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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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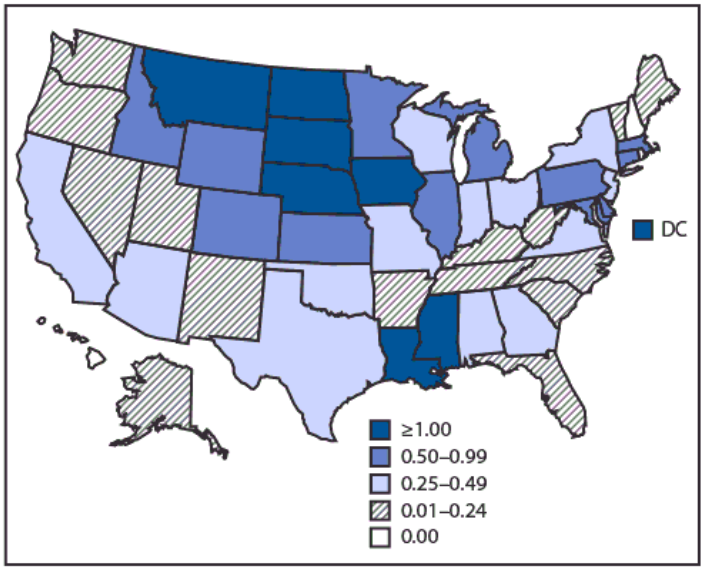
2019 #27 **August 16, 2019**

INSIDE:

CDC Data Shows Cases of West Nile Virus Increasing

Arthropod-borne viruses (arboviruses) are transmitted to humans by bites from infected arthropods such as mosquitoes or ticks, with West Nile virus being the most common cause of domestically acquired arboviral disease in the U.S. "Most human infections are asymptomatic; symptomatic infections commonly manifest as a systemic febrile illness and less commonly as neuroinvasive disease."



Graphic courtesy of MMWR and shows incidence of reported cases of West Nile virus neuroinvasive disease — U.S., 2018 per 100,000 population.

The Centers for Disease Control and Prevention (CDC) recently published "West Nile Virus and Other Domestic Nationally Notifiable Arboviral Disease – United States 2018" in the *Morbidity and Mortality Weekly Report* (MMWR) for August 9th. According to 2018 data, incidence of West Nile virus was close to 25 percent higher than the median incidence from 2008-17.

The report describes CDC surveillance data on nationally notifiable arboviruses excluding viruses that are considered nondomestic such as dengue, chikungunya, and Zika. West Nile virus accounted for 94 percent of U.S. arboviral cases in 2018 (2,647 of 2,813) and occurred in 48 states and the District of Columbia. Sixty-three percent of these cases (1,658) were designated as neuroinvasive disease (e.g. meningitis, encephalitis, and acute flaccid paralysis), which equates to a national incidence rate of .51 cases per 100,000 population, compared to .41 as the median incidence for the previous 10-year period, as 92 percent of patients experienced illness at onset.

(continued on page 2)

CDC Reports Increase in WNV (continued from page 1)

The median age of West Nile patients was 59 years old, and 62 percent of all cases were in males. Overall, 1,774 (67 percent) of infected persons were hospitalized with West Nile virus and 167 of them (6 percent) died. Of the 1,658 cases of West Nile virus neuroinvasive disease cases reported, 908 (55 percent) of patients had encephalitis, 542 (33 percent) had meningitis, and 70 (4 percent) had flaccid paralysis with the remainder considered an unspecified neurologic presentation. One hundred sixty-five (10 percent) patients with neuroinvasive disease died. The highest reported rates of incidence were in North Dakota, Nebraska, South Dakota, Montana, and Iowa.

The authors note that, "[a]lthough the reported number of cases varies annually, arboviruses continue to cause substantial morbidity in the United States. Cases occur sporadically, and the epidemiology varies by virus and geography. Approximately 93 [percent] of arboviral disease cases occurred during April–September in 2018, which is consistent with the peak season in past years." They acknowledge that limitations of the report include:

- ArboNET being a passive surveillance system that underreports the actual incidence of disease; and
- cases might have the wrong classification due to ArboNET not requiring information on clinical signs and symptoms, or lab findings.

