America's Blood Centers®
It's About Life.

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2023 #16 **April 28, 2023**

INSIDE:

Please Note: Thank you to all supporters, participants, partners, speakers, and our sponsor for making the inaugural Blood Advocacy Week a success! Recordings of the virtual events are available for streaming at: www.BloodAdvocacyWeek.org. Please remember, you can also still take action by using the letter writing software on the website. We urge you to contact your members of Congress to advance each day's advocacy priority. Additional coverage will take place in Issue #17 of the *ABC Newsletter* on May 5th.

ABC's Comments to FDA BPAC

America's Blood Centers (ABC) submitted written comments to the U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) ahead of the April 26th meeting this week. The comments explained that there is "an immediate need to modernize the licensure process for blood centers [and that doing so] will ensure blood and blood components are available when patients need them." This is a priority outlined in the 2023 ABC Advocacy Agenda.

The comments recommended that the FDA:

- "reclassify the reporting categories for the implementation of all types of apheresis product collections (red blood cells (RBC), platelets, and/or infrequent plasma) at new fixed site locations, provided that the primary facility is already approved for [the] apheresis product they seek licensure for, from a major change to a minor change, requiring only a description in an annual report (21 CFR 601(12(d)). An inspection by FDA should not be required as part of the submission.
- In the alternative, reclassify the reporting categories for the implementation of all types of apheresis product collections (RBC, platelets, and/or infrequent plasma) from a major change to a moderate change, at new fixed site locations, provided that the primary facility is already approved for [the] apheresis product they seek licensure for, without a requirement for an approved Comparability Protocol (CP), but instead requiring supplement submission at least 30 days prior to distribution of the product made using the change (CBE30) (21 CFT 601.12(c)). An inspection by FDA should not be required as part of the submission."

The comments were based on the "pandemic highlight[ing] and accelerating the need to modernize the licensure process." The comments also detailed how blood centers "began to open new fixed site locations and add[ed] automated collections to existing locations to [adapt]." They explained that "[w]hile accelerated by the pandemic, this move to more collections at fixed blood center collection facilities

(continued on page 2)

ABC BPAC Comments (continued from page 1)

was a change that began before the pandemic and is likely to continue even as the pandemic wanes."

The full comments are available on the ABC website.

(Source: ABC BPAC Comments, 4/24/23)

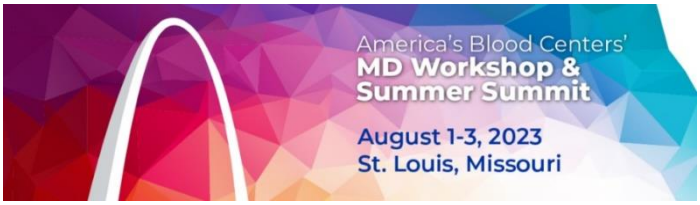
UK Military Freeze-Dried Plasma Program Announced

The United Kingdom's (UK) Ministry of Defen[s]e has announced the "Blood Far Forward" program. According to a news release, from NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the UK, the initiative is designed to "deliver blood and plasma within 30 minutes of injury to soldiers in active warzones." The agency hopes that "[freeze-dried] plasma – which helps the blood to clot – will decrease the Army's reliance on frozen plasma which has to be thawed, taking longer to administer, and could be used by NHS Air Ambulances in the future."

UK Health Minister Neil O'Brien stated in the news release, "this project has the potential to save soldiers' lives by treating significant blood loss with plasma. We are continuing our history of health innovation on the battlefield and investing in cutting-edge treatments by delivering plasma made in the UK to the front line. We work best when we're working together and this project is the perfect example of the government, NHSBT, the Army and medical technologists collaborating to deliver transformative care to people when they need it." Currently, the Army "sources dried plasma from NATO partners, which [are] subject to significant worldwide demand. Sourcing it from the UK will ensure the Army has adequate supply that is not reliant on other countries. The project will also enable single units of plasma to be produced without the need of complex facilities and placed in more convenient, plastic bags. Technological resources for the project will be provided by Velico Medical."

Clinical trials will take place in the UK as the program anticipates costs of £4.9 million. "The Army [is funding] NHSBT to find a way to manufacture dried plasma for use on military operations."

(Source: NHSBT News Release, 4/24/23)



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 recognizes 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.

