

# A B C N E W S L E T T E R

## CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

#### 2023 #17

#### May 5, 2023

**Please Note:** The *ABC Newsletter* will not be published on May 12<sup>th</sup>. We will resume regular publication on May 19<sup>th</sup>. Thank you for your continued interest.

#### More than 400 Individuals Participate in Blood Advocacy Week

The inaugural America's Blood Centers <u>Blood Advocacy Week</u> took place April 24<sup>th</sup>-28<sup>th</sup>. More than 400 individuals from ABC member blood centers, community, government, and industry partners participated in the virtual events throughout the week. During the <u>Day on Capitol Hill</u>, which took place on Day Three, 114 individuals from ABC member centers took part in 172 meetings with congressional offices. Additionally, more than 1,500 shares, likes, and interactions took place across multiple social media platforms using #BloodAdvocacy. ABC thanks our member blood centers, all 55 partners, and our sponsor Fresenius Kabi for making the week such a success. Recordings of the virtual events are still available for streaming at: <u>www.BloodAdvocacyWeek.org</u>. ABC encourages ongoing advocacy in the form of writing letters to members of Congress using the software available on the website.

**Day One:** Analyzing Trends Impacting the Blood Supply and What Must Change Moving Forward. The first day of the week featured Centers for Disease Control and Prevention's Rebecca Free, MD, MPH describing findings from the 2021 National Blood Collection and Utilization Survey Report (NBCUS). She explained that the report included data on the impact of COVID-19 on blood collections and transfusions. The data suggested that the impact of COVID-19 was "transient." Shana Hughes, PhD, MPH from the Vitalant Research Institute also presented on the importance of social science research to uncover the motivations of blood donors. She expressed the need for ongoing research and funding to focus on the donor perspective.

**Day Two:** Promoting Awareness of New Eligibility Criteria. Allie Van Dyke of The Blood Connection shared her blood center's experience with implementing changes to the vCJD deferral. She explained the importance of communicating with a targeted approach to community partners to ensure messaging is reaching the right individuals such as The Blood Connection did with local soccer organizations, veteran's organizations, and military groups. Peter Marks, MD, PhD from the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research shared updates on the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study and the revised HIV guidance. He explained that preprint data from the study is available the agency is hopeful that the final guidance will be issued soon after the agency received an estimated 200 comments. Benjamin Brooks from Whitman-Walker Institute shared the LGBTQ+ perspective on the changes to

#### INSIDE:

ABC Webinar: Héma- Québec's Experience Implementing Individual Donor Assessments3
RESEARCH IN BRIEF3
REGULATORY NEWS4
BRIEFLY NOTED4
WORD IN WASHINGTON
Save the Date: ABC Summer Summit & MD Workshop5
PEOPLE5
MEMBER NEWS5
GLOBAL NEWS6
COMPANY NEWS6
CALENDAR7
POSITIONS8

f **Y O** May 5, 2023

<u>Blood Advocacy Week</u> (continued from page 1)

the deferral criteria in the proposed HIV guidance and the need for the blood community to continue to partner with LGBTQ+ organizations to spread awareness of donor eligibility changes. Kody Keckler from Rep. Mike Quigley's (D-III.) office also presented to express the Congressman's ongoing support for a shift to individual donor assessments.

**Day Four:** When Time Matters – Saving and Enhancing Lives through Access to Blood. Audra Taylor from South Texas Blood & Tissue Center shared her organization's work on their pre-hospital whole blood program and the development and activation of a "Walking Blood Bank" for emergency situations. Mary Homer, PhD from the Biomedical Advanced Research and Development Authority (BARDA) discussed opportunities for the blood community to partner with the agency on next generation blood products and how to build surge capacity. Eric Bank of the Harris County Emergency Medical Services (EMS) discussed their partnership with the local blood community and the importance of their pre-hospital blood program, while sharing insights on how to potentially partner with EMS groups nationwide. Jennifer Holter Chakrabarty, MD explained the importance of prioritizing transfusion in palliative care.

