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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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ACBTSA Explores Strengths, Weaknesses of the Blood Community's Pandemic Response & Recommendations to Ensure Sustainability of the Blood Supply

The U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) recently met to discuss what is working well in the response of blood community stakeholders to the COVID-19 pandemic, threats that have been identified, and changes that can be made in the short-term to support current response efforts as well potential needs as for any future disasters. During the day and a half meeting, the committee reviewed firsthand accounts from the blood community, including comments from America's Blood Centers (ABC) Chief Executive Officer (CEO) Kate Fry, MBA, CAE, that outlined the industry response to the public health emergency and highlighted the need to ensure both the safety and availability of blood for all patients. Stakeholders were asked to specifically address three questions:

- what worked well and the strengths that should be built upon for future public health emergencies?
- What were the weaknesses that were identified as threatening or could threaten the safety and availability of the blood supply and patient care?
- What are the top three to five recommendations to achieve in the next two to four years to increase preparedness and care for patients?

The blood community felt that the industry benefitted from internal coordinated, timely, and consistent national messaging that has been amplified at various points throughout the pandemic by federal officials and the Administration. Additionally, the formation of partnerships and coalitions such as "The Fight Is In Us" campaign, which ABC actively participated in and includes medical and research institutions, blood centers, life science companies, technology companies, philanthropic organizations, and COVID-19 survivor groups that have collaborated to support the rapid development of potential new therapies for patients with COVID-19, added increased awareness of the importance of donating to assist response efforts. Coordination between federal agencies, such as the U.S. Food and Drug Administration (FDA) and the Biomedical Advanced Research and Development Authority (BARDA), with the blood community also aided in ensuring the availability of blood and convalescent during the public health emergency. Though each of these areas have been strengths, stakeholders felt that adjustments and improvements could be made to further advance public health emergency response efforts.

Additional areas for improvement that were recurring themes from industry presenters included:

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ACBTSA Meeting (continued from page 1)

- no national real-time blood and blood product demand and supply data;
- lack of recent national disaster planning exercises;
- need for better coordination between federal, state, and local government officials to include designating blood donation as an essential service and blood center staff as essential employees;
- better supply chain preparedness; and
- expanding the donor base through additional awareness and social science research to uncover motivations for both young and minority donors.

America's Blood Centers identified specific recommendations that the committee and HHS should prioritize:

- continuous recruitment of donors;
- national, near real-time monitoring system for the U.S. blood supply
- development and funding of a comprehensive national disaster plan for the blood supply;
- and revised approval and funding pathways for novel products, tests, and technology.

A recommendation was made by the committee to form working groups that included blood community stakeholders to develop and formulate recommendations to be voted on by the committee in the next 30-45 days and presented to the Assistant Secretary for Health, Admiral Brett Giroir, MD. The working groups will focus on prioritizing specific actionable recommendations for the nation's blood system that were segmented into categories to address:

- supply chain solutions to provide blood products and ensure product availability to hospitals;
- data infrastructure and solutions;
- regulatory/public-private partnerships;
- national disaster/business continuity planning
- governance/locus authority;
- blood donor engagement, growth, and research;
- innovation; and
- financial needs.

The committee will hold its next meeting on September 25th to vote on the recommendations of the working groups. Additional details including a registration link and agenda will be posted on the ACBTSA website.

ABC also submitted written comments that are available on the ABC website.

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

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NIH Publishes Statement on Convalescent Plasma EUA from the COVID-19 Treatment Guidelines Panel

The National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel issued a statement this week regarding the emergency use authorization (EUA) of convalescent plasma after "review[ing] the available evidence from published and unpublished data on convalescent plasma for the treatment for COVID-19, including the FDA analyses that supported the EUA. The statement notes that "[t]here are currently no data from well-controlled, adequately powered randomized clinical trials that demonstrate the efficacy and safety of convalescent plasma for the treatment of COVID-19…Although [the Mayo Clinic Expanded Access Program] data suggest that convalescent plasma with high antibody titers may be beneficial in nonintubated patients, uncertainty remains about the efficacy and safety of convalescent plasma due to the lack of a randomized control group and possible confounding in the Mayo Clinic's EAP. Additionally, antibody levels in currently available COVID-19 convalescent plasma are highly variable, and assays to determine the effective antibody titers remain limited."

