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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

Please Note: The *ABC Newsletter* will not be published on August 5th. We will resume regular publication on August 12th. Thank you for your continued interest.

2022 #27 **July 29, 2022**

INSIDE:

CBER Announces New Variance Approvals

The Centers for Biologics Evaluation and Research (CBER) within the U.S. Food and Drug Administration (FDA) has announced newly approved variances this week in the "Exceptions and Alternative Procedures Approved Under 21 CFR 640.120(a)." The document is available on the FDA website. It includes several variances of note that were approved January-June 2022:

- cold stored platelets;
- 24-hour cryoprecipitate;
- processing height requirement modification for the leukoreduction of red blood cells; and
- approval to release a rare source plasma unit collected from a donor with factor XIII deficiency, for which the serum protein electrophoresis (SPE) and serological test for syphilis (STS) were not performed.

ABC will continue to review the document in consultation with the Quality Blood Regulatory Subcommittee and provide any updates as they become available. Please contact ABC Director of Regulatory Affairs Jill Mastin with any questions or comments.

(Source: CBER Announcement, 7/29/22)

CMS Issues CLIA Fees Proposed Rule

The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule titled "Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories." According to CMS, the proposed rule "would update the Clinical Laboratory Improvement Amendments of 1988 (CLIA) fees and clarify the CLIA fee regulations. This proposed rule includes a proposal to provide "sustainable funding for the CLIA program through a biennial two-part increase of CLIA fees; incorporating limited/specific laboratory fees, including fees for follow-up surveys, substantiated complaint surveys, and revised certificates; distributing the administrative overhead costs of test complexity determination for waived tests and test systems with a nominal increase in Certificate of Waiver (CoW) fees; and clarifying the methodology used to determine program compliance fees."

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CMS Proposed Rule (continued from page1)

The agency also stated that the proposed rule, "would ensure the continuing quality and safety of laboratory testing for the public. This proposed rule would also amend histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes. In addition, this proposed rule would amend the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite state monitoring) to allow for the imposition of such sanctions on CoW laboratories."

Comments on the rule are due by 5 p.m. EDT on August 25th. ABC continues to review the proposed rule and will provide any updates as they become available. Please contact ABC Director of Regulatory Affairs Jill Mastin with any questions or comments.

(Source: CMS Proposed Rule 7/28/22)

WORD IN WASHINGTON

Rep. Pete Aguilar (D-Calif.) recently visited ABC member LifeStream Blood Bank to donate blood. His visit and blood donation come in the wake of regional shortages experienced by the blood bank. "The Inland Empire needs our help," said Rep. Aguilar in a news release. "There is a critical blood shortage in our community which could be dangerous for Inland Empire residents who get sick. I am asking everyone who can, to please find time this week to help save lives by donating blood."

(Source: Rep. Pete Aguilar News Release, 7/25/22)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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 health care 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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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.

Last Call to Register for ABC Summer Summit — Virtual or In-person

Working Conversations' Janel Anderson, PhD will be the keynote speaker at the ABC Summer Summit in August. Dr. Anderson will continue ABC's focus on workforce-specific conversations. As blood centers continue to face increased turnover and retention challenges, it is more important than ever to develop programs to identify and nurture the emerging leaders already within your organization. She will address:

- the research behind the business case for organizational talent development programs;
- the difference between leading with a capital 'L' versus a lower case 'l'; and
- strategies to create comprehensive development programs.

Registration remains open for the ABC Medical Directors Workshop and ABC Summer Summit taking place August 2-4 in Minneapolis, Minn. and being livestreamed for those who cannot attend in-person. A program is available. Over the course of three days, attendees will hear case study rounds, engaging discussions, and have many networking opportunities to connect with peers and colleagues.