**Day Five:** Why Donor Diversity is Critical to Patient Lives. Theresa Pina of Gulf Coast Regional Blood Center explained the importance of ethnic and age diversity in her community. She shared her center's work to engage and recruit donors to fit the unique needs of their diverse community. Sangeetha Lakshmanan, MPH, MSW form the Georgia Health Policy Center described the resources and toolkit developed (Blood-DonorDiversity.com) to ensure a diverse blood supply for those with sickle cell disease (SCD) and thalassemia. Astrid Kyle Mack, MD from the Ann & Robert H. Lurie Children's Hospital of Chicago discussed the hospital's "Blue Tie Tag" program which allows donors to self-select to designate units to be directed to support children with SCD. They also screen donors for SCD trait. Sahil Sood, a student representing HOSA International, described how to attract and motivate young donors. He explained the importance of marketing and tailoring blood drives to younger generations to capture their attention and engage their friend groups. He also shared the importance and success of ABC's partnership with HOSA.

A video highlighting Blood Advocacy Week is available here.



The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2023 by America's Blood Centers. Reproduction of the *ABC Newsletter* is forbidden unless permission is granted by the publisher (ABC members need not obtain prior permission if proper credit is given).

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

#### ABC Webinar: Héma-Québec's Experience Implementing Individual Donor Assessments

America's Blood Centers (ABC) is hosting a webinar on May 17th at 3 p.m. eastern that will feature Héma-Québec's Marc Germain, MD, PhD, FRCP sharing his blood center's experience and perspective during the shift to individual donor assessments in Canada. This webinar aims to:

- describe the public awareness, education, and communication campaigns used during the implementation of the non-gendered criterion;
- discuss the results of a survey conducted among donors at the inception of the new criterion measuring their perception about the acceptability of the new deferral policy;
- identify deferrals resulting from the new criteria; and
- examine infectious disease marker rates pre- and post-implementation (preliminary data).

Members of ABC can register for this webinar through <u>ABC's CollABO</u>rate <u>Member Resources Community</u>. Please contact <u>member services</u> with any issues or questions.

## **RESEARCH IN BRIEF**

Trauma Molecular Endotypes with Differential Response to Transfusion Resuscitation. A study in JAMA Surgery, tested "36 plasma biomarkers that were measured immediately before randomization in the Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR) trial to identify [trauma] endotypes (TE)." The authors "hypothesized that unique molecular endotypes exist early in the presentation of hemorrhagic trauma and that these molecular endotypes are associated with a differential treatment response to resuscitation strategies." The study "analyzed data from 478 participants (median [IQR] age, 34.5 [25-51] years; 384 male [80 percent]; 94 female [20 percent]) of the PROPPR trial...[A]total of 56 percent (270) were assigned to TE-1, and 44 percent (208) were assigned to TE-2. TE-1 [had] higher standardized concentrations of [inflammatory] biomarkers when compared with TE-2." The study also "assessed whether the two endotypes responded differently to randomized transfusion strategies." The authors explained that "[p]articipants assigned to TE-1 had a 30-day mortality of 28.6 percent (40/140) when randomly assigned to a 1:1:2 strategy and a 32.6 percent mortality (42/129) when randomly assigned to a 1:1:1 transfusion approach...In contrast, patients assigned to TE-2 had a 24.5 percent mortality (24/98) at day 30 when randomly assigned to a 1:1:2 strategy but only a 7.3 percent mortality (8/110) when assigned to a 1:1:1 strategy." The authors identified "[i]n [the] final sensitivity analysis, [a] significant interaction between TE and resuscitation strategy for 24-hour mortality (P value for interaction = .03) and 30-day mortality (P value for interaction = .007)." The researchers concluded that the study "in this secondary analysis of the PROPPR randomized clinical trial, identified two distinct endotypes of patients with severe injury and hemorrhagic shock associated with significant differences in 30-day mortality...Importantly, these two endotypes were associated with a differential response to 1:1:1 vs 1:1:2 transfusion strategies, which was not previously identified in the original PROPPR trial...[The] findings suggest that substantial molecular heterogeneity exists in severely injured trauma patients and that a 1:1:1 resuscitation strategy may not benefit all patients equally."

