to pursue," said Mike Ryan, head of the WHO's health emergencies programs, according to *Reuters*. "Because what hyperimmune globulin does is it concentrates the antibodies in a recovered patient. You are essentially giving the new victim's immune system a boost of antibodies to hopefully get them through the very difficult phase. So, it must be given at the right time, because it mops up the virus in the system, and it just gives the new patient's immune system a vital push at the time it needs it. But it has to be carefully timed and it's not always successful. So, it is a very important area of discovery, and I believe they are starting trials on that in China. But it is a very valid way to explore therapeutics, especially when we don't have vaccines and we don't have specific antivirals."

(Source: *Reuters*, <u>Chinese doctors using plasma therapy on coronavirus</u>, <u>WHO says 'very valid' approach</u>, 2/17/20) ♦

COMPANY NEWS

Cerus Corp. announced a partnership this week with the National Trauma Institute as part of participation in the U.S. Department of Defense (DoD) Plasma Resuscitation Without Lung Injury (PROpOLIs) clinical study to evaluate the efficacy of pathogen reduced plasma from the InterceptTM blood system to treat individuals that have suffered severe burns. "The goal of this study is to improve the outcomes of patients being treated for major burns and to effect a volume-sparing intervention that reduces endothelial injury and consequent organ dysfunction," said Cerus CEO Obi Greenman in a news <u>release</u>. "We believe the successful outcome of this study could have implications for volume resuscitation across multiple indications in which crystalloid and colloid solutions have been used for early volume replacement." The study is planned to begin this year and will take place at five burn facilities across the U.S.:

- the U.S. Army Burn Center (Fort Sam Houston, Texas);
- the University of Washington Regional Burn Center (Seattle, Wash.);
- the Ross Tilley Burn Centre-Sunnybrook Health Sciences Centre (Toronto, Calif.);
- the Burn Center at MedStar Washington Hospital Center (Washington, D.C.); and
- the Vanderbilt Burn Center (Nashville, Tenn.).

"This study could have meaningful clinical implications for the care of burn patients. Fluid replacement that also corrects the endotheliopathy of burns may provide valuable clinical benefit, including reduced morbidity, shorter ICU stay, decreased hospital costs, and improved survival," said Leopoldo Cancio, MD, FACS, principal investigator for PROpOLIs and the Director of U.S. Army Burn Center, Fort Sam Houston. Ninety-four patients are expected to be enrolled in the randomized study and will receive treatment with either Intercept plasma or a crystalloid-based solution. "The evaluation of INTERCEPT plasma with reduced risk of transfusion-transmitted infection to treat severe burn injuries is another step in our evolving portfolio of novel therapeutic blood components focused on addressing unmet clinical needs to improve patient outcomes," added Laurence Corash, MD, Cerus' chief scientific officer and a co-investigator of PROpOLIs, in the news release. "This study complements our strategy to leverage our foundational technology for other novel applications such as pathogen-reduced cryoprecipitate."

(Source: Cerus News <u>Release</u>, 2/18/20) •



America's Blood Centers[®] It's About *Life*. 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.

February Blood Bulletin Available

ABC's Scientific, Medical, and Technical (SMT) Publications Committee, has published the February 2020 Issue (<u>PDF</u> or <u>MS Word</u> versions) of the <u>Blood Bulletin</u>, titled "Transfusion-Associated Circulatory Overload (TACO): Underreported and Underappreciated."

The article was written by Richard Gammon, MD, Medical Director at OneBlood & Nanci Fredrich, RN, BSN, MM, Transfusion Safety & Blood Management Officer at Versiti. *Blood Bulletin* is reviewed and edited by ABC's SMT Publications Committee.

ABC publishes the *Blood Bulletin* for use by member blood centers in their educational programs as a value-added service for hospital customers. Current and previous issues can be accessed at any time on the ABC member <u>website</u>.

Please note: The MS Word version may not display properly for users with older versions of MS Word. For those individuals, we recommend viewing and using the PDF version of this publication instead.