(Source: MCN 22-062, 7/15/22)

RESEARCH IN BRIEF

The Current Role of Premedication to Prevent Transfusion Reactions. A study in *Vox Sanguinis* was designed "to realize the overall incidence of transfusion-associated adverse reactions (TAARs) and the premedication rate before transfusion in Taiwanese, [and] to evaluate whether there was a relationship in the frequency of TAARs with the administration of transfusion premedication." The investigators also examined "whether the introduction of an educational program could improve the understanding of physicians related to the unnecessary use of premedication…This [was] a retrospective study that included outpatients who received transfusions from April 2017 to October 2018…The program on evidence-based transfusion was provided [from] December 2017 to February 2018 to educate physicians related to the unnecessary use of premedication." The study included "[a] total of 5,018 units [transfused] to 803 outpatients…The most frequently transfused component was leukocyte-reduced packed red [blood] cells (n = 4,338), followed by leukocyte-reduced apheresis platelets (n = 540)…According to the number of transfusions, 290 events (11.6 percent) were first-time transfusions, 493 events (19.8 percent) were second to fourth transfusions, while 1,708 (68.8 percent) were fifth or more transfusions…Additionally, 335 events (13.4 percent) were transfusions to patients with history of TAARs." The authors explained that "[p]remedication[s] includ[ed] the use of antipyretics (14.3 percent), antihistamines (56.0 percent) and steroids (37.6 percent)…In the study, 28 events of TAARs were reported: 10 febrile non-hemolytic transfusion reactions (FNHTRs) and 18 minor allergic reactions (MARs)…Among these, one FNHTR and four MARs did not have premedication…The premedication rate was 92.4 percent before the educational program and decreased to 76.7 percent after [completion] ($p < 0.001$)." The study found that "[i]mportantly, it seemed that the occurrence of TAARs per transfusion event was almost unchanged in the post-educational period compared to the pre-educational one (1.11percent vs. 1.14 percent, $p = 0.964$)…It revealed that previous history of TAARs ($p < 0.001$) and transfusion of platelet/plasma with or without red [blood] cells ($p = 0.002$) were significantly associated

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RESEARCH IN BRIEF (continued from page 3)

with TAARs." The authors concluded that the "decreased use of premedication is not associated with increased incidence of TAARs in outpatients receiving leukocyte-reduced blood components…Thus, present results provide substantial evidence of the need to revise the clinical practice in the era of leukocyte-reduced blood products."

Citation: Yu, Y.-B., Lee, T.-C., Ho, C.-Y., Lin, H.-J., Chen, W.-C., Chang, C.-C. The abrogated role of premedication in the prevention of transfusion-associated adverse reactions in outpatients receiving leukocyte-reduced blood components. *Vox Sang*. 2022.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

COVID-19 Convalescent Plasma (CCP) Trials. A pre-print study upcoming in *CHEST* addresses whether "rigorously selected CCP with neutralizing anti-SARS-CoV-2 antibodies [is] an efficacious treatment for adults hospitalized with COVID-19?" The authors of this multicenter, blinded, placebo-controlled clinical trial examined the efficacy of CCP in adults hospitalized with COVID-19 for more than 14 days and randomly assigned enrolled patients to receive "one unit of CCP (n=487) or placebo (n=473)…Successful follow-up for survival through day 28 was completed for 947 (98.6 percent) patients." The study found that "[a]t 14 days after study infusion, there was no difference in the COVID-19 Clinical Progression Score between the [CCP] group and placebo group in the overall population (aOR: 1.04; 1/7 SI: 0.82 to 1.33), seronegative population (aOR: 1.15; 1/7 SI: 0.74 to 1.80), or seropositive population (aOR: 0.96; 1/7 SI: 0.72 to 1.30). There was no difference in the primary outcome when the analysis was limited to the as-treated population, when patients in the [CCP] group who received units without neutralizing function were excluded (post-hoc analysis), or when the analysis was stratified into subgroups defined by the patient's age, race/ethnicity, or indicators of illness severity." The authors concluded that "[i]n this multicenter, randomized, placebo-controlled clinical trial among adults hospitalized with COVID-19 in the U.S., treatment with CCP demonstrated no signs of clinical efficacy." They added that "CCP used in the trial was selected based on the presence of anti-SARS-CoV-2 antibodies with neutralizing activity, while most prior trials used CCP selected based on binding antibody titers only without laboratory confirmation of neutralizing activity." Limitations of the trial included "prior vaccination against COVID-19 was an exclusion for both plasma donation and trial participation. Trial results may not be directly generalizable to vaccinated populations. Second, the volume of convalescent plasma used in this trial was one unit (200-399 mL); some prior trials and clinical protocols used larger volumes of convalescent plasma. Third, the CCP used in this trial was mostly collected from donors in Tennessee, while recipients were geographically dispersed across the U.S."

