Please Note: The ABC Newsletter will not be published on March 13th. We will resume regular publication on March 20th. Thank you for your continued interest.

ABC Publishes COVID-19 Resources as AABB Interorganizational Task Force Issues National Call for Blood Donors

This week, the AABB Interorganizational Task Force on Disasters issued a national news release encouraging blood donation to help stock supplies as confirmed cases of COVID-19 continued to increase across the country. The release stated, “[i]t is imperative that healthy individuals donate to minimize disruptions to the blood supply and ensure blood is available for patients. If the outbreak of coronavirus expands, additional challenges may arise, which could potentially reduce the number of eligible donors and disrupt collection events. Since it is the blood already on the shelves that saves lives, maintaining a sufficient blood supply is essential to ensure patients in need receive optimal treatment.”

Additionally, America’s Blood Centers (ABC) held a webinar to provide member blood centers with the latest information on the outbreak and preparedness strategies to help mitigate the impact of the outbreak on blood center operations. The association has also prepared several resources for member blood centers to assist their efforts in navigating and communicating the implications for blood centers to various audiences should the outbreak continue to increase.

A COVID-19 hub has been created which provides regular updates and communications from ABC, its blood community partners, and government agencies including talking points, position statements from ABC, and a link to sign-up for ABC’s COVID-19 email distribution list. In its latest statement, ABC expressed

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COVID-19 Resources (continued from page 1)

that “ABC strongly encourages all healthy individuals and sponsors of blood drives to schedule appointments and keep commitments to donate blood. Healthy eligible donors of all ages and ethnicities are needed now more than ever as the blood supply must be constantly replenished.”

Slides from the webinar and a recording are now available on the ABC COVID-19 hub. ABC will continue to monitor the outbreak and provide timely updates to member blood centers. As of March 5th, the number of cases in the U.S. had risen to 164 with 11 deaths and 19 states reporting cases.


South Texas Blood & Tissue Center Receives FDA Approval to Develop Licensed Cold-stored Platelets

America’s Blood Centers member South Texas Blood & Tissue Center has been granted approval from the U.S. Food and Drug Administration to produce licensed cold-stored platelets. This makes the organization the first blood center to receive such permission from the FDA. “We believe this breakthrough new process will increase availability of platelets and reduce expirations – in short, save more lives,” said South Texas Blood & Tissue Center Chief Operating Officer Elizabeth Waltman in a news release. “This is especially significant in light of continuing platelet shortages across the country. It also helps to keep platelets available to rural critical access hospitals so they can treat maternal hemorrhage and traumatic injury.”

The FDA approval allows South Texas Blood & Tissue Center to refrigerate platelets rather than storing them at room temperature. Cold-stored platelets are refrigerated within two hours of collection which can extend their shelf life up to 14 days in comparison to platelets stored at room temperature whose shelf life is five days. “Without the vision and assistance of all our collaborators, we would not have been able to achieve this transfusion medicine milestone,” added Ms. Waltman. “We expect to begin providing cold-stored platelets to hospital partners within the next few months.”

In November of 2019, the FDA’s Blood Products Advisory Committee (BPAC) met to discuss the use of cold-stored platelets in blood transfusion. ABC Board President Mike Parejko, chief executive officer of Mississippi Valley Regional Blood Center (Davenport, Iowa), presented the association’s position on the use of cold stored platelets in blood transfusions. He focused on the expiration date, while mentioning the constraints that blood centers are currently operating under with the short-shelf life of platelets and how long it takes to get a variance approved by the FDA.

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South Texas Blood & Tissue Center Approved for Cold-Stored Platelets (continued from page 2)

“The 30,000 deaths that happen each year are preventable. Doing some quick math that is 82 a day. That’s nearly 3.5 an hour. We’ve been here [in this meeting] for about 7 hours. Since we’ve had this discussion, 24 deaths have happened that may be preventable. I think when we look at big numbers we forget about the small sometimes. So, in the period of time that we’ve been here, 24 to 25 deaths could have been prevented,” he told the committee. Additionally, ABC voiced the views of the membership to the committee and FDA asking both entities to:

- seek data that would support use of cold stored platelets in these and other settings and not limit it only to trauma situations; and
- to think broadly in their consideration of cold stored platelets and to seek data that would support expeditious decision making by the agency once the data is available.

