CBER Publishes 2019 Report from the Director

The U.S. Food and Drug Administration’s (FDA) Center for Biologics Evaluation and Research (CBER) released its fiscal year 2019 year-end report from agency Director Peter Marks, MD PhD. Among the accomplishments highlighted of interest to the blood community were the Office of Blood Research and Review’s (OBRR) “ongoing efforts to ensure the safety of the nation’s blood supply [including] approval of two assays that detect the genetic material of the Babesia species of protozoan parasites in whole blood specimens: the Procleix Babesia Assay and the cobas Babesia test for use on the cobas® 6800/8800 System. These assays enable screening of donated blood and living donors of organs and tissues.”

Additionally, the report noted the Blood Products Advisory Committee held a public meeting to discuss strategies to reduce the transmission of Zika and the FDA’s deferral policy of men who have sex with other men (MSM). Public workshops were hosted that examined the “Perspectives on In Vitro Diagnostic Devices Regulated by the Office of Blood Research and Review” and “Pathogen Reduction Technologies for Blood Safety,” with the latter seeking to foster development and implementation of pathogen reduction technology for transfusable blood products. The report also provided a complete listing of the guidances issued by the agency throughout the year. Some of note included:

- **Bacterial Risk Control Strategies for Blood Collections Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Guidance for Industry**;
- **Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry**;
- **Considerations for the Development of Dried Plasma Products Intended for Transfusion; Draft Guidance for Industry**; and
- **Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry**.

The full report is available on the FDA’s website. It summarizes “achievements, which reflect the [staff’s] continued dedication to CBER’s mission and [the agency’s] ongoing commitment to improve public health globally.”

(Source: CBER Announcement, 12/26/19)
REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) issued a reminder in the form of an announcement on December 20th for blood and blood product donors that stated that anyone who has ever tested positive for HIV should not donate blood. According to the announcement, “[a] recent study of the blood supply in the United States identified some HIV-positive blood donations from individuals who were taking antiretroviral drugs”. To date, there have been no reported cases of HIV transmission to transfusion recipients by blood donated by such individuals. However, FDA is concerned about the risk that such donations pose to the overall safety of the blood supply. FDA-approved antiretroviral drugs are safe and effective and can reduce the HIV viral load of individuals to undetectable levels as determined by conventional testing. However, these antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient.”

(Source: FDA Announcement, 12/20/19)


RESEARCH IN BRIEF

Results from an adeno-associated virus (AAV)-mediated gene therapy clinical trial published in The New England Journal of Medicine (NEJM) shows promise as a potential functional cure for patients with hemophilia A. Researchers found “multiyear factor VIII expression and effective control of bleeding” in 13 male patients infused with the one-time gene therapy. Each participant did experience at least one adverse event with “[t]he most common adverse event [being] an elevation of the alanine aminotransferase level, with 14 reported events (13 events of grade 1 and 1 event of grade 2) in 11 participants.” An expanded phase three trial is ongoing with more than 130 patients.


The U.S. Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER) disseminated a poster on microparticles from sickle cell disease in red blood cells. It illustrates the identification of oxidative reactions of hemoglobin (Hb) with membranes of sickled red blood cells that produce microparticles containing highly reactive Hb and is available on the FDA website for download as a resource.

(Source: FDA Announcement, 1/2/20) ♦
BRIEFLY NOTED

The U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) has announced Brad Smith as the director of the Center for Medicare & Medicaid Innovation (CMMI) and senior advisor to HHS Secretary Alex Azar for value-based transformation. “Brad will help HHS and CMS continue and accelerate the value-based transformation work that we have begun under President Trump,” said Secretary Azar in a joint news release from HHS and CMS. “Brad has impressive experience with innovative care delivery and paying for value, and he will help expand Administrator Verma’s and CMS’s efforts to ensure Medicare and Medicaid beneficiaries are getting better care, and better health, at a lower cost.” Mr. Smith previously served as the chief operating officer of Anthem’s Diversified Business Group. CMS Administrator Seema Verma added, “Brad’s experience thinking outside-the-box to improve healthcare as a successful entrepreneur, along with his stellar academic and policy background, have prepared him well to lead CMMI and bring innovative solutions to our healthcare system’s most pressing challenges”

(Source HHS & CMS Joint News Release, 1/6/20)