Meanwhile, authors in the *Annals of Hematology* published results of a study that "investigated the clinical and laboratory response to the combination of remdesivir and convalescent plasma (CP) in a considerably large cohort of B-cell-depleted subjects." The study included individuals who had tested for COVID-19 via a PCR test and "demonstrated a profound B-cell lymphopenia based on flow cytometry analysis of peripheral blood lymphocyte subpopulations. They showed undetectable baseline anti-SARS-CoV-2 immunoglobulin (Ig) levels before CP transfusion according to the results of automated anti-SARS-CoV-2 nucleocapsid- and Spike protein1-receptor binding domain (S1-RBD)-specific total Ig tests. Each patient received a complete course of remdesivir and at least one unit (200 mL) of ABO-compatible CP during their treatment for COVID-19. Post-transfusion anti-SARS-CoV-2 Ig levels were measured 12 [hours] after CP administration and regularly thereafter." The trial included 20 patients. "The median length of hospital stay was 22.5 days (10–83), while patients receiving remdesivir and CP simultaneously were discharged earlier compared to patients treated consecutively ($p = 0.007$). Simultaneously treated patients also experienced a remarkably reduced time to PCR negativity ($p = 0.012$) and loss of oxygen demand ($p = 0.017$), while there was no difference in the length of oxygen therapy after initiation of CCP therapy. Furthermore,

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RESEARCH IN BRIEF (continued from page 4)

early CP administration led to an early cessation of oxygen demand, compared to patients receiving CCP at least 10 days after COVID-19 diagnosis (p = 0.006). All patients presented detectable anti-SARS-CoV-2 IgG 12 hours after the first CP transfusion. Anti-SARS-CoV-2 nucleocapsid- and S1-RBD-specific total Ig levels were median 10.7 (0.3–30.2) cut-off index (COI) and 17.2 U/mL (2.8–31.0) after the first, while 12.2 (2.8–37.9) COI and 24.6 U/mL (8.4–126.1) after the second dose of CCP therapy, respectively." The authors concluded that "[o]ur results support the assumption that the early combination of antiviral therapy and passive immunotherapy facilitates clinical recovery from COVID-19 and viral clearance of SARS-CoV-2. Passive transfer of COVID-19-specific neutralizing antibodies with CP therapy was effective and safe in a patient population with compromised immune systems, irrespective of the cause resulting in B-cell lymphopenia." They acknowledged that a limitation of the study included it being "non-randomized [without] control group comparisons."

Citations: Self, W.H., Wheeler, A.P., Stewart, T.G., *et al*. Neutralizing COVID-19 convalescent plasma in adults hospitalized with COVID-19: a blinded randomized placebo-controlled trial. *CHEST*. 2022.

Magyari, F., László, I.P., Páyer, E., Farkas, K. *et al*. Early administration of remdesivir plus convalescent plasma therapy is effective to treat COVID-19 pneumonia in B-cell depleted patients with hematological malignancies. *Annals of Hematology*. 2022.

INFECTIOUS DISEASE UPDATES

MONKEYPOX

The World Health Organization (WHO) has declared the global monkeypox outbreak a public health emergency of international concern. "WHO's assessment is that the risk of monkeypox is moderate globally and in all regions, except in the European region where we assess the risk as high. There is also a clear risk of further international spread, although the risk of interference with international traffic remains low for the moment. So in short, we have an outbreak that has spread around the world rapidly, through new modes of transmission, about which we understand too little, and which meets the criteria in the International Health Regulations. For all of these reasons, I have decided that the global monkeypox outbreak represents a public health emergency of international concern," said WHO Director-General Tedros Adhanom Ghebreyesus, PhD in an agency statement. The U.S. Food and Drug Administration (FDA) also issued an update on July 29th of the agency's response efforts. "The FDA has been closely tracking reports of monkeypox transmissions in the United States with our federal public health partners and coordinating preparedness efforts accordingly," said FDA Commissioner Robert M. Califf, MD in the agency communication. "We understand that while we are still living with COVID-19, an emerging disease may leave people feeling concerned and uncertain, but it's important to note that we already have medical products in place, specifically an FDA-approved vaccine for the prevention of monkeypox disease and an FDA-cleared diagnostic test. The FDA is using the full breadth of its authorities to make additional diagnostics and treatments available. We will continue to collaborate with our partners across all sectors to expand accessibility to countermeasures and bolster the tools in our arsenal as appropriate." Previously, the Association for the Advancement of Blood & Biotherapies' (AABB) Transfusion Transmitted Diseases (TTD) Committee published an interim fact sheet on the monkeypox virus. This follows a previously released monkeypox virus outbreak summary. Monkeypox is not known to be transfusion transmissible and there have been no documented cases of transmission via blood transfusion.