Citing the available evidence, the panel determined that:

- [t]here are insufficient data to recommend either for or against the use of convalescent plasma for the treatment of COVID-19;
- [a]vailable data suggest that serious adverse reactions following the administration of COVID-19 convalescent plasma are infrequent and consistent with the risks associated with plasma infusions for other indications. The long-term risks of treatment with COVID-19 convalescent plasma and whether its use attenuates the immune response to SARS-CoV-2, making patients more susceptible to reinfection, have not been evaluated;
- [c]onvalescent plasma should not be considered standard of care for the treatment of patients with COVID-19;
- [p]rospective, well-controlled, adequately powered randomized trials are needed to determine whether convalescent plasma is effective and safe for the treatment of COVID-19. Members of the public and health care providers are encouraged to participate in these prospective clinical trials; and
- [t]he Panel will continue to evaluate emerging clinical data on the use of convalescent plasma for the treatment of COVID-19 and will update the Convalescent Plasma section of the Guidelines in the near future.

(Source: COVID-19 Treatment Guidelines Panel Statement, 9/1/20)

FDA Updates CCP Guidance

The U.S. Food and Drug Administration (FDA) issued a revised guidance titled "Investigational COVID-19 Convalescent Plasma." According to the guidance, the agency intends to exercise temporary enforcement discretion for 90 days, until November 4th, regarding the investigational new drug (IND) application requirements for the use of investigational COVID-19 convalescent plasma (CCP). This allows blood centers to use investigational CCP units for 90 days while they develop the necessary operating procedures to manufacture CCP in accordance with requirements set forth in the Emergency Use Authorization (EUA). Three pathways remain available for administering or studying the use of convalescent plasma:

- Emergency Use Authorization;
- Clinical Trials; and
- Expanded Access (including Single Patient IND).

Donor eligibility criteria remains the same, though it has been clarified that for donors without a positive

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CCP Guidance Updated (continued from page 3)

diagnostic test, two different approved antibody tests are required to qualify the donor. For collection of CCP under emergency use authorization (EUA), all units must be tested using the Ortho VITROS SARS-CoV-2 IgG test. The FDA has also provided an alternate test approval pathway for other tests. Requests for alternative test should be submitted to CBER-EUA-CCP-Assays@fda.hhs.gov. Units collected before the issuance of the EUA may continue to be transfused during the temporary enforcement discretion period but must be labeled for "investigational use." Once the EUA enforcement discretion period ends, units labeled as investigational can only be used under an IND.

(FDA Guidance, 9/2/20)

RECENT REVIEWS

Diagnosis and Management of TACO In Adults and Children. According to a review in *ISBT Science Series*, "the incidence of transfusion associated circulatory overload (TACO) has increased significantly over the past years" varying from one percent to eight percent in adults." A "review of TACO in pediatric intensive care units (ICU), reported [three studies of 481 patients] with [a] variable incidence between 1.5 and 76 percent." "Cardiovascular disease, renal failure, and positive fluid balance" are all considered "risk factors" for individuals who develop TACO "Children younger than three years were reported to be at highest risk, as were adults older than 60 years." The "2017 Serous Hazards of Transfusion (SHOT) report found that "TACO occurs more commonly where transfusion is given for anemia." TACO tends to present as "respiratory distress (dyspnea, tachypnea) during or after a blood transfusion…Associated signs and symptoms are hypoxia, hypertension, tachycardia, positive fluid balance, high central venous pressure and pulmonary edema…Headache is common. The review states that "systolic and/or diastolic dysfunction…as well as elevated BNP or NT-pro BNT, is helpful for the diagnosis…[S]ome studies have found [fever]… incidences varying from 20 to 67 percent." In the absence of high-quality studies, "the optimal threshold to diagnose TACO remains to be determined in future studies in the pediatric population…The [f]irst [step for treatment is that] the blood transfusion should be stopped as soon as respiratory distress occurs or symptoms suggest TACO." The researchers also note that "[t]he patient should be positioned upright and supplemental oxygen administered. Diuretics are helpful…In more severe [cases] ventilatory support may be necessary." To prevent TACO "it is important to avoid unnecessary transfusions [that] should not be based solely on a laboratory test…A pretransfusion risk assessment (cardiovascular, respiratory, and renal function) and volume status should be done…If a transfusion is required, rapid administration…should be avoided…[P]retransfusion diuretics can be used in [adult and pediatric] patients at risk…[N]ursing supervision is mandatory to monitor vital signs [and] assess patient status…up to 24 h[ours] after transfusion for patients at higher risk." The authors conclude by stating that "[a]s TACO is the most commonly reported cause of transfusion-related mortality and major morbidity; all preventives measures should be taken to avoid it."