(Source: MCN <u>20-015</u>)

ABC Newsletter

ADRP Webinar: How NHS Blood and Transplant Solved the O- Problem

<u>Register</u> today for the Thursday, February 27th ADRP Webinar entitled "How NHS Blood and Transplant solved the O- problem." This webinar will take place at 1 p.m. eastern and feature Jon Latham, associate director of Donor Relationships at NHS Blood and Transplant. Attendees will receive information on how his organization increased the donor base and donor satisfaction, while lowering costs. ADRP subscribers may register for free and non-subscribers can participate for \$25.

(ADRP <u>Announcement</u>, 2/10/20)

Register for the 2020 ABC Annual Meeting

<u>Registration</u> is open for America's Blood Centers' (ABC) 58^{th} Annual Meeting in Washington, D.C. March $9^{th} - 11^{th}$, 2020 at the Ritz-Carlton (Pentagon City). Join us for the premiere blood community meeting that brings blood center, regulatory, legislative, and medical leadership together to focus on key issues which will ultimately impact blood center bottom-lines. From implementation challenges for the new bacterial guidance to the operational complexities entailed in gender identification, the ABC Annual Meeting will provide you with the latest updates on these topics and more, along with the opportunity to help shape the association's advocacy and policy efforts. Additionally, attendees will have the chance to work collaboratively with their peers and ABC leadership in developing solutions that address internal and external needs ranging from health policy to donor motivations. This meeting also includes a day on Capitol Hill to let our voices be heard. Contact <u>Jeanette Brown</u> for available sponsorship opportunities and to see if hotel availability still exists at the group rate. Registrant substitutions are accepted any time at no charge. Registrations

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

cancelled after February 16 will be refunded, less \$200. No refunds after March 8. CME and P.A.C.E.® credits will be offered. Schedule at a glance:

- ABC Board Meeting (*open to ABC Members only) (March 8th)
- General Sessions & SMT Forum & Celso Bianco Lectureship (March 9th)
- ABC Members' Meeting (*open to ABC Members only) & Public Awareness Forum & Advocacy Forum (March 10th)
- 23rd Annual Awards of Excellence (March 10th)
- Advocacy Day Capitol Hill Visits (March 11th)

(Source: MCN <u>19-086</u>, 12/18/19)

ABC Survey on Donor Deferrals Due to Blood Pressure

The America's Blood Centers (ABC) Scientific, Medical, and Technical (SMT) Committee is evaluating the mandatory donor blood pressure and prescribed ranges set forth by the Final Rule in 21 CFR 630.10. Members of ABC have indicated that donors are unnecessarily being deferred for out of range blood pressure because of the requirement in 630.10(f)(2) that a "physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating." This cannot be delegated to the blood drive supervisor or other qualified staff per 630.5(b)(1)(i). Since doctors are not generally on mobile drives, any donors with blood pressures outside the established range are deferred. Member assistance is needed to measure the impact of this issue. A survey has been designed for ABC members to complete to objectively determine how many donors are being deferred because of blood pressure outside of the U.S. Food and Drug Administration's (FDA) established range and to estimate the impact on donors and staff time. ABC members can <u>access</u> a link to the survey and a copy of the survey questions in MCN 20-010. The survey will gather data on the number of donors with blood pressures outside of established ranges and how many of them are qualified or deferred. ABC understands that not all organizations are able to easily break that information down between donors with low or high blood pressures. Please provide as much data as possible by completing the survey by February 28th. If you have any questions, please contact ABC Director of Regulatory Services Ruth Sylvester.

> **ABC-ADRP PUBLIC** RENESS FORUM 1 ALIGNING EFFORTS TO CREATE MEANINGFUL CHANGE March 10 | 8 am - 10 am sustainable blood supply. The evolving viewpoints and behavior of younger generations in **ABC Annual Meeting** relation to blood donation is of particular concern for continued resiliency and long-ter **Ritz Carlton - 2nd Floor** sustainability. Join us for a national dialogue around blood donation, one that prioritizes increased education and awareness about the blood supply and external partnerships that Pentagon City, VA support and align with blood center needs. Questions? Contact info@adrp.org RSVP: https://form.jotform.com/200265360462043

(Source: MCN 20-010, 1/29/20)

† • • February 21, 2020

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 <u>newsletter@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.)