America's Blood Centers
Chief Executive Officer: Kate Fry
Chief Medical Officer: Jed Gorlin
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: $390

Send subscription queries to
memberservices@americasblood.org
America's Blood Centers
1717 K St. NW, Suite 900, Washington, DC 20006
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

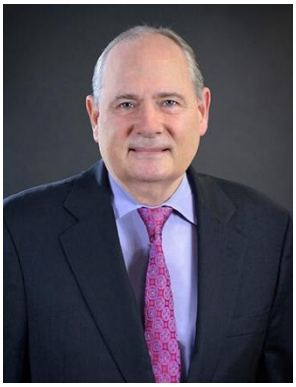
RESEARCH IN BRIEF

Outcomes of Trauma Patients Receiving Whole Blood Vs. Components. A study in the *Journal of Clinical Research* addressed "a need for a systematic review and meta-analysis of the outcomes of adult civilian trauma patients transfused with whole blood (WB) versus (vs.) blood components (COMP) vs. both (WB+COMP)." The authors noted that "[t]he primary outcomes were mortality at 24 hours (h) and 30 days (d)…The secondary outcomes were transfusion volume at 6 h and 24 h, intensive care unit – length of stay (ICU-LOS), and complication rates, including infection, deep vein thrombosis (DVT), and pulmonary embolism (PE)." The researchers conducted a "search of three databases, 18,400 studies were identified, [and] 16 met eligibility criteria." They explained that "[a]ll were U.S. studies of civilian patients conducted between 2013 and 2022…A [m]eta-analysis indicated that patients transfused with COMP had a significantly higher risk of 24-h mortality vs. patients transfused with WB + COMP (relative risk [RR]: 1.40 [1.10, 1.78])...[T]here was no significant difference in 30-day mortality for the patients transfused with WB + COMP vs. COMP (RR: 0.93 [0.79, 1.10])…[T]here was no significant difference in 24-h mortality between the patients transfused with WB vs. COMP (RR: 1.11 [0.73, 1.68])." The study also found that there was no significant difference in 30-day mortality between the patients transfused with WB vs. COMP (RR: 0.90 [0.69, 1.16])." Additionally, a "[m]eta-analysis for red blood cells (RBCs) at 6 h demonstrated significantly reduced mean volume transfused to the patients who were transfused with WB vs. COMP (-2.26 [-3.82, -0.70])…Of the studies recording 24-h RBC transfusion volume, there was a significant reduction in RBCs transfused with WB vs. COMP (-1.94 [-3.22, -0.65])…[C]omparing the rates of infections in patients transfused with WB vs. COMP demonstrated no significant difference between the groups (RR: 1.35 [0.53, 3.46]) nor was there a significant difference in the rates of DVT (RR: 2.52 [0.93, 6.87]) or PE (0.49 [0.15, 1.61])…[C]omparing ICU-LOS in patients transfused with WB vs. COMP demonstrated no significant difference between the groups (RR:-0.91 [-2.64, 0.83])." The authors concluded that "key findings are that transfusion with both WB+COMP offer a 24-h mortality benefit versus COMP alone and transfusion with WB was associated with lower transfusion volumes of RBCs."

Citation: Ngatuvai M., Zagales I., Sauder M., *et al*. Outcome of Transfusion with Whole Blood, Component Therapy, or Both in Adult Civilian Trauma Patients: A Systematic Review and Meta-Analysis. *J Clin Res*. 2023.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

PEOPLE



Brian Gannon, president and chief executive officer (CEO) of Gulf Regional Blood Center, plans to retire "as early as the end of 2023," according to an announcement from the organization. Mr. Gannon has led the organization for more than 17 years. "Before his appointment at Gulf Coast Regional Blood Center, Mr. Gannon brought over 20 years of experience as a healthcare administrator and executive and eight years in corporate product management to meet the challenge of providing for the transfusion needs of the world's largest medical community. He had also served 14 years as president and CEO of The Blood Center for Southeast Louisiana. Prior to his tenure in Louisiana, he held numerous leadership positions, including chief operating officer of Belle Bonfils Memorial Blood Center and a Neurosciences Program Administrator at the Swedish Medical Center, both in Denver, Colo." Mr. Gannon stated in the announcement, "[i]t has been my great honor to serve in this role and for this community for so long, and while there is never a good time to leave, I look forward to my retirement and know that the organization will be placed in good hands. With the time given, I intend to work with the Board for a seamless transition and ensure the organization is well-prepared. I am proud of this organization and look forward to the remarkable work the talented staff will continue to build upon in the future." Gulf Coast Regional Blood

(continued on page 4)

PEOPLE (continued from page 3)

Center Board Chair Elizabeth Torres, MD added in the announcement, "Mr. Gannon has successfully led the organization for more than 17 years to ensure the patients in the 26 counties we serve have life-saving blood products when they need them. We appreciate his unwavering contributions to the medical community and steady leadership through unprecedented times."