Citation: Gauvin, F., Robitaille, N. Diagnosis and management of transfusion-associated circulatory overload in adults and children. *ISBT Science Series*. 2020. Doi: 10.1111/voxs.12531.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

August SMT Journal Club Webinar Recording Available

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

- Cost-effectiveness evaluation of the PROPPR trial transfusion protocols (*Transfusion*);
- A case study of 10 patients administered HBOC-201 in high doses over a prolonged period: outcomes during severe anemia when transfusion is not an option (*Transfusion*); and
- Is SARS-CoV-2 transfusion transmitted? (*Transfusion*).

Additional details including the presentations and a playback of the webinar are available to ABC members in MCN 20-079.

(Source: MCN 20-079, 8/25/19)

ADRP Digital Marketing Solutions Virtual Master Class Begins in Less Than 2 Weeks

Registration is still open for the upcoming Digital Marketing Solutions Virtual Master Class. This series of three single-day events will occur over the course of three weeks and has been designed to move beyond the basics and build upon the skills needed to excel at your job while providing participants with the latest tools and trends to incorporate into their current business plans.

Not convinced? Watch ADRP President Lisa Entrikin explain why this event is essential and like no other in the industry.

August *Blood Bulletin* Now Available

ABC's Scientific, Medical, and Technical (SMT) Publications Committee, has published the August 2020 Issue (PDF or MS Word versions) of the *Blood Bulletin*, titled "An Overview of Approved CAR-T Cell Therapeutics."

The article was written by Minh-Ha Tran, DO, Clinical Professor at University of California Irvine, School of Medicine; Cham Nguyen, PharmD, Pharmacy Specialist Oncology, University of California Irvine, Department of Pharmacy; and Deepa Jeyakumar, MD Assistant Clinical Professor, University of California Irvine School of Medicine. *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 website.

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 20-075, 8/24/20)

REGULATORY NEWS

The Centers for Medicare and Medicaid Services (CMS) published guidance this week in the *Federal Register* titled "Medicare and Medicaid Programs, Clinical Laboratory Improvements (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency." This guidance establishes requirements for CLIA laboratories to report COVID-19 test results to the Secretary of Health and Human Services. The requirement is not limited to diagnostic testing and includes all "molecular, antibody, and antigen methods." The language of this rule does not appear to exclude blood centers as currently written. ABC has reached out to CMS to discuss applicability to blood centers and we will update you as soon as possible.

(Source: CMS Guidance, 9/2/20)

BREIFLY NEWS

The National Institutes of Health's National Center for Advancing Translational Sciences has provided the Vanderbilt University Medical Center (VUMC) with a $34 million grant for nationwide study examining the safety and efficacy of convalescent plasma as treatment for hospitalized patients. It will include "pregnant women, the elderly, patients with chronic heart, liver, or kidney disease and those who are immune compromised." "As doctors, we continue to lack adequate therapies to treat patients with COVID-19," said Todd Rice, MD, MSc, associate professor of Medicine and director of VUMC's Medical Intensive Care Unit in a news release. "Convalescent plasma could offer promise, but we must answer this question rigorously in a randomized trial, especially for the sickest patients at increased risk of mortality." The Passive Immunity Trial of the Nation for COVID-19 (PassItOnII) will include 1,000 participants from more than 50 sites nationwide and is expected to complete enrollment by the end of October. "Our goal is to rapidly complete a scientifically rigorous, randomized, placebo-controlled trial of anti-SARS-2 convalescent plasma to inform clinical practice," said Wesley Self, MD, MPH, associate professor and vice chair for Research in the Department of Emergency Medicine at VUMC. "We believe VUMC is ideally positioned to lead this study and help answer this critical question." ABC member Blood Assurance (Chattanooga, Tenn.) will be responsible for the collection and distribution of the convalescent plasma to participating study sites according to the release.