Citation: Thau, M.R., Liu, T., Sathe, N.A., *et al.* <u>Association of Trauma Molecular Endotypes With Dif</u>ferential Response to Transfusion Resuscitation Strategies. *JAMA Surg.* 2023

Contributed by Richard Gammon, MD, Medical Director at OneBlood







# **REGULATORY NEWS**

The Association for the Advancement of Blood & Biotherapies (AABB) has "<u>revised</u>" the draft of the donor history questionnaire (DHQ) version 4.0 and accompanying materials. According to a May 2<sup>nd</sup> announcement, the revisions come in the wake of feedback from the U.S. Food Drug Administration (FDA) and the revised DHQ has been submitted to the agency for "formal review and acceptance." AABB stated that revisions include:

- "A change to the sequence of the questions in the timeframe, "In the past 3 months" to reflect the placement of new information at the top of the order;
- Restoration of the question, 'In the past 3 months, have you lived with a person who has hepatitis?';
- Restoration of the question, 'Have you ever had a bleeding condition or blood disease?';
- Revision to language in specific questions as highlighted;
- Rearrangement and revision of the donor educational material;
- If provided by FDA in the final guidance, a placeholder has been added for the definition of "new partner" in the donor educational material. This placeholder language is based on the Canadian definition and is subject to change. If a definition is not provided in the final guidance, this language will be removed; and
- Removal of the definition of "day of donation" from the user brochure. Facilities interested in the development of policies that define "day of donation" should contact FDA."

The rule is currently at The White House Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). OIRA is the federal government's "central authority for the review of Executive Branch regulations, approval of Government information collections, establishment of Government statistical practices, and coordination of federal privacy policy."

(Source: AABB <u>Announcement</u>, 5/2/23) •

# BRIEFLY NOTED

According to data <u>reported</u> in the "National Hospital Flash Report: April 2023" from Kaufman Hall, hospitals "improved slightly in March as hospital leaders navigate high expenses and economic pressures. While margins continue to stabilize, they remain below pre-pandemic levels—leaving hospitals in a vulnerable position should a recession or new public health emergency arise." The report also explained that "median Kaufman Hall Year-To-Date (YTD) Operating Margin Index reflecting actual margins -1.0 percent in January." Other takeaways included:

- "[m]aterial expenses are burdening hospitals; and
- [p]atient volumes continue to rebound."

The full report is available <u>here</u>.

(Source: Kaufman Hall, National Hospital Flash Report: April 2023, 5/3/23)

#### WORD IN WASHINGTON

**President Biden** <u>announced</u> on May 1<sup>st</sup> that the Administration is ending the COVID-19 vaccination requirement for federal employees and contractors on May 11<sup>th</sup>. The statement explained that "[w]hile vaccination remains one of the most important tools in advancing the health and safety of employees and promoting the efficiency of workplaces, we are now in a different phase of our response when these measures are no longer necessary." The COVID-19 public health emergency is also set to end on May 11<sup>th</sup>.

(Source: White House <u>Statement</u>, 5/1/23)



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) <u>Summer Summit and Medical Directors Workshop</u> in St. Louis, Mo. The meeting will take place August 1<sup>st</sup>-3<sup>rd</sup>. Hotel <u>reservations</u> 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.

#### PEOPLE

ABC Newsletter



**Dan Galasso** has been named chief financial officer (CFO) at LifeSouth Community Blood Centers as of April 4<sup>th</sup>. According to a blood center announcement, Mr. Galasso "has held multiple leadership positions with the organization since 2012." He most recently served as LifeSouth's vice president of Finance since 2017. In his new role, Mr. Galasso "will continue to oversee planning, direction, and control of all finance and accounting functions, including LifeSouth's business office, facilities, purchasing, and supply chain. As CFO, [he] will [also] continue to provide strategic leadership for the organization's continued growth, helping advance LifeSouth's mission and fulfill their commitment to the hospitals they serve."

(Source: LifeSouth Announcement, 5/1/23)

#### **MEMBER NEWS**

To support the critical need for blood resources in Ukraine, **Carter BloodCare** has <u>donated</u> a retired mobile collections coach for transport to the Eastern European country. Carter BloodCare personnel added personal touches to the overseasbound vehicle, bedecked in the yellow-and-blue colors of the Ukrainian flag and the red-white-and-blue of the Texas flag. Staffers signed the sides of the vehicle with well wishes, inspirational drawings, and uplifting words of support for the people of Ukraine. "Those who give blood voluntarily are lifesavers for those who have lost blood involuntarily," said



May 5, 2023

Veronica Moore, vice president of Marketing and Operations Support at Carter BloodCare in the announcement. "The need for blood is one that the health care professionals and people of Ukraine understand all too well. We're optimistic that Carter BloodCare's mobile collections coach will be a vital vehicle of support and healing for Ukrainian patients in need."