(Source: Gulf Coast Regional Blood Center Announcement, 4/28/23)

BRIEFLY NOTED

Legislation has been introduced in the Iowa General Assembly that would expand the sales and use tax exemption allowed for non-profit blood centers. According to the bill, "[u]nder current law, tangible personal property sold or test laboratory services furnished are exempt from sales and use tax if sold or furnished to a nonprofit blood center that is registered by the [U.S. Food and Drug Administration], and the property or services are directly and primarily used in the processing of human blood. The bill provides that tangible personal property or specified digital products sold or any services furnished are exempt from sales and use tax if sold or furnished to a blood collection and processing establishment. The bill defines blood collection and processing establishment to mean the same as an establishment described in 216 C.F.R. §607.3(c), which means a place of business under one management at one general physical location. The term includes, among others, human blood and plasma donor centers, blood banks, transfusion services, and other blood product manufacturers and independent laboratories that engage in quality control and testing for registered blood product establishments."

(Source: House File 722, 4/26/23)

The American Society for Clinical Pathology (ASCP) has launched the 2023 Wage Survey. According to the announcement, the survey serves "as the primary source of information for academic, governmental, and industry labor analysts. Results from past surveys show that laboratory medicine is a rapidly evolving field…The survey will remain open until May 3rd."

(Source: ASCP Announcement, 4/6/23)

MEMBER NEWS

San Diego Blood Bank (SDBB) has "launched" the expansion of its Precision Blood™ initiative. According to news release from the blood bank, grants from The Conrad Prebys Foundation and the David C. Copley Foundation are "support[ing] the first phase of SDBB's Precision Blood™ initiative [in which] over 30,000 blood donations collected and processed by SDBB have received Precision Blood™ typing to better match with blood recipients." The Precision Blood™ initiative "is based on medical research showing there are over 30 blood groups containing over 300 antigens which impact how well a person will respond to blood transfusions or match with a donor. This is a new frontier in precision medicine for blood transfusion patients. By comparison, only two blood groups and three antigens are typically considered for routine transfusion (involving the widely known blood types A+, A-, B+, B-, AB+, AB-, O+ and O-)." SDBB and its division, Southern California Blood Bank, are also "issuing a call for research funding; hospital and laboratory partners; and more diverse blood donors in order to truly scale the Precision Blood™ typing process." SDBB Chief Business Officer Nikhil Nayak added in the news release, "[w]e want people to know the thought of advanced medical research happening in the future is actually happening now with Precision Blood™. Our initial work reveals how Precision Blood™ is positively changing and saving lives today. With the funding we need to continue this groundbreaking innovation, we will be able to expand our capabilities to meet the needs of more transfusion patients."

(Source: SDBB News Release, 4/24/23)

America's Blood Centers®
It's About *Life.*

INSIDE ABC

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

Save the Date: ABC Summer Summit & MD Workshop

Mark your calendars for America's Blood Centers (ABC) Summer Summit and Medical Directors Workshop in St. Louis, Mo. The meeting will take place August 1st-3rd. Hotel reservations can be made now through the ABC block at Live! by Loews (St. Louis). Attendees will hear updates on blood center operational, scientific, and medical issues, case studies, engaging discussions, and have networking opportunities to connect with peers and colleagues. Additional details, including registration information and a preliminary agenda, are coming soon.

GLOBAL NEWS

A clinical trial of an investigational Zika virus vaccine is underway in the United Kingdom (UK). The first individual participating in the trial has been "dosed," according to an April 26th news release. "It's hoped that the vaccine, designed to be suitable for use during pregnancy, will generate highly protective and long-lasting immunity. Having shown promising results in animal studies, the vaccine has now moved into a 'first in human' Phase I trial. If successful, the new trial could lead to a major breakthrough in tackling the Zika virus, for which there are still no approved vaccines or treatments available anywhere in the world." The news release also explained that "[h]ealthy volunteers recruited to the trial will receive two doses of the new vaccine to evaluate its safety, tolerability, and its ability to produce an immune response. The vaccine will be assessed in groups of four volunteers at a time, with numbers increasing as evidence of safety accumulates. Up to 40 volunteers in this phase of work is planned, which will be taking place over the next nine months. In addition, the performance of the vaccine will also be assessed in people who have had exposure to other viruses that circulate in the places where Zika virus is found, such as dengue virus, or yellow fever vaccine."