(Sources: WHO Statement, 7/23/22; FDA Update, 7/29/22; AABB Monkeypox Interim Fact Sheet, 6/8/22; AABB Monkeypox Virus Outbreak Summary, 5/27/22)

PEOPLE

Jim Decker, DHA, FACHE, chief executive officer (CEO) of MEDIC Regional Blood Center has announced that he will retire effective April 30, 2023. Dr. Decker has held the position at MEDIC since October 2006. In a letter to the board of directors announcing his retirement, he stated, "[w]hile such a decision is never easy, I feel that the time has come for me to step aside…My wife, Michelle, and I hope to find more time to spend with our one-year-old grandson, as well as to do some traveling to places that are on our bucket list. MEDIC is a great organization and I feel honored to have had the opportunity to work here for the past 16 years." Jack Bryan, chair of the board of directors at MEDIC added in a news release, "Jim has provided great leadership to MEDIC for the past 16 years. He has led MEDIC through some very challenging times as the entire blood industry has undergone a significant transformation. He has also provided steady and consistent leadership over the past two-and-a-half years in response to the challenges posed by the COVID-19 pandemic. MEDIC has grown under his leadership and is recognized as one of the leading blood centers in America…Jim's leadership style is that of a Servant Leader. He does not often seek personal recognition but prefers to let those around him be recognized for their achievements. His quiet demeanor and reserved personality sometimes place him in the shadows of others. Yet his knowledge of the healthcare industry, the countless contributions he has made to communities throughout Tennessee, and the humility he displays on a daily basis speak volume."

(Source: MEDIC Regional Blood Center News Release, 7/21/22)

New York Blood Center Enterprises (NYBCe) recently announced the retirement of **Constance "Connie" M. Westhoff, SBB, PhD**. The organization celebrates the extraordinary career and contributions of Dr. Westhoff, an internationally recognized investigator in the field of transfusion medicine known for her seminal discoveries regarding Rh – what we know as Rh Positive or Negative – and the role Rh proteins play in ammonia/ammonium transport and defining our understanding of the genetic diversity and mutations in RH genes. She is also recognized for establishing high-throughput DNA methods to genotype blood group antigens, which has led to advances that fundamentally changed and improved standard practice in blood transfusion. Dr. Westhoff earned her bachelor's degree in biology (summa cum laude) and her PhD in molecular genetics. She did postdoctoral research in autoimmune disease, and in 1998, received a NIH Fellowship in Transfusion Medicine at the University of Pennsylvania and served as Adjunct Assistant Professor of Pathology and Laboratory Medicine at the Penn's Perelman School of Medicine. At Penn, she made seminal discoveries in Rh structure and function and RH genetics. In 2006, Dr. Westhoff established the first laboratory entirely dedicated to blood typing by DNA, the National Molecular Blood Group and Platelet Antigen Testing Laboratory for the American Red Cross in Philadelphia, as the Scientific Director. In 2010, NYBCe was honored to add Connie to our outstanding cadre of pioneers in blood group discoveries when she became Director of Immunohematology and Genomics. In 2016, she was the founding scientist and director for NYBCe's National Center for Blood Group Genomics, as the Executive Scientific Director. Dr. Westhoff has lectured worldwide and was a member of the Board of Directors of AABB and the Board of the National Blood Foundation after being inducted into the NBF Hall of Fame in its inaugural year. She has authored over 150 peer-reviewed papers and numerous book chapters and reviews. She served as an Associate Editor of Transfusion, an editor of several editions of the *AABB Technical Manual* and has been on countless corporate scientific advisory boards. She received a Doris Duke Innovations in Clinical Research Award, AABB's John Elliott Memorial Award, and Dale Smith Award for Innovation in Transfusion Medicine. In 2021, she was awarded the

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PEOPLE (continued from page 6)

exceptionally prestigious E. Donnall Thomas Lecture and Prize by the American Society of Hematology and The Sally Frank Memorial Award by AABB. NYBCe is honored to recognize Connie's exceptional and lasting contributions which have advanced and improved the science, technology, and practice of transfusion medicine, dramatically improving the lives of countless patients worldwide with a special focus on those with Sickle Cell Disease.