(Source: CDC MMWR, 8/9/19)

RECENT REVIEWS

Authors in the *Journal of the American Medical Association* (*JAMA*) reviewed the "reemergence" of extracorporeal life support (ECLS) in adults with respiratory failure. They conducted a search of literature prioritizing clinical trials, large longitudinal observational studies, and recent articles basing their selections on the merits of the articles' contributions to current practice of ECLS or ongoing research questions assessing implications for the effect of ECLS on past, present, and future patient outcomes. Based on their findings, they conclude that while technological advances "[hold] the promise of changing the approach to treatment for respiratory failure, and while the role of ECLS will no doubt continue to grow, the need for high-quality research to guide this growth has never been greater."

Citation Brodie, D., Slutsky, A., Combes, A. Extracorporeal Life Support for Adults with Respiratory Failure and Related Indications. *JAMA*. 2019. Doi: 10.1001/jama.2019.9302.

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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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REGULATORY NEWS

The U.S. food and Drug Administration (FDA) published a notice acknowledging a shortage of immune globulin (IG) products that could potentially impact patient care. It stated that while the FDA does not have "legal authority" to require companies to manufacture or increase production of drugs, the agency does work with companies to "mitigate shortages" when it becomes aware of them. "The Agency is working very closely with the applicants/manufacturers [to help] mitigate the supply situation for IG products as best as possible. It is also working with industry in exploring ways to improve the manufacturing yield of IG products, which are derived from donor plasma. In addition, the FDA has been informed by the Plasma Protein Therapeutics Association (PPTA) that they have been working with some manufacturers of IG products, to assist healthcare providers in obtaining specific products needed by patient(s)." The agency also acknowledged that the shortage could alter the treatment practices of healthcare providers by causing them to prioritize which patients would receive IG treatments. The FDA encouraged hospitals and medical systems to:

- develop evidence-based approaches that drive decision-making; and
- to consider adding another IG product contract if a facility currently only has one.

The *Wall Street Journal* featured an article that examined the shortage, potential causes, and described the story of patients and their families that are being impacted by the shortage. "My concern is the risk of her getting an infection now and it causing a flare [up] because she doesn't have IVIG (intravenous immune globulin) to keep her symptoms at bay," said Angela Swan to the *Wall Street Journal* concerning the plight of her 3-year-old daughter who relies on IG treatments regularly. Some manufacturers believe the shortage is due to the combination of "increased demand [for IG] combined with the length of time it takes to produce plasma-derived products…[this] has led to [a] very tight supply and, in some cases, supply interruptions for certain products across the U.S. market."

(Sources: FDA Notice, 8/12/19; *Wall Street Journal*, Drug shortage leaves patients without immune-disorder treatment, 8/9/19)

The National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) has announced the "Sickle Cell Science: Path to Progress" webinar series. It will take place throughout the month of September as the agency recognizes Sickle Cell Awareness Month with a weekly webinar each Wednesday. Registration is open and free as the webinars aim to "address some the educational and informational needs expressed by patients, family members, researchers, health care providers, and others in the sickle cell disease community. The webinar series will cover implementation efforts in the U.S. and worldwide, genetic therapies, bone marrow transplants and other therapies, and progress in pain management." Topics include:

- Serving the Sickle Cell Disease Community Here and Abroad (9/4)
- Genetic Therapies in Sickle Cell Disease (9/11)
- Bone Marrow Transplants, Other Therapies, and Sickle Cell Disease (9/18)
- Sickle Cell Disease Care in the Emergency Department: Improvement Initiatives and Ongoing Research (9/25).

(Source: NHLBI Announcement, 8/14/19)

Upcoming ABC Webinars – Don't Miss Out!

- **SMT Journal Club Webinar** – August 19. Additional details available to ABC members in MCN 19-054!
- **ADRP AABB Standards and Accreditation in Plain English Webinar** – August 22. Register here!