(Source: University of Liverpool News Release, 4/26/23)

The World Health Organization (WHO) is launching the new "Preparedness and Resilience for Emerging Threats Initiative" (PRET) to assist member states with pandemic preparedness, prevention, and response. A WHO news release stated that the organization will "use a mode of transmission approach to guide countries in pandemic planning, given that many capacities and capabilities are common among groups of pathogens. PRET answers the call for technical guidance and support for promoting and strengthening integrated preparedness and response, as outlined in World Health Assembly resolutions…The PRET Initiative's first module focuses on respiratory pathogens, including influenza, coronaviruses, and respiratory syncytial virus. Given the ongoing COVID-19 pandemic and the possible threat of avian influenza, this module will enable countries to critically review, test, and update their respiratory pandemic planning efforts to ensure they have the functional capacities and capabilities in place. A process is underway to identify the next group of pathogens, such as arboviruses, to be addressed under this initiative. This will follow priorities identified through the ten proposals to strengthen the global architecture for health emergency preparedness, response, and resilience."

(Source: WHO News Release, 4/26/23)

COMPANY NEWS

MAK-System announced a partnership with **Amazon Web Services** (AWS) this week and the launch of the new "MAK.care" platform. In the April 25th news release, the company stated that the blood management platform is "a managed service [that] leverages the power and scalability of AWS to provide the highest level of service and security for users." Difa Niculescu, chief technology officer at MAK-System added in the news release, "MAK.care will dramatically increase the speed of innovation and delivery for clients taking advantage of technologies such as autoscaling, automated environment test and build and the use of serverless and container systems, ushering in a new era of efficiency and access to cutting edge technologies for blood and biologics." AWS Head of Healthcare for EMEA Jens Dommel stated in the news release, "We are pleased to be working with MAK-System on this strategic initiative. AWS cloud technology will provide the necessary services and support to ensure MAK.care is able to scale and meet the demands of the global blood management market."

(Source: MAK-System News Release, 4/25/23)

Editas Medicine, Inc. has received the Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for an investigational gene therapy to treat sickle cell disease. In an April 27th announcement, the company stated that "[t[he gene therapy is currently being investigated in a clinical study in patients with severe sickle cell disease (RUBY trial, NCT04853576) and transfusion-dependent beta thalassemia (EDITHAL trial, NCT#05444894)…The FDA's Orphan Drug Designation program provides orphan status to drugs or biologics intended for the prevention, diagnosis, or treatment of diseases that affect fewer than 200,000 people in the United States. Sponsors of medicines that are granted Orphan Drug Designation are entitled to certain incentives, including tax credits for qualified clinical trials, prescription drug user-fee exemptions, and potential seven-year marketing exclusivity upon FDA approval." Editas Medicine plans "to dose" 20 patients in the RUBY trial in 2023.

(Source: Editas Medicine, Inc. News Release, 4/27/23)

A biologics license application (BLA) for a sickle cell disease gene therapy has been submitted to the FDA by **bluebird bio, Inc.** According to an April 24th news release, "the BLA includes a request for 'priority review,' which, if granted, would shorten the FDA's review of the application to six months from the time of filing, versus a standard review timeline of 10 months. If approved, [the investigational gene therapy] will be bluebird bio's third *ex-vivo* gene therapy approved by the FDA for a rare genetic disease and its second FDA approval for an inherited hemoglobin disorder." The investigational treatment, lovotibeglogene autotemcel, is designed to for sickle cell disease patients who are "ages 12 and older who have a history of vaso-occlusive events (VOEs)…[T]he BLA submission is based on efficacy results from 36 patients [with] a median 32 months of follow-up and two patients [with] 18 months of follow-up each. The BLA submission also includes safety data from 50 patients treated across the entire lovotibeglogene autotemcel program, including six patients with six or more years of follow-up. The FDA previously granted [the investigational gene therapy] orphan drug designation, fast track designation, regenerative medicine advanced therapy (RMAT) designation, and rare pediatric disease designation for the treatment of sickle cell disease."

(Source: bluebird bio, Inc. News Release, 4/24/23)

Upcoming ABC Webinars – Don't Miss Out!

- **Héma-Québec's Perspective – Implementation Experience with Individual Donor Assessment** – May 17 from 3-4 PM EDT. More information coming soon.

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.)*

2023

May 4. **The National Biodefense Science Board, managed and operated by the Administration for Strategic Preparedness and Response, Public Meeting (Virtual).** Registration is open. More information available here.

May 9-11. **2023 ADRP Conference, Charlotte, N.C.** Registration is open. Additional information is available here.

May 10-11. **29th IPFA/Paul-Ehrlich-Institut[e] (PEI) International Workshop on Surveillance and Screening of Blood-borne Pathogens, Bologna, Italy.** More information available here.

May 17. **Héma-Québec's Perspective – Implementation Experience with Individual Donor Assessment.** More information coming soon.