(Source: NYBCe Announcement, 7/25/22)

Contributed by Chandler P. Wilson, MPA, Director of Marketing Communications and Design at NYBCe.

Gordon Smith has joined Blood Assurance as the chief financial officer. Prior to this role, Mr. Smith spent almost 30 years honing his skills in both the for-profit and non-profit sectors, focusing on all facets of corporate accounting and finance including financial reporting, compliance, and debt issuance/service. In addition to core accounting and finance, the latter part of his career has been spent on organizational improvement, strategic planning, and operational excellence. Mr. Smith spent the last 10 years in the non-profit world at both a professional association and the nation's largest pediatric rehabilitation hospital system. Prior to that he worked as Treasurer/VP of Finance for a multi-national recycled paperboard manufacturer and with clients including Bloomberg L.P. and Morgan Stanley Trust Company. "We are delighted to welcome Gordon Smith to the Blood Assurance family," said Blood Assurance CEO J.B. Gaskins in an organization announcement. "With an extensive background in finance and health care, Gordon brings a wealth of expertise and knowledge to his new role. We expect Gordon to make an immediate impact in continuing the organization's mission of saving lives."

(Source: Blood Assurance Announcement, 7/26/22)

Contributed by Caitlin Stanley, Director of Marketing and Public Relation at Blood Assurance.

BRIEFLY NOTED

The National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH) is closing registration on August 1st for the 2022 NHLBI Annual Sickle Cell Disease (SCD) Research Meeting. The event "brings together SCD investigators, practitioners, interested health care providers, patients, and advocates to:

- "share progress of ongoing SCD clinical trials;
- hear from investigators participating in SCD studies;
- learn about new developments in the scientific and clinical aspects of SCD; and
- network with other investigators and NHLBI program staff."

(Source: NHLBI Announcement 7/27/22)

The FDA has issued an emergency use authorization (EUA) for the Novavax COVID-19 vaccine. According to an agency news release, the vaccine "has met the statutory criteria for issuance of an EUA. The data support that the known and potential benefits of the vaccine outweigh its known and potential risks in people 18 years of age and older, and that this vaccine may be effective in preventing COVID-19…The Novavax COVID-19 Vaccine, Adjuvanted is administered as a two-dose primary series, three

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BRIEFLY NOTED (continued from page 7)

weeks apart. The vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual." The Centers for Disease Control and Prevention also "endorsed" the vaccine for use in adults 18 years of age or older.

(Sources: FDA News Release, 7/13/22; CDC News Release, 7/19/22)

MEMBER NEWS

Photo courtesy of advertising, digital marketing, and public relations agency, MVNP.

Blood Bank of Hawaii recently welcomed blood donation advocate Bob Barnes of Syracuse, N.Y. as he completed his cross country bike trek to visit all 50 state capitols over the past year to raise awareness for blood donation. Mr. Barnes cycled close to 17,000 miles according to *Hawaii News Now* as he arrived in Oahu. "Basically, I had to dig deep and just push through it," said Mr. Barnes according to the news outlet. "And you know, you got to know yourself. And I knew if I pushed through it, I'd get through it and continue the message." Mr. Barnes was greeted and congratulated by Blood Bank of Hawaii staff and other blood donors as he donated for the ninth time on his nationwide journey.