2020

Mar. 9-11. 2020 ABC Annual Meeting, Washington, D.C. Registration is open.

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

April 1. U.S. Food and Drug Administration (FDA) Public Meeting on FDA's Communications About the Safety of Medical Devices. Silver Spring, Md. More details available <u>here</u>.

April 2-3. U.S. Food and Drug Administration (FDA) Blood Products Advisory Committee Meeting. Silver Spring, Md. More details available <u>here</u>.

April 14-15. **16th Annual FDA and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** More details available <u>here</u>.

April 23-24. **13th Annual FDA/AdvaMed Medical Devices and Diagnostics Statistical Issues Conference, Washington D.C.** More details available <u>here</u>.

May 12-13. AABB and Mayo Clinic Laboratories Transfuse 2020, Rochester, Minn. 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 available here.

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

Sept. 23-25. 4th European Conference on Donor Health and Management. Hamburg, Germany. More details available <u>here</u>.

Oct. 3-6. 2020 AABB Annual Meeting, Baltimore, Md. More information available here.

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

Notes: For the most up-to-date information on all events, members of ABC may check the <u>calendar</u> on ABC's Member Site. Non-members may attend all events; information will be updated on ABC's <u>Public Site</u>.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: <u>newsletter@americasblood.org</u>

POSITIONS

Director of Donor Recruitment. Do you have a passion for community service, leadership and sales? Are you a goal-oriented people person? Arkansas Blood Institute is seeking qualified candidates for Director of Donor Recruitment in the Little Rock area. This is a vital and rewarding position that will play a key role in expanding our footprint and sharing our lifesaving mission in Central Arkansas. Arkansas Blood Institute is part of one of the fastest-growing independent blood centers in the U.S., providing blood to more than 30 hospitals in Arkansas, including four major hospitals in Little Rock. Arkansas is home to 52 state parks set on gorgeous mountains, lakes, streams and forests. Little Rock is beautifully located along the Arkansas River and has more than fifteen miles of scenic riverfront, cultural and historic attractions, entertainment and world-class dining. Qualifications: Three to five years of work experience directly related to blood banking. Associate's degree is required, bachelor's degree preferred. Benefits: Arkansas Blood Institute offers a competitive salary, excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and a relocation package for candidates who do not reside in the Little Rock area. Apply online only at http://arkbi.org/careers/. EEO M/F/D/V/Drug Free Work Environment

Hematologist/Medical Director. OneBlood is expanding its clinical practice offerings in the areas of outpatient transfusion medicine, therapeutic apheresis & phlebotomy, pre-op anemia management, cell therapy, treatment of blood disorders. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking/transfusion medicine, hematology and outpatient clinical services, IRL, therapeutic apheresis, cellular therapy, research, consider joining our medical team as a regional Medical Director. This position includes a highly competitive salary, benefits package, including the option of free medical coverage, retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, etc. The position is based out of the Ft. Lauderdale, Florida area. Qualified candidates should possess: minimum of three years' experience, M.D. or D.O. degree with board certification in Internal Medicine/Hematology and sub-specialty board certification 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. Candidates must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. For more detailed information, visit One-Blood's *Careers* page at www.oneblood.org. OneBlood,

Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.

Vice President, Donor Services (RN). Kentucky Blood Center, located in Lexington, Kentucky, seeks a dynamic professional to direct the activities of the Blood Collections departm3ents in accomplishing collection goals. Responsibilities will include the development of strategic plans, budgeting, and oversight of employee training, processes, and procedures in compliance with equipment manufacturer, FDA, AABB and EU guidelines/regulations. The position has oversight of employees at multiple locations throughout Kentucky, in addition to mobile blood drive operation. Qualified applicants must have a minimum of a four-year degree, Registered Nurse (RN), with a minimum of five years management experience. Must be knowledgeable of industry regulations including FDA, AABB, and EU. Must be proficient with MS Office, Outlook and Adobe with the ability to navigate webbased applications and other internal systems. Should possess proven data analysis skills and be highly organized, reliable, and have outstanding interpersonal skills. Strong written and oral communication skills, a do-whatit-takes work ethic, and a team player attitude are required. All resumes must contain a cover letter. To be considered, candidate must reside in or be willing to relocate within 1 hour of the Lexington area. Relocation assistance available. Competitive salary and benefits package. Click here to apply.

