

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

URRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2023 #34

September 22, 2023

ACBTSA Publishes Recommendations to Be Voted on During Next Meeting

The U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has released recommendations that will be considered via a vote at an upcoming meeting. The recommendations come in the wake of ACBTSA's <u>July meeting</u> and include the following:

- "during national and regional emergencies, government resources are made available to assist blood collection centers with the transport of blood samples and other key supplies that may be needed in affected areas of the country. The Emergency Support Function (ESF) #8 planning document should specifically incorporate this provision into their planning function. This may be done with an annex to the ESF.
- The Committee further recommends an analysis of all required blood supply functions with cross-reference to the ESF #8 planning document to ensure that all functions are appropriately covered with an annex to the ESF.
- The Committee recommends that the Zika payment model be used during long-term emergencies to support the collection and manufacture of blood components to allow for a minimum 10 percent increase over baseline usage during emergencies when surge capacity is required.
- The Committee recommends that Secretary Becerra fund additional public awareness campaigns including funding for data analytics to increase the donor pool and determine effectiveness."

America's Blood Centers is reviewing the recommendations and plans to submit <u>comments</u> to the committee prior to their next meeting.

(Source: ACBTSA <u>Recommendations</u>, 9/21/23)

ABC Supports Workforce Coalition Letter

America's Blood Centers (ABC) recently joined a laboratory workforce letter, led by the American Society for Clinical Pathology (ASCP), in support of section 212 of the Bipartisan Primary Care and Health Workforce Act. The letter, sent to the

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<u>Workforce Coalition Letter</u> (continued from page 1)

Senate Health, Education, Labor, and Pensions (HELP) Committee, urged Congress to "authorize funding for a workforce innovation grant program within the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services for community health centers and rural health clinics to carry out innovative, community-driven models to educate and train a wide range of allied health professionals, such as laboratory professionals...The section amends existing law to authorize the Secretary to award grants and contracts to provide allied health training opportunities for high school students. This change would allow allied health training programs to inform high school students of allied health careers, including a range of skilled positions serving patients in clinical and public health laboratories, and available financial aid...This legislation represents an acknowledgement of the vital roles allied health professionals play in these systems." The Senate HELP Committee approved the bill this week and the bill will now go to the full Senate for a vote.

(Source: Coalition Letter, 9/20/23)

WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) have <u>published</u> a request for information (RFI) and comments in the *Federal Register* "regarding critical scientific challenges and opportunities to advance the development of individualized cellular and gene therapies (CGTs)." According to the RFI, "FDA intends to gather information and comments submitted in response to this RFI to inform potential planning of future town halls, workshops, or discussion papers which could ultimately facilitate the development of additional regulatory science tools, standards, or guidance." America's Blood Centers' Blood & HCT/P Regulatory Review Subcommittee is reviewing the RFI with <u>comments</u> due November 20th.

(Source: Federal Register <u>RFI</u>, 9/21/23)

The U.S. Food and Drug Administration has "<u>approved</u> and authorized for emergency use" updated COVID-19 vaccines. According to an agency announcement, the updated vaccines have been "formulated to more closely target currently circulating variants and to provide better protection against serious consequences of COVID-19, including hospitalization and death. Today's actions relate to updated mRNA vaccines for 2023-2024 manufactured by ModernaTX Inc. and Pfizer Inc. Consistent with the totality of the evidence and input from the FDA's expert advisors, these vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5."

(Source: FDA <u>News Release</u>, 9/11/23) ♦

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and 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