(Source: VUMC News Release, 8/21/20)

GLOBAL NEWS

Canadian Blood Services recently opened the first of three voluntary plasma donation collection sites aimed at increasing the nation's ability to meet its plasma needs. "We collect currently 13.5 percent of the plasma required for Canadian patients," said Teri-Mai Armstrong, business development manager for plasma operations at Canadian Blood Services, to CTV News. "The other 87 percent right now we purchase from the United States…So, it's very important for us to be more self-sustainable. The collection piece is really large and we're really counting on Sudburians to come out and feed that need and get us the collections we need to meet the targets for Canadians." In 2018, Health Canada, the nation's regulatory authority, announced the publication of a report examining the country's self-sustainability of the immune globulin (Ig) supply in which an expert panel commissioned by the agency applied an "evidence-based assessment" exploring the impact of commercial expansion of the plasma industry on the Canadian blood supply and overall sustainability of the nation's Ig supply. The findings of that report determined that a crisis did not exist in the "medium term" as supply can meet demand though efficiencies could be improved to collect more plasma and increase utilization.

(Source: CTV News, Plasma donation centre opens in Sudbury, 9/1/20)

COMPANY NEWS

BioMarin Pharmaceutical Inc. received a complete response letter from the U.S. Food Drug Administration (FDA) informing the company that its hemophilia A gene therapy candidate (valoctocogene roxaparvovec) "[indicating] that the review cycle for an application is complete and that the application is not ready for approval in its present form." According to a news release from BioMarin, the FDA made a new recommendation for two years of "follow-up safety and efficacy data on all study participants" following the completion of its phase III study. "We remain committed to the hemophilia community and to leading the way to the first ever gene therapy in hemophilia A," said Jean-Jacques Bienaimé, chairman and chief executive officer (CEO) at BioMarin. "We are surprised and disappointed that the FDA introduced new expectations for the first time in the Complete Response Letter. We are confident in valoctocogene roxaparvovec gene therapy and its potential to redefine the treatment paradigm for people with hemophilia A." BioMarin noted that the new recommendation was not part of the original data requirement specified by the FDA. Also, the gene therapy is still in the process of being reviewed by the European Medicines Agency.

(Source: BioMarin Pharmaceutical Inc. News Release, 8/19/20)

Roche and **Regeneron** have announced a partnership for the development, manufacturing, and distribution of Regeneron's REGN-COV2 antibody therapy to fight COVID-19. "We are excited about the potential for one medicine to serve both as a treatment for those infected as well as protection for people exposed to the virus." REGN-COV2 could be a critical line of defense against the COVID-19 pandemic," said Roche Pharmaceuticals CEO Bill Anderson in a news release. "We're committing our manufacturing expertise and capacity, and our global distribution network, to bring Regeneron's potential antibody combination to as many people around the world as we possibly can." The monoclonal antibody therapy is "currently being studied in two Phase II/III clinical trials for the treatment of COVID-19 and in a Phase III trial for the prevention of COVID-19 in household contacts of infected individuals." Regeneron President and CEO Leonard S. Schleifer, MD, PhD added, "Regeneron has progressed the REGN-COV2 research and development program at record speed and worked tirelessly to maximize our in-house manufacturing capacity. This major collaboration with Roche provides important scale and global expertise to bring REGN-COV2 to many more patients in the United States and around the globe."

(Source: Regeneron News Release, 8/19/20) ♦

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

Sept. 9. **10th Annual Symposium Red Cell Genotyping 2020: Visionary Solutions (Virtual attendance only).** More details available here.

Sept. 10. **39th Annual Immunohematology and Blood Transfusion Symposium. (Virtual).** More details available here.

Sept. 15. **Grifols Virtual Transfusion Science Educational Course**. More information available here.

Sept. 16, 23, 30. **ADRP Digital Marketing Solutions Virtual Master Class.** More details available here.

Sept. 25. **HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Meeting (Virtual).** More details available here.