Vice President of Technical Operations (Oklahoma City, OK). The Vice President of Technical Operations provides planning, operational management, budgeting and leadership to the Oklahoma Blood Institute. It will oversee and direct the operational and quality systems in the Testing Laboratory, Manufacturing Laboratory, Quality Control Laboratory, Logistic & Distribution, and Client Relations & Contracting departments. He/She will develop and administer capital expense budgets and operating budgets. This position requires a thorough understanding of regulations and laws applying to Oklahoma Blood Institute. Qualifications: Requires a Bachelor of Science degree in Medical Technology, master's degree strongly preferred, minimum of eight years progressive management in a related medical industry. Salary Range: Competitive salary and excellent benefits package including health, dental, vision, life insurance, long term disability, 401(k), paid time off, etc. How to apply: http://obi.org/careers/.



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Assistant Director of Quality Assurance. This position at Shepeard Community Blood Center assists the Director of QA in management and implementation of organizational Quality Plan. Monitors regulatory compliance in all areas of operation and reviews new and revised regulations, standards and other compliance documents. Assists in management of corrective and preventative action, change control, document control, record storage, equipment and validation. Coordinates and facilitates center training and competency programs. Serves as resource for quality and compliance issues for staff. Qualifications: bachelor's in laboratory science or related discipline required; three to five years' experience in blood bank or transfusion service, management experience, working knowledge of PC software using Windows, Microsoft Word, Excel and other software programs as required, familiarity with FDA/AABB Regulations/Standards, OSHA and CLIA requirements; working knowledge of regulations and standards for biologics to include blood and blood products. Working knowledge of donor suitability criteria and infectious disease testing. Must maintain knowledge of and perform according to Standard Operating Procedures (SOPs) and policies. Must maintain knowledge of cGMP, CLIA regulations, applicable OSHA rules, and current industry standards. Licenses/Certifications: MT or MLT with appropriate certification preferred or BS-RN acceptable with appropriate work experience. Please upload cover letter, resume, relevant documentation and complete an application at www.shepeardblood.org.



Director, Regulatory Affairs. America's Blood Centers (ABC), North America's largest network of communitybased, independent blood programs, is seeking a Director, Regulatory Affairs. The position will be actively involved and accountable for the development, implementation, execution and advancement of the ABC regulatory agenda before federal agencies and other stakeholders. In addition, the position will assist in the facilitation of member education, evaluation and coalescing of member input in the development of industry positions, data collection from internal and external sources, and primary and secondary research. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on regulatory affairs and public policy issues pertaining to the nation's blood supply. A bachelor's degree is required for the position, which is based in Washington, D.C. This individual should: have a thorough understanding of the federal regulatory processes and landscape, particularly with the FDA; have knowledge of and experience in health policy; blood industry knowledge preferably (but not required); be able to collect, analyze, and synthesize information from varied sources; have strong critical thinking, analytical, and problem-solving skills; be selfmotivated and goal oriented; have the ability to multitask and determine priorities; be able to network and collaborate effectively with colleagues and volunteers; have strong communication skills - verbal, written, and presentation; and be able to travel, sometimes at short notice. ABC offers a salary commensurate with experience as well as an excellent benefit package including medical, dental, LTD, and 401k contribution. We are a hybrid virtual office that promotes a flexible work environment. This is a full-time staff position including benefits and a stipend for internet and telephone services. ABC prohibits discrimination and provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws. The full job description is available here. Interested applicants should send a cover letter and resume to careers@americasblood.org.