(Source: *Hawaii News Now*, Blood donation advocate who cycled through every state capital ends journey in Honolulu, 7/26/22)

GLOBAL NEWS

The Australian Therapeutics Goods Administration (TGA) has approved the removal of "the geographical deferral of blood and plasma donors from the United Kingdom (UK), which was put in place to minimi[z]e the risk of variant Creutzfeldt-Jakob disease (vCJD), commonly known as 'mad cow disease' revised its donor deferral for individuals." According to the announcement from the regulatory agency, "[t]his decision follows an application made to the TGA from the Australian Red Cross Lifeblood to remove the deferral which is applicable to blood and plasma donors having spent a cumulative length of time of six months or more in the UK between 1980 and 1996. The TGA conducted a scientific, epidemiological, and clinical assessment of the risk model submitted by Lifeblood. The TGA concluded that the modelled risk is reliable and by removing the deferral of vCJD the risk of transfusion transmission of vCJD would remain very low." The change is expected to "result in a potential modest increase in the number of blood and plasma donors in Australia. Lifeblood Executive Director of Donor Services Cath Stone added in a news release, "It's taken some time; however, we're so pleased our comprehensive review of the evidence and our risk modelling has found this rule is no longer required. It means that from today, we're thrilled to welcome these newly eligible donors to our cent[ers] around the nation. Our teams are in the process of contacting donors who have previously been unable to donate due to this rule. We're fortunate to have one of the safest blood supplies in the world, and we're continuing our focus to make it easier for all Australians to donate, while ensuring our blood supply remains safe for patients."

(Sources: TGA Statement, 7/25/22; Lifeblood News Release, 7/25/22)

COMPANY NEWS

Terumo Blood and Cell Technologies and **Eliaz Therapeutics** announced a collaboration to "help combat acute kidney injury (AKI) and sepsis-induced acute kidney injury (S-AKI) by focusing on the selective removal of an upstream inflammatory protein called Galectin-3 (Gal-3) from blood plasma." According to a news release, the partnership will consist of large animal and human trials using "Terumo's Spectra Optia® Apheresis System with ETI's novel XGal-3® column that is designed to selectively remove Gal-3 from blood plasma…The in-hospital mortality rate for patients with AKI has been estimated at 20 percent to 25 percent." AKI is a known complication in anemic patients who receive transfusions during surgery.

(Source: Terumo Blood and Cell Technologies News Release, 7/26/22)

Editas Medicine, Inc. recently confirmed the "dosing and successful neutrophil and platelet engraftment of the first patient" in a phase I/II clinical trial of its investigational cellular therapy to treat severe sickle cell disease. In a news release, the company also stated that the U.S. Food and Drug Administration (FDA) has "removed the previously disclosed partial clinical hold on the RUBY trial, which enables the Company to include efficacy data from patients in a marketing application...The trial is enrolling additional study participants at multiple centers in the U.S. and Canada. [Editas] has successfully edited CD34+ cells from patients in preparation for reinfusion and remains on track to announce top-line clinical data by year-end."

(Source: Editas Medicine, Inc. News Release, 7/27/22)

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.

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!

CALENDAR

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

2022

Aug. 2-4. **ABC Summer Summit and Medical Directors Workshop**, **Minneapolis, Minn.** Registration is open. More information available here.

Aug. 8-10. **2022 National Heart, Lung, and Blood Institute (NHLBI) Annual Sickle Cell Disease Research Meeting**, **(Virtual).** Registration is open. More information available here.

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CALENDAR (continued from page 9)

Aug. 29-30. **NHLBI of the National Institutes of Health (NIH) and the Office of the of the Assistant Secretary of Health (OASH) of the Department of Health and Human Services (HHS) 2022 State of the Science in Transfusion Medicine Workshop (Virtual)**. More information coming soon.

Sept. 19-22. **American Association of Tissue Banks Annual Meeting, San Antonio, Texas.** More information available here.

Sept. 21-22. **28th IPFA/ Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Porto, Portugal.** Registration is open. More information available here.

Sept. 28-29. **2022 ADRP Master Class (Virtual).** Registration is open.

Sept. 28-29. **BEST Meeting LXIV, Cocoa Beach, Fla.** More information available here.

Oct. 1-4. **Association for the Advancement of Blood & Biotherapies Annual Meeting, Orlando, Fla.** Registration is open. More information available here.

Nov. 15-16. **The Biomedical Advanced Research and Development Authority (BARDA) Industry Day (Virtual).** More details available here.

2023

Mar. 6-8. **ABC Annual Meeting, Washington, D.C.** More information coming soon.

May 9-11. **2023 ADRP Conference, Charlotte, N.C.** More information coming soon.