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CALENDAR (continued from page 7)

Oct. 3-5. **2020 AABB Annual Meeting (Virtual).** More information available here.

Oct. 27. **Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2020 (Virtual).** More information available here.

Nov. 22-24. **2020 ADRP Conference, Phoenix, Ariz.** More details available here.

2021
Mar 8-10. **ABC Annual Meeting, Washington, D.C.** More details coming soon.

June 25-26. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details coming soon.

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany.** More details available here.

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

Manager of Immunohematology Reference Laboratory (St. Paul, MN). Primary duties are to coordinate and supervise all activities in the Immunohematology Reference Laboratory (IRL) and the Reagent Donor Program (RDP). IRL responsibilities include overseeing clinical laboratory testing procedures, management of rare blood inventory, and supervision of laboratory staff. In addition to immunohematology testing this position is also responsible for red cell and platelet genotyping for characterizing donor genotypes and to assist with serology patient work ups. Provides expertise and consulting leadership within the Enterprise. RDP responsibilities include supplying manufacturers of immunohematology reagents with red cells and plasma. Provides excellent customer to the reagent vendors and oversees the recruitment of donors for patients and the RDP. Qualifications: Medical Technologist MT (AMT) or Medical Laboratory Scientist MLS (ASCP). Five years relevant technical experience working in an Immunohematology Reference Laboratory. Three-year experience in supervising others. Specialist in Blood Banking (SBB), or SBB eligible. **Other:** Excellent oral and written communication skills. Ability to work independently organizes and prioritize duties and occasionally work irregular hours. Excellent interpersonal, communication and leadership skills. Understanding of red cell and platelet serologic methods. View full job descriptions on innovativebloodresources.org/careers/. EEO Employer

Outside Sales Representative/Event Planner (Ardmore, Okla., USA). Account Consultants/Outside Sales Representatives must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, 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/.

Quality Assurance Specialist (Bradenton, FL). SunCoast Blood Centers is accepting applications for a Quality Assurance Specialist to work at our Lakewood Ranch Head Quarters. This position performs duties in all areas of the quality assurance program, including, but not limited to error management, document control, lookback

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POSITIONS (continued from page 8)

activities, and auditing. Other duties include: Acts as a liaison for external inspections. Conducts required annual staff trainings and maintains blood bank training files. Performs validations prior to implementation of new processes, equipment, or software version updates, and other duties as assigned. Qualified applications should possess a bachelor's degree in Medical Technology or equivalent experience. Prefer applicant to have MT licensure, but not required. Applicant must have three years blood center production or clinical laboratory experience plus two years medical administration or other medically related experience. To apply and view a complete Job Description of this position please visit https://www.scbb.org/careers.html. EOE. Applicant drug testing required.

Operations Manager. Blood Assurance is seeking an Operations Manager to manage our collection efforts in the greater Nashville, TN and surrounding areas. This position will be responsible for operational oversight of collection services for multiple collection teams in an assigned territory. Supervises staff in coordination with other department leaders and ensures compliance with all Standard Operating Procedures, FDA and AABB regulations. Monitors performance in the areas of productivity, proficiency and customer service. A bachelor's degree with some prior supervisory/management experience in blood banking is required. Advanced skills in leadership, teamwork, analytics and communications are also required. Blood Assurance offers a competitive base wage with healthcare benefits and a 401K retirement plan. Qualified candidates are encouraged to submit an online employment application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

Chief Medical Officer (Associate Professor, Full Professor). The University of Washington, Department of Laboratory Medicine and Pathology and Bloodworks Northwest is accepting applications for Chief Medical Officer (Associate Professor, Full Professor). This position involves overall responsibilities for providing medical direction and support for all aspects of Bloodworks' activities. The position requires licensure as a physician (M.D. or D.O.) and board certification in Blood Banking/Transfusion Medicine. In lieu of board certification, candidates who meet the requirements for CLIA laboratory director with 3 years' experience in blood collections, immunohematology, apheresis, and cellular therapy will also be considered. University of Washington faculty engage in teaching, research, and service. Please apply at https://usr58.dayforcehcm.com/CandidatePortal/en-US/bloodworks/. EO employer – M/F/Vets/Disabled