New Therapies for an Old Disease

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Please note: 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.

Acquired thrombotic thrombocytopenia purpura (aTTP) is characterized by microangiopathic hemolytic anemia, thrombocytopenia and severe autoantibody-mediated deficiency of a disintegrin and metalloprotease with thrombospondin type 1 repeats and, member 13 (ADAMTS13). This results in microthrombi within the microcirculation. Therapeutic plasma exchange (TPE), by removing autoantibodies and excess ultra-large von Willebrand factor (vWF) multimers and replenishing ADAMTS13 activity with plasma, remains the first-line treatment. It has improved survival from 10 percent to 80 percent. Despite current therapies, approximately 13 percent of patients are refractory (no response by Day 30 or no durable response by Day 60 of treatment). Furthermore, 30-50 percent eventually relapse (recurrent thrombocytopenia within 30 days or a TTP event after 30 days).

Immunosuppressive therapies such as steroids are routinely initiated with TPE to suppress autoantibody production, with prednisone found superior to cyclosporine for suppression of anti-ADAMTS13 and increasing its activity. Rituximab, an anti-CD20 monoclonal antibody was initially administered as adjunct therapy in refractory aTTP patients. While an observational study, a phase 2 clinical trial and retrospective and cohort and observational studies showed shortened hospitalization, lowered relapse rate and increased time to relapse, these studies were not randomized and possibly had suboptimal study designs and confounding factors. As less than half of aTTP patients relapse without this medication, a strategy to reduce risk of overtreatment may entail identifying and targeting patients with higher relapse risk (e.g., ADAMTS13 activity <10 percent and/or recurrence of anti-ADAMTS13 antibody). Other immunomodulatory therapies being studied include bortezomib, a proteasome inhibitor that may trigger apoptosis in differentiated plasma cells persistently producing anti-ADAMTS13 autoantibodies. A small number of case reports described this drug to be effective in refractory TTP patients failing multiple prior therapies.

More recently therapies are being developed targeting vWF. Caplacizumab is a recently U.S. Food and Drug Administration (FDA)-approved nanobody that binds to the A1 domain of vWF to inhibit its interaction with the platelet glycoprotein Ib-IX-V receptor, thus diminishing platelet aggregation and microthrombi formation. Phase 2 and 3 trials of adding caplacizumab to first line therapy (TPE + steroids/rituximab) showed promise and demonstrated quicker platelet normalization times and lower recurrence (exacerbation and relapse) rates. The caplacizumab group also had reduced numbers of TPE procedures, decreased hospital stays, and lowered thrombotic rates compared to placebo. Anfibatide, a snake venom-derived platelet GP1b receptor antagonist, also inhibits vWF-platelet interaction. In murine (mice) TTP models, platelet aggregation was inhibited. N-acetylcysteine (NAC) targets vWF by cleaving disulfide bonds within ultra-large vWF multimers to reduce vWF size. In case studies, adjunct NAC was associated with normalized platelet function and ADAMTS13 activity, but these results were confounded by concomitant use of other adjunct drugs. A pilot study was completed on three patients, but results are pending.

Recombinant ADAMTS13 (rADAMT13) may diminish the transfusion reactions and risks associated with plasma replacement. A Phase 1 clinical trial with rADAMTS13 in congenital TTP found increased ADAMTS13 levels as well as reduced ultra-large vWF-multimers. No anti-ADAMTS13 antibodies developed during the 30-day follow-up. rADAMTS13 treatment may also benefit aTTP. *In-vitro* incubation of plasma from aTTP patients with high concentrations of rADAMTS13 increased ADAMTS13 activity. A study is underway to evaluate the pharmacokinetics, safety, and efficacy.

(continued on page 5)

New Therapies for an Old Disease (continued from page 4)

The authors concluded that prognosis of aTTP has significantly improved with initial therapy of TPE. Use of upfront immunosuppressive drugs, therapies targeting vWF and rADAMTS13 may further diminish morbidity and mortality in the future.