Microsoft recently announced that it awarded a signature grant to the World Mosquito Program to support the prevention of mosquito-borne disease as dengue and Zika. The grant is a part of the organization’s $50 million commitment to the Artificial Intelligence (AI) for Earth initiative that aims to use AI to improve the future of the Earth. A portion of the funding will be used to assist with the creation of genetically modified mosquitoes that contain Wolbachia bacteria that limits their disease-carry ability. These mosquitoes are released into the environment to mate with other mosquitoes to combat the spread of viruses. “The World Mosquito Program started with the objective of figuring out how to attack a problem. In this case, they worked out how to neutralize the disease-carrying ability of mosquitoes,” said Lucas Joppa, chief environmental officer at Microsoft in a company announcement. “Then they worked out where they needed to release these mosquitoes. “They started collecting tons of data. It then became a really messy data problem as they tried to compare a bunch of different data sets to work out where they could be most efficient. Ultimately, this is where machine learning comes in. It allows you to take all of that data, abstract it down to a single estimate of probability and map it out. It is cost-effective, and it is super scalable. Instead of figuring out data visualization and analytics for one particular area, you can now do it for an entire city, for an entire country, for the entire world. That is because the data sets they are using are globally generalizable. One model that works here can work everywhere.”

(Source: Microsoft Announcement, 1/9/20) ♦
Prehospital Plasma Transfusions Provide Survival Benefit During Extended Transport

Over the past 10 years, the critical role of blood transfusion for resuscitation following severe trauma and hemorrhagic shock has been demonstrated with early transfusion being incorporated into military and civilian clinical practice guidelines. The current protocol is to include plasma to achieve a 1:1 to 1:2 plasma to red blood cell ratio. The Prehospital Air Medical Plasma (PAMPer) clinical trial showed a nearly 30 percent reduction in mortality with prehospital plasma transfusion, while the Control of Major Bleeding After Trauma (COMBAT) clinical trial showed no survival improvement. A recent study published in JAMA Surgery examined the data sets of both studies to address the post hoc hypothesis that the benefits of prehospital administration of plasma were influenced by transport time. The primary outcome was 28-day mortality. Secondary outcomes included 24-hour mortality and international normalized ratio (INR). Prehospital transport time was defined as time from ambulance arrival on scene (AOS) to arrival at the emergency department (AED). It was divided into either within 20 minutes or longer than 20 minutes.

A total of 626 patients (467 men [74.6 percent] and 159 women [25.4 percent], median age, 42 [27-57] years) were included two clinical trials. Patients with trauma and hemorrhagic shock were randomly assigned to receive either standard care with crystalloid resuscitation or two units of thawed plasma followed by standard care in the prehospital setting. The study found that the 28-day mortality was lower in the plasma group (61 of 297 patients [20.5 percent]) than in the standard care group (94 of 329 patients [28.6 percent]) (P = .02). A similar pattern was observed for 24-hour mortality (HR, 0.62; 95 percent CI, 0.42-0.93; P = .02). Increased mortality was observed in patients in the standard care group when prehospital transport was longer than 20 minutes (HR, 2.12; 95 percent CI, 1.05-4.30; P = .04), while increased mortality was not observed in patients in the prehospital plasma group (HR, 0.78; 95 percent CI, 0.40-1.51; P = .46). Patients who received prehospital plasma were 47 percent less likely to present to the emergency department with coagulopathy (INR >1.3) compared with those who received standard care (OR, 0.53; 95 percent CI, 0.35-0.80; P = .002); this association was isolated to transport times longer than 20 minutes.

The authors concluded that the data suggested that prehospital plasma when compared with the standard of care was associated with a survival benefit when transport times were greater than 20 minutes. The findings also implied that prehospital plasma administration provided an additional advantage beyond that of a balanced in-hospital transfusion regimen. The present findings have important implications for the treatment of patients with traumatic hemorrhage when surgical care and in-hospital transfusion may be delayed, such as in military settings, in rural and remote trauma, and in civilian disaster scenarios.

An accompanying editorial emphasized that clinical studies of prehospital trauma care are particularly challenging (and expensive) because they require enrollment of patients with a waiver of informed consent and include data that are difficult to collect and analyze. It highlighted the cost savings using the combined data from COMBAT and PAMPer trials. Additionally, there are ethical benefits of avoiding unnecessary human subjects’ research and maximizing knowledge gained from the existing data. Finally, because these studies were performed in trauma centers in the U.S., the findings from the research were immediately applicable to civilian healthcare.