(Sources: South Texas Blood & Tissue Center News Release, 2/28/20 News Release, ABC BPAC Statement, 11/22/19)
RESEARCH IN BRIEF

Inhibiting Complement to Overcome Platelet Refractoriness. While, finding human leukocyte antigen (HLA)-matched platelet donors for patients in need can be challenging, a large proportion of alloimmunized patients develop platelet refractoriness. Recent data has suggested complement activation can lead to the destruction of platelets bound by HLA alloantibodies and that it may play an important role in antibody-mediated platelet refractoriness. “Eculizumab is a monoclonal antibody that binds and inhibits C5 complement.” A pilot clinical trial published in the British Journal of Haematology used eculizumab to treat HLA alloimmunized patients. This study was conducted in adult patients aged 18 to 75 years requiring transfusions for a platelet count of less than 10,000/uL without bleeding or less than 30,000/uL in the presence of active bleeding. “Patients were required to have detectable anti-HLA A and/or B antibodies and immune-mediated platelet refractoriness. They received a single intravenous infusion of eculizumab (1,200 mg) followed by the first platelet transfusion within 48 hours. Patients were defined as responding if one of the first two platelet transfusions following eculizumab resulted in a 10–60-minute Corrected Count Increment (CCI) > 7,500 together with an 18–24-hour CCI > 5,000. Total complement (CH50) was used to measure for complement inhibition. Ten HLA alloimmunized patients were enrolled (median age 39.5 years) and none of the patients had splenomegaly or had undergone a splenectomy. “After eculizumab treatment, CH50 decreased significantly to <10,000 U/L compared to a pre-treatment median of 55,000 U/L, P = 0.006. Four of 10 transfusion-refractory patients had a response with refractoriness resolving following the administration of eculizumab using CCI-based criteria. In three of four responders, the administered platelet product was HLA incompatible and no drug-related adverse events were observed. Additionally, the responders had a reduction in the requirement for platelets: mean number two weeks before and two weeks after eculizumab infusion decreased from 9.3 to 5.3. When compared to non-responders, the responders had a greater mean increment in one-hour post-transfusion platelet counts (26,000 vs. 9,400, P = 0.038) (Figure 1) and a trend towards a longer time to the next transfusion (2.5 vs. 1.4 days, P = 0.10). The authors stated that this was “the first systematic study to evaluate complement inhibition as a method to overcome platelet refractoriness.” The study showed eculizumab may allow time to acquire better or fully HLA-matched platelets or until platelet recovery. The authors called for additional larger studies.


Contributed by Richard Gammon, MD, Medical Director at OneBlood
RECENT REVIEWS

A systematic review published in *Vox Sanguinis* examined the impact of freeze-dried plasma (FDP) as a treatment in cases of major bleeding compared to the standard of care. The authors note that the limited regulatory approval of FDP as a treatment, which is currently authorized in the U.S. and France in the “military setting and austere environments only” and “for civilian care” in Germany, Norway, and Denmark. Their review included studies that used FDP in adult hemorrhagic patients that were 18 years of age and older excluding *in vitro* studies, reviews, abstracts, animal, and case studies. Using a systematic literature search, the researchers intended to perform a subgroup analysis “for studies assessing FDP for prehospital use and for those assessing in-hospital use,” but the studies were too “heterogeneous” for characteristics such as administration of blood products and confounders. They included a total of nine studies in the review, “one study was an RCT comparing FDP to fresh frozen plasma (FFP), while eight studies were nonrandomized. Of the eight nonrandomized studies, two studies had a control group: one study compared FDP to FFP and one study compared FDP + red blood cell (RBC) to whole blood. The six other studies were uncontrolled.” Based on their findings the researchers conclude that the “available research does not document a clinical benefit of FDP.” Thus, they “cannot recommend or discourage use of FDP in major haemorrhage based on the currently available research.”