Citation: Racine-Brzostek, S., Shi, P. Emerging roles of adjunct therapies in acquired thrombotic thrombocytopenia purpura. *Transfusion.* 2019. Doi: 10.1111/trf.15438.

Vitamin K Causes Yellow Plasma

A 54-year-old male patient with left lower extremity pain and swelling arrived at the Emergency Department. During the examination, a spontaneous case of epistaxis occurred. The International Normalized Ratio (INR) was greater than 8.18 (normal 0.85-1.15). 10 mg of intravenous phytonadione (vitamin K) (AquaMEPHYTON) was used in the treatment of the patient's supratherapeutic INR. Anticipating a plasma transfusion, a type and screen was sent to the blood bank laboratory. A bright yellow discoloration of the plasma was observed after centrifugation. Further investigation revealed that the type and screen was drawn concurrently with the administration of intravenous vitamin K. The package insert stated AquaMEPHYTON injection was "a yellow, sterile, aqueous colloidal solution of vitamin K available for injection." The authors believed this was the first case of intravenous vitamin K resulting in plasma discoloration.

Photo courtesy of Transfusion.

Citation: Karp, J.K., Piacentino, J., et al. Intravenous vitamin K as a cause of bright yellow plasma discoloration. *Transfusion*. 2019. Doi: 10.1111/trf.15342. ♦

WORD IN WASHINGTON

A cybersecurity report from the U.S. Government Accountability Office (GAO) has been published that addresses the need for federal agencies to create risk management programs in the face of growing cybersecurity threats. It denotes several specific recommendations for the U.S. Department of Health and Human Services (HHS) including that agency:

- develop a cybersecurity risk management strategy featuring elements from in the report;
- update the agency's policies to require a cybersecurity risk assessment that tailors security controls;
- create a process for conducting the security risk assessment; and
- establish and document a process for coordination between cybersecurity risk management and enterprise risk management functions.

HHS responded to the report with written comments stating, "HHS is working actively with a broad coalition of partners to enhance cybersecurity within the agency and across the Healthcare and Public Health Sector. HHS continues to work across the sector to raise awareness for the cybersecurity threats and tackle the shared challenges collaboratively. HHS is committed to the security and resiliency of the agency and healthcare community."

(GAO Report, 7/25/19) ♦

MEMBER NEWS

Unyts (Williamsville, N.Y.) has re-branded and become **ConnectLife**. According to a recent announcement, the rebrand is meant to better encompass everything that the organization does to assist its community, while sharing the story of the lives both saved and enhanced by the organization's work. "We wanted a name that better represented what we do, which, at its core, is connecting families, neighbors, and communities," stated the frequently asked questions document. "ConnectLife emerged as the name that was best associated with not only connecting people through blood, organ, eye, and tissue donation, but also conveying a sense of warmth, caring, optimism, and hope." Additional information is available on ConnectLife's new website. "We're the same trusted organization reborn with a greater effort to encourage our community to get involved," said ConnectLife Board Chair Martha Lamparelli in an article published by *Niagara Frontier Publications*. "Alongside our partners and neighbors, our impact can be boundless."

(Sources: ConnectLife Announcement, 8/15/19; *Niagara Frontier Publications*, Unyts is now ConnectLife, 8/15/19)

Community Blood Center (Dayton, Ohio) has reported more than 1,700 donors, with 171 being first-time, have signed-up to give blood following the tragic mass shooting in Dayton's Oregon District. "I live in the Oregon District," said donor Jessica Busker in a blood center news release, who donated in the wake of the shooting for the first time. "I've been thinking about it. When the shooting happened, I wanted to make sure I did." The blood center also hosted a "Dayton Strong Blood drive on August 9th that resulted in close to 150 individuals donating. On the day after the shooting, almost170 individuals presented to donate, a group that included the state's Lieutenant Governor Jon Husted, along with Congressional members Rep. Tim Ryan (D-Ohio) and Sen. Rob Portman (R-Ohio).

(Community Blood Center News Release, 8/12/19)

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.