Rasmussen, T.E., Brosch, L.R. Getting Our Money’s Worth from Clinical Care Studies of Prehospital Trauma Care. JAMA Surg. 2019.

Contributed by Richard Gammon, MD, Medical Director at OneBlood ⬇️
WORD IN WASHINGTON

The Kay Hagan Tick Act was signed into law by President Trump on December 20th after being passed by Congress as part of the bipartisan spending package that funds the federal government through September 2020. “The inclusion of the Tick Act in the appropriations agreement is a major victory for the hundreds of thousands of Americans who contract Lyme and other tick-borne illnesses each year,” said Sen. Susan Collins (R-Maine) in a joint news release with Sen. Tina Smith (D-Minn.). “I am grateful for the countless advocates who shared their struggles with these diseases and conveyed the urgent need for this comprehensive, bipartisan bill. With a national effort the Tick Act [establishes], we can stop the spread of these devastating tick-borne illnesses and protect our health.” The two Senators introduced the bill in 2019 which addresses the increasing incidence of tick and vector-borne diseases and disorders. The legislation:

- requires the U.S. Department of Health and Human Services to create a national strategy to promote research, better testing, and encourage interagency coordination from the federal government;
- reauthorizes $50 million in funding over five years for Regional Centers of Excellence in Vector-Borne Disease; and
- allows the Centers for Disease Control and Prevention to issue $20 million dollars annually in grants to state health departments to improve the collection of data, surveillance efforts, treatment, and awareness of vector-borne diseases.

The bill is named in honor of former Sen. Kay Hagan (D-N.C.) who passed away in October from complications associated with the tick-borne disease Powassan virus.

(Sources: WGME CBS-13, New act allots $150 million in federal funds to fight tick-borne diseases, 12/31/19; Sens. Susan Collins & Tina Smith Joint News Release, 12/17/19)
INFECTIONOUS DISEASE UPDATES

INFLUENZA

The Centers for Disease Control and Prevention (CDC) reported that the flu activity is widespread in 45 states and Puerto Rico. Only Maine, North Dakota, Kansas, and Vermont, are exhibiting regional activity, while Hawaii and the District of Columbia are reporting local activity respectively as of the final week of 2019. More than 2,600 hospitalizations have been linked to flu as of CDC’s latest figures from October 1st, 2019 – December 28th, 2019. The hospitalization rate per 100,000 people is currently 9.2 compared to 5.4 during the same timeframe during the 2018-19 season. Twenty-seven children have died this season from flu. CDC officials note that the best defense against the flu remains the flu vaccine and that it’s not too late to get vaccinated.

(Sources Centers for Disease Control and Prevention Summary of Weekly FluView Report, 1/3/20)

PEOPLE

David Neal has joined San Diego Blood Bank (SDBB) as chief financial officer. He brings more than 25 years of executive experience to SDBB, with a recent 14-year focus in non-profit biobanking and life-science research. Mr. Neal is a licensed certified public accountant (Arizona) and brings insights on operational and strategic issues to help further SDBB’s mission. In addition to his life-science background, he has previously held senior financial leadership positions in higher education, software development, and semi-conductor equipment manufacturing. Mr. Neal received his B.S in Accountancy from the University of Illinois, Urbana.

(Source: San Diego Blood Bank Announcement, 12/24/19)

Upcoming ABC Webinars – Don’t Miss Out!

- Facebook Blood Donation Tool Training for ABC Members Webinar – January 16th from 1 – 2 p.m. (ET). Additional details and login information available here.
- ABC QA Education Webinar: Irradiator Replacement at Blood Centers – January 21st from 3 – 4:30 p.m. (ET). Additional details and login information available here.
Register for the 2020 ABC Annual Meeting

Registration is open for America’s Blood Centers’ (ABC) 58th Annual Meeting in Washington, D.C. March 9th – 11th, 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 is the only meeting in the industry that focuses solely on advocacy and includes a day on Capitol Hill to let our voices be heard. Please make your hotel reservations by February 1st to ensure best availability and the group rate. Contact Jeanette Brown for available sponsorship opportunities.

Registrant substitutions are accepted any time at no charge. Registrations 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 Annual Meeting
- ABC Board Meeting (*open to ABC Members only) (March 8)
- General Sessions & SMT Forum & Celso Bianco Lectureship (March 9)
- ABC Members’ Meeting (*open to ABC Members only) & Public Awareness Forum & Advocacy Forum (March 10)
- 23rd Annual Awards of Excellence (March 10)
- Advocacy Day – Capitol Hill Visits (March 11)

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

**ABC Blood Bulletin Feedback Sought**

ABC is requesting member feedback regarding the ABC Blood Bulletin publication in an effort to ensure that it continues to serve as a valuable resource. The publication attempts to provide the ABC membership with the most recent scientific and technical information on current transfusion medicine topics for sharing not only with their hospital customers, but also with employees at your blood center.