Upcoming ABC Webinars – Don't Miss Out!

- **ABC SMT Journal Club Webinar** – August 10th from 3-4 PM EDT. More information including a login link is available in MCN 22-064. Contact us to receive a copy of the MCN.
- **ABC Human Resources Forum** – August 17th from 3-4:30 PM EDT. More information coming soon.
- **ABC HIPAA & Privacy in Blood Banking Webinar** – September 13 from 3-4 PM EDT. More information coming soon.
- **ABC Cybersecurity Threats & Mitigation for Blood Centers Webinar** – September 20 from 3-4 PM EDT. More information coming soon.

EQUIPMENT AVAILABLE

For Sale. New and Unused CompoMat G5 Units. The Blood Bank of Alaska has three new and unused CompoMat G5 Units for sale. These units have not been validated or used. If interested, please contact Bryan Baynard at bbaynard@bbak.org or (907) 222-5664.

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

Sr. Vice President, Contracting and Business Development (Blood Centers of America). Blood Centers of America (BCA) is a national cooperative comprising over 50 blood center members. BCA is seeking an individual with industry experience to serve as a Sr. Vice President, Contracting and Business Development. Candidate will be responsible for identifying and pursuing opportunities that meet the company's objectives for growth and /or savings. Position negotiates agreements with healthcare manufacturers, distributions and other suppliers that support the operations of the BCA membership. In addition, this position seeks and establishes relationships and contracts with Cell Therapy companies, CRO's, Cell Banks and Academic Researchers and Plasma companies. Candidate should have eight to 10 years of experience in business development in the healthcare products industry or progressive managerial experience in health care or blood center industry. Candidate should have an in-depth knowledge of blood center operations, and strong negotiation skills. Position requires approx. 20-30% overnight travel. Submit resume to careers@bca.coop. Click here to view the detailed job description.

Director of Quality and Regulatory Services (LIFELINE Blood Services). The Director of Quality and Regulatory Services plans, coordinates, directs, and evaluates the quality and compliance programs related to regulations, standards, and guidelines of licensing, accreditation, and certification agencies that govern blood center operations. The Director oversees the center-wide review and approval of Standard Operating Procedures. Responsible for maintaining all section Standard Operating Procedures (SOPs) to be in compliance with FDA regulations, AABB standards, and other regulatory guidelines pertinent to LIFELINE Blood Center operations. Keeps abreast of changes to quality regulations and guidelines. Guides efforts to reduce and prevent errors, improvements in the safety and quality of our manufacturing operations, and the protection of the health and safety of our donors and employees. Manages the overall deviation management program to include investigation, root cause analysis, corrective and preventative actions and documentation. Oversees and/or performs Quality Assurance audits to evaluate the effectiveness of the total quality system. Aids in the development and implementation of audit tools used by the department as well as the review and follow up of all corrective actions. Serves as an Authorized Official in pertinent matters with the Center for Biologics Evaluation and Research (CBER) and the FDA. Oversees and/or performs reviews and approvals of validation plans and results of validation activities. Coordinates and assists in maintaining safety and risk management functions that are performed by operational and administrative departments of the blood center. Interacts with hospitals and clients on Quality Assurance related issues. Develops and monitors department budget. Performs Donor counseling as needed. Bachelor's degree or equivalent experience in medical technology or a clinical, allied health field. Please visit www.lifelinebloodserv.org to view the full job description and apply.

Medical Director (Gulf Coast Regional Blood Center). Reporting to the Chief Medical Officer, this individual will assist in providing oversight of operational and implementation expertise across multiple areas of a large community blood center. Areas of responsibility include medical oversight of selection and care of donors, collection, processing, and testing of blood, and disease notification. In addition, this individual will provide guidance for The Blood Center's transfusion service activities and cellular therapy programs, as well as serving as a liaison with medical staff in the community to address transfusion concerns and assure the appropriate utilization of blood products. Requirements: Doctor of Medicine or Doctor of Osteopathy degree from an accredited university with at least four years of combined education and experience in blood banking/transfusion medicine or related field. Board certified or board-eligible in Pathology, Hematology, or related field. Specialty training and/or certification in Blood Banking, Hematology, or a similar related field is highly desirable. Eligible for medical license in the state of Texas. Applicants with additional medical or management experience in apheresis related to cellular therapy and transplant are strongly encouraged to apply. Click here to apply.