BRIEFLY NOTED

Ambrosia, the company that offered the controversial plasma infusions from young donors claiming it helped with health and aging, has ceased operations once again according to a report from *Business Insider*. The company's founder Jesse Karmazin appears to be starting a new venture called Ivy Plasma which "will provide transfusions not limited to those from young people," states the *Business Insider* article. Mr. Karmazin added, "[t]he FDA considers age-specified plasma (i.e. young plasma) to be a new drug. Ivy Plasma is not offering young plasma, only plasma." Earlier this year, the FDA warned the public about the claims of establishments that offer plasma infusions from young human donors to treat aging and ailments such as dementia and Parkinson's disease. Several establishments had opened around the U.S. marketing the supposed benefits of young plasma infusions, which concerned the FDA. In the February 19th joint statement released from former FDA Commissioner Scott Gottlieb, MD and director of FDA's Center for Biologics Evaluation and Research (CBER) Peter Marks, MD, PhD, the FDA stated "[t]here is no proven clinical benefit of infusion of plasma from young donors to cure, mitigate, treat, or prevent these conditions, and there are risks associated with the use of any plasma product…Our concerns regarding treatments using plasma from young donors are heightened by the fact that there is no compelling clinical evidence on its efficacy, nor is there information on appropriate dosing for treatment of the conditions for which these products are being advertised. Plasma is not FDA-recognized or approved to treat conditions such as normal aging or memory loss, or other diseases like Alzheimer's or Parkinson's disease. Moreover, reports we're seeing indicate that the dosing of these infusions can involve administration of large volumes of plasma that can be associated with significant risks including infectious, allergic, respiratory and cardiovascular risks, among others." Ambrosia previously shutdown in the wake of the FDA letter, but had resumed operations in two cities (San Francisco, Calif. and Tampa, Fla.) according to a June report from *Business Insider*.

(Sources: *Business Insider*, The founder of a startup that charged $8,000 to fill your veins with young blood says he's shuttered the company and started a new one, 8/14/19; *Business Insider*, A controversial startup that charges $8,000 to fill your veins with young blood and halted operations after an FDA warning now says it's back up and running, 6/17/19; *FDA* Advisory, 2/19/19; Scott Gottlieb, MD & Peter Marks, MD, PhD Joint Statement, 2/19/19) ♦

COMPANY NEWS

GenCure, a subsidiary of BioBridge Global, announced completion of production runs that expanded and harvested human mesenchymal stem cells (hMSCs) in an 80-liter bioreactor. "This is a tremendous step in advancing new therapies in cell therapy and regenerative medicine," said GenCure Chief Operating Officer Becky Cap in a news release. "In cell therapy, you need large numbers of cells per batch to create clinical doses that are consistent to give to multiple patients. With this bioreactor technology, you can increase the number of patients treated with a single, consistent production run, by tenfold." GenCure and RoosterBio, Inc. partnered on the development and implementation of the process that is compliant with current good manufacturing practice (cGMP) standards. According to the release, "[t]he harvest was the first series of runs in which a 50-liter batch of approximately 1 billion bone-marrow-derived hMSCs were expanded to tens of billions within a 10-day timeframe."

(Source: GenCure New Release, 8/13/19) ♦

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!

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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.

ADRP Webinar: AABB Standards and Accreditation in Plain English

Register for the Thursday, August 22nd ADRP Webinar entitled "AABB Standards and Accreditation in Plain English." This webinar will take place at 1 p.m. eastern and feature Anne Chenoweth, senior director of Accreditation and Quality at AABB. Attendees will receive information explaining the rationale for AABB Standards and how they are set and revised. Additionally, they will learn how to use the AABB accreditation process for both risk mitigation and peer to peer performance improvement, while discovering ways to use the standard process and the assessment to improve the performance of an organization. ADRP subscribers may register for free and non-subscribers can participate for $25.