Please complete the survey no later than January 17th. A link to the survey is available in MCN 19-085.

(Source: MCN 19-085, 12/18/19)
INSIDE ABC (continued from page 7)

**Facebook Hosting Webinar for ABC Member Blood Centers**

Facebook is hosting a training webinar for ABC member blood centers. Please mark your calendars as the webinar will take place on Thursday, January 16th from 1-2 p.m. Eastern and provide an opportunity for ABC members to have questions answered regarding the functionality and use of the blood donation tool developed by Facebook that was launched nationwide in December (see MCN 19-087). Instructions to join the webinar are included in MCN 20-001.

Additionally, please note that this webinar will be hosted on Facebook’s webinar platform (BlueJeans) which may require a plugin to be downloaded for your web browser. Please click [here](#) for additional instructions. Feel free to [contact us](#) with questions or concerns. Thank you.

(Source: [MCN 20-001](#), 1/7/20)

**MEMBER NEWS**

**Stanford Blood Center** (SBC) has once again partnered with The Tech Interactive (The Tech), a San Jose-based science and technology center that specializes in experiential educational activities to foster innovation, creativity, and problem-solving, on the “Give Good” initiative. As part of the collaborative effort, The Tech hosted a blood drive and is providing space for SBC’s interactive “World of Blood Exhibit” at The Tech for six days throughout the month of January. “The focus of ‘Give Good’ is to generate awareness about the importance of blood donation, so we can continue to help local patients during these critical winter months, all while supporting a terrific organization with a charitable mission,” said SBC Chief Executive Officer Harpreet Sandhu, MBA in a joint news release. “We are proud to team up with institutions like The Tech Interactive in their efforts to broaden the horizons of children and teens in our community by providing them with hands-on learning opportunities.” The partnership is now in its seventh year and also includes a charitable contribution from SBC to The Tech for each individual that presents to donate during the month of January. The funds will be used to support educational initiatives for underserved youth at The Tech. “We are thrilled to partner with SBC to help educate our community on the critical need for blood and the role donors play in helping save lives,” said Gretchen Walker, vice president of Learning at The Tech in the news release. “Here at The Tech, we strive to motivate the next generation of innovators. This generous contribution will help us inspire the leaders of tomorrow and engage children of all ages with programs that help them discover their own problem-solving power.”

(Source: Stanford Blood Center and The Tech Interactive Joint News [Release](#), 1/2/20)
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 newsletter@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.)

2020


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

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.
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: newsletter@americasblood.org

POSITIONS

Hematologist/Medical Director. Our growing clinical practice in the area of outpatient therapeutic apheresis and therapeutic phlebotomy is seeking a board-certified hematologist to broaden our clinical services to include pre-op anemia management, cell therapy and treatment of blood disorders. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of outpatient clinical transfusion medicine, blood banking, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of 3 years’ experience and a 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. 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 lifesaving 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.

Technical Director. This position’s responsibilities include coordination/management of the departments of Distribution, Component Production, Testing and Labeling (North Texas) and Hematology (North Texas and East Texas). He/she will manage departmental operations with strong planning and developmental skills. This individual will also be responsible for advising and informing all senior management regarding departmental activities, requirements, and the requirements of the region’s hospitals and transfusion services. Also, the position will maintain effective and regular communication with hospital representatives, both in the laboratory and at the administrative level. Other requirements include: Bachelor’s degree required, MBA preferred, MT degree or equivalent, 10 years’ experience in blood bank administration/management; and five years’ experience in blood banking with experience in inventory management and a working knowledge of component production issues; and five years’ experience in blood bank laboratory operations including product quality control and

quality assurance activities. Knowledge of hematology instrumentation, bacterial detection testing and environmental monitoring a plus. Equivalent combination of education and experience, working knowledge of all applicable AABB standards and FDA regulations associated with production, distribution, storage, and transportation of blood products. Understanding of employment law, OSHA requirements, departmental planning, cost accounting, and budgeting. Carter BloodCare is an EEO/Affirmative Action employer. For full posting, visit www.carterbloodcare.org.

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