Director of Hospital Services and Manufacturing. Blood Bank of Alaska (BBAK) is seeking a director to oversee our Hospital Services and Manufacturing Department in Anchorage, AK. This position is responsible for ensuring our manufacturing and distribution areas are operating in compliance with applicable government regulations, and accrediting agency standards. Also ensuring there is a dedicated focus on the production and distribution of quality products while providing the highest level of customer service. The Director will participate as a member of the blood bank's management team in planning, program formulation, and decision making for the functions and technical support of the manufacturing and distribution of blood products. The incumbent for this role must possess excellent conceptual, communication and analytical skills. Must understand general workflow processes and equipment used in a medical facility. The right candidate will have a bachelor's degree in a relevant field (required) and five years of supervisory experience in a highly regulated, fast-paced, and compliance-driven environment (preferred). We are committed to providing our employees with the support they need. At BBAK we offer an attractive benefit package that includes: Medical, Dental, Vision, Life Insurance, Health Savings Plan, Paid Time Off, 401 K with matching and Short Term & Long-Term Disability

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POSITIONS (continued from page 11)

coverage. If you meet the above qualifications, please apply by sending your resume to: mcannon@bbak.org. For more information about the Blood Bank of Alaska, please visit our website at https://www.bloodbankofalaska.org.

Regional Operations Director (Baton Rouge, LA). LifeShare Blood Center is seeking an Operations Director to oversee blood collection and donor recruitment operations in the Baton Rouge, LA region. Relocation assistance available. The Operations Director will develop and implement strategic and tactical plans for donor recruitment and collections within the donor center and community-based activities; direct, develop and coach teams for achievement of established goals and KPI's; develop relationships with community leaders and groups to promote our mission and business needs; ensure operations adhere to standards and regulations governing the blood banking industry; and model LifeShare's mission and values, integrating them into daily decisions, behaviors and actions. **Join us in our important mission to connect blood donors and the lives they impact!** LifeShare offers a competitive salary, commensurate with experience plus incentive bonus opportunities, as well as a generous benefits package, including employer paid medical, life and disability insurance; 401k with employer contributions (6%), paid time off bank, and employee wellness program. Visit our Careers Page to apply.

Donor Testing Laboratory Director. LifeSouth Community Blood Centers and The National Blood Testing Cooperative (NBTC) are currently seeking a skilled individual for the Donor Testing Laboratory Director position in the NBTC owned Donor Testing Laboratory in Stone Mountain, GA. This position is responsible for the strategic planning, development, organization, coordination, management, and daily oversight of all activities associated with a blood testing laboratory. This position will also ensure the laboratory performs in accordance with all regulatory requirements and will possess the oversight and responsibility of all standard operating procedures (SOPs) within the lab. Must have bachelor's degree in: chemical, physical, biological, clinical laboratory science, or medical technology. Scientific and technical knowledge from current sources, such as the AABB Standards and relevant guidances related to FDA, CLIA, and CMS, both state and federal. Minimum of four years of management/supervisory experience required; Equivalent combination of demonstrated work experience and education may be considered. Starting salary range is $120,000 - $132,000 annually. Please click here to apply.

QRA Supervisor (Stanford Blood Center). Responsibilities: Quality Assurance/Training/GMP/GTP/GLP: Lead the department's quality activities, initiatives, and process improvement activities. Perform training on QRA core functions and activities, Good Manufacturing Practice/Good Tissue Practice/Good Laboratory Practice, and safety. Compliance: Ensure compliance to current regulations and accreditation requirements by federal, state, county, and accreditation agencies. Team Leadership: Manage the performance of direct reports. Set team objectives, priorities, and resources to align staff with Blood Center objectives. Safety: Lead the safety, emergency, and disaster management of the organization. Quality Management System: Provide oversight on the appropriate use of the quality management tools in handling the various documents, records, and activities of the blood center. Registration and Licensure: Ensure all licenses, permits and certificates are current and regulatory requirements are met. Qualifications: Bachelor's degree required. One to two plus years supervisory experience in a regulated or GMP (Good Manufacturing Practice) required. Please click here to view the full job description and apply.