BRIEFLY NOTED

Findings from the 2017 National Blood Collection and Utilization Survey (NBCUS) have been published in *Transfusion*. The data in the report includes aggregate blood collections, processing, and testing, blood and blood component transfusions, modification of components, and prices paid by hospitals for blood components in the U.S. The overall response rate for NBCUS was 94 percent (61 of 65) for community-based blood collection centers, 85 percent (92 of 108) for hospital-based blood collection centers, and 86 percent (2,435 of 2,847) transfusing hospitals. Key findings include that the number of total components transfused was 16,029,000 compare to 17,227,000 in the 2015 NBCUS and the estimated rate of life-threatening events associated with transfusion declined, while the overall rate of adverse events associated with transfusion “remained stable.” Additional findings from the current and past report are available on the U.S. Department of Health and Human Services website.


The U.S. Health Resources and Services Administration (HRSA) has published results of its 2019 National Survey of Organ Donation Attitudes and Practices. It measures and benchmarks public opinion regarding organ donation and transplantation. Information contained within the report include data on:

- current support for organ donation;
- whether individuals have signed up to be an organ donor and where;
- insights into discussion with family members about organ donation and their wish;
- beliefs about organ donation and transplantation;
- preferences of individuals to have their organs allocated by medical urgency or locally; and
- sources of information on organ donation in the past year.

The complete report, supplemental findings, and a recorded webinar are available on the HRSA website.

(HRSA Announcement, 3/4/20)
INFECTIONOUS DISEASE UPDATES

EBOLA

An end to the latest Ebola outbreak in the Democratic Republic of Congo appears to be near. The World Health Organization (WHO) announced this week that the last patient that was being treated for Ebola has been discharged. The outbreak has been ongoing for 19-months. More than 2,200 individuals died during the outbreak. The region has gone more than two weeks without a new confirmed case. According to Reuters, WHO Director General Tedros Adhanom Ghebreyesus said “[this is] very good news, not just for me, but for the whole world,” while others within the WHO cautioned that “[b]ecause of the complex security environment, Ebola transmission outside of groups currently under monitoring cannot be ruled out. A single case could re-ignite the epidemic.”

Throughout the outbreak, the Centers for Disease Control and Prevention (CDC) and the WHO did not classify the affected areas as having “widespread transmission of Ebola virus,” which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that “in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2).”

As of March 3rd, there were 3,444 confirmed cases with 2,264 confirmed deaths.

Confirmed and probable Ebola virus disease cases by week of illness onset, data as of March 3rd*

![Epidemic curve by active health zones](image)

*Excludes n=153 cases for whom onset dates not reported. Data in recent weeks are subject to delays in case confirmation and reporting, as well as ongoing data cleaning.

PEOPLE

Cerus Corp. recently named Vivek Jayaraman, MBA, Nina Mufti, PhD, and Yasmin Singh, PhD to new roles within their executive team. The announcement is part of a growth strategy to achieve greater operational effectiveness, “[t]hese promotions from within our senior leadership team are intended to create an organizational structure that is focused on the ownership of key deliverables, both commercially and across our development portfolio, and are expected to provide Cerus with the continued growth opportunities required to achieve its mission of making INTERCEPT Blood System the global standard of care in transfusion medicine,” said Cerus President and CEO William ‘Obi’ Greenman in a news release. Mr. Jayaraman joined Cerus in 2016 as the organization’s chief commercial officer and has helped the organization’s global revenues more than double in that time. In his new role of chief operating officer, he will be responsible for supply chain, customer service, and the manufacturing operations teams while continuing to lead the Cerus’ commercial efforts. Mr. Jayaraman holds a Master of Business Administration degree from the University of Pennsylvania’s Wharton School. Dr. Mufti has been named vice president of Development and Red Blood Cell Program Leader. Her career at Cerus began in 2007 as she has overseen “clinical studies in support of the premarket approval (PMA) submissions and approvals for Intercept platelets and plasma during her tenure.” In her new role, Dr. Mufti will focus on red blood cell program strategy including clinical study execution and commercial launch readiness. She holds a doctorate in Biochemical Engineering from Cornell University. Dr. Singh currently serves as the vice president of Program and Portfolio Management. In her new role as the vice president of Development and Platelet, Plasma and Therapeutics Program Leader, she will “lead the development portfolio for the Intercept platelets, plasma and therapeutics business.” Dr. Singh holds a doctorate in Pharmacology and Toxicology from University of California, Davis.