June 5-9. **U.S. Food and Drug Administration's (FDA) Regulatory Education for Industry (REdI) Annual Conference 2023 (Virtual).** Registration is open. More information available here.

Aug. 1-3. **ABC Medical Directors Workshop and Summer Summit, St. Louis, Mo.** More information available here.

Sept. 17-20. **American Association of Tissue Banks Annual Meeting, National Harbor, Md.** More information available here.

Sept. 20-21. **2023 ADRP Master Class (Virtual).** More information coming soon.

Oct. 9-11. **Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif.** More information available here.

Oct. 14-17. **AABB Annual Meeting, Nashville, Tenn.** More information available here.

Oct. 18-20. **American Society for Clinical Pathology (ASCP), Long Beach, Calif.** More information 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 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

Instructor – Collections Training (Carter BloodCare). Principal Accountability: The Instructor position is responsible for the training and continuing education of the Collection Services staff in all procedures involved in the blood collection process. This includes but is not limited to medical history, donor lookup, phlebotomy, quality control, and CPR. This position is responsible for ensuring that trainees receive adequate clinical experience, safely performing all required skills and successfully completing competency testing. This position plans for and guides the learning process to help students achieve required objectives. The Instructor should be able to communicate information in a clear manner both verbally and in writing, should be able to use a computer to make schedules, input data and run reports. The Instructor must have adequate transportation to travel throughout our coverage area when needed. This position is required to maintain regular full-time attendance during office hours and may be required to work overtime. Education: High school diploma or equivalent. Some college a plus. Experience: Six months supervisory experience required; Minimum of one year of blood banking preferred; Six months apheresis experience preferred; and Some experience teaching adults preferred. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job # 38784.

Community and Diversity Outreach Specialist – Community Relations (Carter BloodCare). Principal Accountability: The primary responsibility of the Community and Diversity Outreach Specialist is to develop a program and outreach initiatives focused on Carter BloodCare's Hispanic and/or Black blood donor heritage and historically underrepresented communities. This individual will perform a wide range of duties to coordinate, such as helping create the strategic plan and organizing day-to-day operations. The incumbent demonstrates an understanding of and commitment to quality healthcare, donor diversity, and excellent customer service, acting as a key public facing liaison working closely with donor recruitment, medical services, marketing, and public relations. Individual must be regularly available to work at least 8 hours per day, 40 hours per week. Regular full-time attendance is required during office hours. Education: bachelor's degree in marketing, Business, Communications, Minority Studies or other related field from an accredited four-year college or university, preferred. Experience of two years with non-profit fundraising, public administration, or outreach activities. Experience: Minimum two years' experience; Blood Banking experience preferred; and Bilingual in Spanish language is required for Hispanic Outreach. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job # 39087.

Director of Donor Resources. The Northern California Community Blood Bank (NCCBB) seeks an exuberant and outgoing team player with extraordinary people skills to join us as Director of Donor Resources. Located in the heart of the magnificent coastal redwoods of Northern California, NCCBB offers the opportunity to be part of an organization with a vibrant community relationship and a mission that can be personally gratifying and meaningful. The Director of Donor Resources is responsible for the development and direction of programs related to recruitment and retention of blood donors in Humboldt and Del Norte Counties. The Director oversees all recruitment efforts, ensuring that they reach collection targets and are in accordance with regulatory standards. Recruitment efforts include mobile and in-house blood drives, community outreach and education, marketing, and publicity. The Director oversees programs for telephone, text, and email donor recruitment. For details and to apply, visit www.nccbb.net/employment.html.

Enterprise Medical Director. This position is part of an enterprise-wide Chief Medical Office. This role is responsible for providing medical directorship, administrative, technical, and clinical operations of the assigned hospitals, systems, program, and services as well as support medical directorship of New York Blood Center (NYBC) or the greater NYBC enterprise. This position supports management in making information medical decisions, develops and reviews medical oversight and responsibility for the technical and medical policies, processes, and procedures of specific operations. New York Blood Center Enterprises (NYBCe) is one of the largest community-based, non-profit blood collection and distribution organizations in the United States. We proudly serve as a vital community lifeline dedicated to serving patients and advancing global public health. Our four-part mission is to provide high quality blood products, therapeutic apheresis, cord, and stem cell services, conduct innovative research, develop new products and technologies, and train the next generation of industry leaders. We serve more than 600 hospitals through our six east coast and mid-west divisions and work with dozens of research organizations, academic institutions, and biopharmaceutical companies through our five research enterprises. Click here to view the full job description and apply: Enterprise Medical Director in New York, New York.