(ADRP Announcement, 8/12/19)

Updated Disaster Response Plan

ABC and Blood Centers of America, Inc. (BCA) have reviewed and updated disaster plans and documents. Version 2.0 of the ABC/BCA Disaster Plan is available and has been amended to reflect industry changes over the past decade. The previous Disaster Plan depended on the use of the ABC Hub and Spoke system which no longer fit the current need due to mergers and consolidations within the industry. In lieu of the Hub and Spoke system, operational responses to disasters will continue to be coordinated by BCA with regulatory and communication support provided by ABC. The ABC/BCA Disaster Plan Version 2.0 reflects these changes. We strongly encourage members to review the plan with your internal teams to acquaint yourself to the process and incorporate into your own disaster plans. The disaster page on the ABC Member site contains links to various documents that have been updated as appropriate to assist members in disaster planning and response.

(Source: MCN 19-052, 7/19/19)

August SMT Journal Club Webinar Articles Announced

The ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar on August 19th at noon EDT will feature the articles below:

- Financial impact of alternative approaches to reduce bacterial contamination of platelet transfusions (*Transfusion*);
- Response to random apheresis platelets versus HLA-selected platelets versus pooled platelets in HLA-sensitized patients (*Transfusion*); and
- Platelets stored in whole blood at 4 C: in vivo posttransfusion platelet recoveries and survivals and in vitro hemostatic function (*Transfusion*).

Additional details are available to ABC members in MCN 19-054.

(Source: MCN 19-054, 7/25/19)

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INSIDE ABC (continued from page 8)

July *Blood Bulletin* Available

ABC's Scientific, Medical, and Technical (SMT) Publications Committee has published the July 2019 Issue **(PDF or MS Word versions)** of the *Blood Bulletin*, titled "Using Group A Plasma to Support Emergently Bleeding Patients."

The article was written by Jonathan Hughes, MD, Medical Director at Vitalant and Chris Gresens, MD, Senior Chief Medical Officer, North & West Divisions at Vitalant. *Blood Bulletin* is reviewed and edited by ABC's SMT Publications Committee.

ABC publishes the *Blood Bulletin* for you to use in your educational programs as a value-added service for hospital customers.

(Source: MCN 19-055, 7/26/19)

ABC 2020 Meetings & Workshops

Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9th-11th	Washington, DC	Ritz-Carlton (Pentagon City)	More details coming soon!
ADRP 2020 Conference	May 19th-21st	Phoenix, AZ	Hyatt Regency	More details coming soon!

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

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2019

Sept. 13. **Carter BloodCare 2019 Enrichment Lab, Euless, Texas.** A continuing education program designed for medical technologists and clinical laboratory specialists, interested in transfusion medicine. Attendees can earn up to 6 hours of P.A.C.E.® credit. More details available here.

Sept. 19. **National Institutes of Health Clinical Center Immunohematology and Blood Transfusion 38th Annual Symposium, Bethesda, Md.** More details available here.

Sept. 20. **Red Cell Genotyping 2019: Patients First, Bethesda, Md.** This 9th annual symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. More details available here.

Sept. 23-25. **The MedTech Conference, powered by AdvaMed, Boston, Mass.** More details available here.

2020

Mar. 9-11. **2020 ABC Annual Meeting, Washington, DC.** More details coming soon.

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CALENDAR (continued from page 9)

May 13-14. **IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens", Porto, Portugal.** More details available here.

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details coming soon.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Director, Blood Collection Operations (The Community Blood Center, Appleton, WI). Are you looking for a meaningful career creating a culture of highly-engaged staff, collaborating to provide customers with exceptional service? Our organization is looking for a dynamic leader for our blood collection team. You will coach and engage a team of 60 staff, create and implement systems and processes to provide outstanding service and be part of a team of professionals united in the mission of Connecting Lives | Sharing Life. Responsible for oversight of the activities of Collections staff and ensuring all processes are compliant and safe. Oversight consists of allocation of resources, monitoring, correcting, improving and updating all technical, regulatory, administrative, and personnel functions. Responsible for accomplishment of key department and organizational objectives including assigned goals, operational productivity targets, compliance measures and staff engagement metrics. Ensure compliance with quality control functions, documents and industry regulations. Develop plans to maintain or adjust operations as needed based on financial forecasting. Requires a bachelor's degree and 10 years management experience, ideally with increasing levels of responsibility. Medical background or blood center experience desired. Excellent leadership, staff development and team building skills. High level of data analysis skills. How to apply: https://www.communityblood.org/careers.