(Source: Cerus News Release, 3/2/20)

MEMBER NEWS

Sister Cities International recently awarded the Global Blood Fund (GBF), a 501 (c)(3) started by Oklahoma Blood Institute (OBI) in 2008, with its Global Leadership Award. Randal Juengel, MD, a member of both the GBF and OBI Board of Directors accepted the award on February 27th. It honored the GBF for its work in improving accessibility to safe blood worldwide. Since its inception, the GBF has “assisted dozens of blood collections agencies and hospitals in resource-poor communities around the globe improve transfusion care. It has facilitated the transfer of millions of dollars’ worth of repurposed equipment, vehicles, and supplies. It has also provided multiple donor recruitment programs and training tools to help build the donor base necessary to sustain a reliable blood supply,” according to an announcement by GBF.

(Source: GBF Announcement, 3/2/20)

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 calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!
GLOBAL NEWS

The World Health Organization (WHO) has developed an action framework to improve access to safe blood globally. The framework provides strategies that will drive organization’s aimed at coordinating and collaborating with partners worldwide towards the goal of strengthening blood systems and accessibility to safe blood products for patients worldwide. It outlines six key objectives for all countries to aspire towards including:

- “appropriately structured, well-coordinated and sustainably resourced national blood systems;
- regulatory capacity to ensure the quality and safety of blood;
- functioning and efficiently managed blood services;
- effective implementation of patient blood management to optimize transfusion practices;
- effective surveillance, hemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems; and
- partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.”

The full framework is available for download the WHO’s website.

(Source: WHO Announcement, 2/26/20; Framework, 2/19/20)

The German Red Cross Blood Donor Service Baden-Württemberg-Hessen (GRCBDS) is partnering with ERYTECH to provide red blood cells (RBCs) for ERYTECH’s development of innovative therapies according to a recent news release. “We are pleased to enter into this agreement with ERYTECH as the development of RBC-based therapeutics is a highly innovative and exciting approach,” said Erhard Seifried, medical director of the GRCBDS in the news release. “As leaders in the field of blood product procurement, we are happy to support ERYTECH as the company progresses its development plans with eryaspase and other therapeutic candidates.” This is the second alliance with a European blood provider as the company previously announced an alliance with the French blood service, French Etablissement Francais du Sang (EFS). “This strategic partnership with the GRCBDS is consistent with our long-term strategy of selectively diversifying and expanding RBC sourcing for the production of our late stage candidate, eryaspase, and other product candidates,” added Gil Beyen, chief executive officer of ERYTECH in the news release. “Importantly, this supply agreement with the GRCBDS, along with our existing agreement with EFS, provides us with a second reliable partner with sufficient scale to enable the production of clinical and initial commercial supply of eryaspase in Europe. We look forward to a productive relationship with the GRCBDS.” In November 2018, ERYTECH also announced a partnership with America’s Blood Centers member New York Blood Center.

(Source: ERYTECH News Release, 2/20/20) ♦

RESEARCH BRIEFS

America’s Blood Centers welcomes contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America’s Blood Centers. If you are interested in contributing a brief for potential publication please contact us 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 meeting also includes a day on Capitol Hill to let our voices be heard. 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 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 19-086, 12/18/19) ✨
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.)

**POSTPONED**


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2020


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 here.


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


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### ABC 2020 Meetings & Workshops

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<td>ADRP 2020 Conference</td>
<td>May 19th-21st</td>
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**Notes:** For the most up-to-date information on all events, members of ABC may check the calendar on ABC’s Member Site. Non-members may attend all events; information will be updated on ABC’s Public Site.
CALENDAR (continued from page 10)


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

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

Director, Regulatory Affairs. America’s Blood Centers (ABC), North America’s largest network of community-based, 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 self-motivated 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.

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

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POSITIONS (continued from page 11)

holidays, etc. The position is based out of the Ft. Lauderdale, Florida area. Qualified candidates should possess: minimum of 3 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 OneBlood’s Careers page at www.oneblood.org, OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.