(Source: Carter BloodCare <u>Announcement</u>, 5/3/23)

Contributed by James Black, Senior Public Relations Specialist at Carter BloodCare

-5-



# **GLOBAL NEWS**

**ABC** Newsletter

**Experts from the World Health Organization (WHO) and the Pan American Health Organization (PAHO) recently held a webinar to discuss "methods to control the [chikungunya] disease vector, factors that facilitate its spread and support to countries to tackle a growing number of cases [in the Americas]."** A recording of the May 3<sup>rd</sup> webinar is available. According to the organizations, "[i]n the first four months of 2023, increased chikungunya circulation was detected in the region, with over 214,000 cases reported cases...Although there are seven chikungunya vaccines under development — three in phase III clinical trials — currently there is no approved vaccine or specific treatment for the disease."

(Source: PAHO <u>News Release</u>, 5/4/23) ♦

#### **COMPANY NEWS**

**Belief BioMed Group** (BBM) <u>announced</u> the completion of patient dosing in a phase III clinical trial of its gene therapy to treat hemophilia B. According to a company news release, the gene therapy is "indicated for prophylactic treatment of bleeding in adults with hemophilia B [and] is the first adeno-associated virus (AAV) gene therapy for hemophilia B with investigational new drug application (IND) approval for registrational clinical study in China." The company also added in the news release that the trial aims to "evaluate the safety and efficacy of a single intravenous infusion of BBM-H901 in hemophilia B patients  $\geq$ 18 years of age with endogenous blood coagulation factor IX (FIX) activity  $\leq$ 2 IU/dL ( $\leq$  2 percent). As of today, its dose exploration and dose escalation studies have been completed in China, and positive results have been obtained in terms of efficacy and safety: 100 percent [of] patients stopped FIX treatment, and the annual bleeding rate (ABR) was reduced to zero; the level of coagulation factors was significantly increased and persisted in all patients; safety profile was good with no serious adverse event reported."

(Source: BBM <u>News Release</u>, 4/23/23)

**Blood Centers of America** (BCA) recently <u>honored</u> several partners with 2023 Critical Infusion Awards. The distinction recognizes "each partner's innovative solutions to address critical challenges associated with the nationwide blood shortage that has persisted since the beginning of the pandemic...[The award] was developed to honor BCA suppliers who helped [members of BCA] overcome the unique challenges posed to the blood and plasma donation field, in addition to thanking and recognizing [partners] for their dedication to serving patients." The 2023 recipients include:

- Abbott;
- BD (Becton, Dickinson and Company); and
- Fisher Healthcare.

(Source: BCA <u>News Release</u>, 4/20/23)





# Upcoming ABC Webinars – Don't Miss Out!

• Héma-Québec's Perspective – Implementation Experience with Individual Donor Assessment – May 17 from 3-4 PM EDT. Registration is open.





#### CALENDAR

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

2023

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

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

May 17. Héma-Québec's Perspective – Implementation Experience with Individual Donor Assessment. <u>Registration</u> is open.

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

June 13-14. FDA Science Forum (Virtual). Registration is open. More information available here.

July 31. Blood Centers of America (BCA) Medical Directors Meeting, St. Lois, Mo. The meeting will be held from 9-5 pm at the Loews. Please contact <u>Stacy Conway</u> for more information.

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 <u>here</u>.

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 <u>here</u>.

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: <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a>

#### POSITIONS

**Regional Manager.** LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Regional Manager for McDonough, GA is responsible for overseeing daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range collection goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position and to apply. <u>https://www.lifesouth.org/work-at-lifesouth/</u>

Purchasing Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Purchasing Manager at our headquarters location in Gainesville, FL is responsible for vendor selection, negotiation, establishment and maintenance of all purchased materials, supplies, equipment, and services used by the company. The Purchasing Manager oversees daily operations of the Purchasing team, is organized and decisive, and can motivate the team to reach daily and long-range goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position and to apply. https://www.lifesouth.org/work-at-lifesouth/

Instructor - Collections Training (Carter Blood-Care). 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 nonprofit 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.

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.