Medical Apheresis RN/Nurse (Houston, Texas). Gulf Coast Regional Blood Center is looking for a Medical Apheresis RN/Nurse for its newly expanded, state-of-the-art apheresis center. This person is responsible for patient/donor care during apheresis procedures and must be able to apply the nursing process with patients and donors. Duties include assisting in the development of new procedures, performing required equipment maintenance, evaluating and maintaining technical procedures, communicating with physicians regarding patient status, remaining current on national standards and trends in the area of apheresis and making appropriate suggestions as to necessary changes or updates, maintaining all records required by AABB, FDA and other accrediting agency or vendor standards, participating in management and coordination of clinical research studies if necessary. Qualifications for this position are: a graduate degree from an accredited School of Professional Nursing, a current RN license, three years of recent direct patient care nursing experience (preferably in an acute-care setting), demonstrated proficiency in peripheral intravenous access, certification in Basic Life Support or ACLS (Advanced Cardiovascular Life Support). For more information or to apply, click here. Contact name, address and telephone number: Tracy Reynolds Talent Acquisition Manager, 1400 La Concha Lane, Houston, Texas 77054-1802; Phone: (713) 791-6395.

Medical Technologist II - San Francisco, CA (Req:191052). Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Founded in 1943, Vitalant is one of the nation's oldest and largest nonprofit transfusion medicine organizations. Bachelor's degree in a chemical, physical, biological, medical technology or clinical laboratory science required. Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. CA Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. SBB preferred. State licensure (as required by regulations). Three years' experience in a clinical laboratory setting required or SBB. Experience in developing and conducting formal training preferred. Please click here to apply.

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine

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POSITIONS (continued from page 10)

clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. Service and teaching responsibilities will be shared with three other full and part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ233, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Quality Assurance Director (Oklahoma City, OK). The Oklahoma Blood Institute, the nation's fifth largest blood center and Oklahoma's largest Bio-Tech company, has an immediate opening for a director for our quality assurance systems. This position will provide direct supervision for quality systems consultants, promote a quality culture within the organization and ensure that policies, procedures, processes, work instructions and training programs comply with industry standards and regulatory requirements. The position also ensures that the firm's quality plan and objectives are implemented throughout each phase of blood/tissue manufacturing and clinical services. Qualifications: Requires a Bachelor of Science degree in medical technology or related field and eligible for registration with the ASCP; minimum of five years' experience in managing quality systems; strong written and verbal communication skills. Salary Range: Competitive salary, relocation package is possible, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, tuition reimbursement and holiday pay. How to Apply: http://obi.org/careers/.

Quality & Regulatory Affairs Specialist. The Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the general supervision of the Director of Quality and Regulatory Affairs, this position will perform the quality and regulatory affairs duties and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, validations, and assist with development, as necessary. Develop, perform and report departmental, system audits, and safety inspections. Perform Good Manufacturing Practice (GMP) and safety training, trend analysis of events and quality indicators, root cause analysis, process improvement, corrective and preventive actions; maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports, when required. Core Duties include: Review validation plans, procedures, training documents, PDIF records, product and equipment QC for regulatory compliance and assist with development and training as necessary. Develop, perform and generate departmental reports and system audits. Develop, revise, institutional QRA SOPs and training. Perform GMP, QRA and safety training. Perform trend analysis of events, complaints, and quality indicators with subsequent performance of root cause analysis, and process improvement. For complete job description and to apply, visit www.stanfordhealthcarecareers.com and reference job # 51343

Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified 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. We have two openings; one based out of the Jacksonville, Florida area and the other based out of the Ft. Lauderdale area, both locations have some of the most gorgeous beaches in the nation! If you want to join our life saving 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.