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RESEARCH IN BRIEF

ABC Newsletter

Does Decreasing Incubation Period in Antibody Screen Affect Sensitivity? The hypothesis of a study in Transfusion Medicine, "is that the incubation period used in the antibody screen can be reduced when using Glass or Gel-based column agglutination technology (CAT), or a solid-phase red cell adherence (SPRCA) assay." The authors explained that, "[t]his study aimed to analy[z]e all [samples] available during the period [of] February to August 2018 that were from [100] unique patients." They noted that, "[f]or each screening method, 10 quality control (QC) samples and two phenotyping reagents containing antibody of differing specificity were tested using incubation times of 1, 5, 10, and 15 minutes (min.), and 20 min. (SPRCA assay only)...The shortest incubation period producing at minimum a 1+ reaction with all 12 samples was selected as the optimi[z]ed time...In the Gel CAT system all antibodies produced at least a 1+ reaction when using the 15-min. incubation period...In the Glass CAT system, all antibodies produced at least a 1+ reaction when incubated for 15 or 10 min." The researchers stated that, "[i]n the SPRCA method, reaction grades of 1+ or higher were produced using the standard 20-min. incubation, and the reduced periods of 15, 10 and 5 min...Overall, with the optimi[z]ed incubation times, the Glass and Gel CAT systems had sensitivities of 98.9 and 96.6 percent, respectively, and the SPRCA method had a sensitivity of 98.9 percent... To determine if any of the optimi[z]ed systems differentially detected antibody/ies of certain specificity/ies, the reaction grades produced by each antibody in the three systems were compared...Reaction grades obtained with samples containing anti -D, -E, -c, or -Fy^a were not significantly different between the three methods (p > 0.05)...In all methods, the association between antibody tit[er] and reaction strength was significant, though this was weaker in the SPRCA method (Gel CAT, p = 0.001; Glass CAT, p < 0.001; SPRCA, p = 0.041)...This study suggests that the incubation period used in the antibody screen can be decreased to 5 and 10 min. when using the SPRCA and Glass CAT methods, respectively, without decreasing assay sensitivity." The authors concluded that, "[t]his may allow pre-transfusion testing to be expedited in laboratories resulting in earlier administration of crossmatch-compatible blood products if required."

Citations: Kenneday, G., Chih, H.J., Finch, S., Ellery, P. "Does decreasing the incubation period used in the antibody screen affect its sensitivity?" *Transfusion Medicine*. 2023

Contributed by Richard Gammon, MD, Medical Director at OneBlood 🍐

NEW on CollABOrate



SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC <u>CollABOrate</u> Online Member Community include:

- <u>Regulation/Standard for Culturing Eyewash Stations</u> (QUALITY BYTES)
- <u>Saline Washed Apheresis Platelets</u> (ALL MEMBER FORUM)
- <u>Post-donation Callback Instructions</u> (MEDICAL ISSUES)

ABC members are encouraged to login and join the conversations today!

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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 staffs only, unless otherwise specified.

SAVE THE DATE: ABC WELC Webinar Featuring Dr. Meghan D. Kinter Set for Oct. 26th

America's Blood Centers (ABC) Women's Executive Leadership Community (WELC) will host its first webinar on October 26th at 2 p.m. EDT. Meghan D. Kinter, PhD, will be the guest speaker and present on overcoming the tyranny of the urgent. This webinar will feature breakout sessions for attendees and a question and answer session with Dr. Kinter who has, according to her bio, spent more than two decades "expertly guid[ing] businesses and individuals through the complexities of their challenges, helping them navigate from feeling 'stuck' to achieving clarity and momentum. She's been a pivotal force behind various local, regional, and national movements advocating for social wellness, tackling critical issues such as domestic violence, substance misuse, religiosity, and behavioral/mental health. In her career, Dr. Kinter was the director of Marketing at the Community Blood Bank of Northwest Penn. and Western N.Y. and has had an opportunity to work with them later in her career as a consultant. She holds a doctorate and master's in Organizational Learning and Leadership and a bachelor's in Public Relations. She currently serves as Sr. Director of Strategy and Business Development for the Achievement Center of LECOM Health and LECOM Health's Behavioral Health Service Line." The WELC is a complimentary offering open to all employees of ABC member blood centers and industry partners. Through this initiative, ABC strives to empower leaders throughout the blood community through networking and professional development. ABC encourages individuals to join WELC and its LinkedIn Community, and share this information with those who may be interested.

ABC Joins Steering Committee of Prehospital Blood Transfusion Initiative Coalition

A Prehospital Blood Transfusion Initiative Coalition (PHBTIC) has been established to help address the availability of and access to blood products on emergency medical response vehicles. According to a news release, the PHBTIC will be led by a steering committee, which includes America's Blood Centers, that is, "building a multi-disciplinary, collaborative initiative to advance four pillars of focused activity to promote prehospital blood transfusion programs: establish reimbursement for blood products transfused in the prehospital setting; EMS scope-of-practice allowing the initiation of prehospital blood products in states where it currently is not allowed; strategic preparedness for homeland defense and mass casualties; [and] outreach and education, including regulatory, protocols, and best practices for programs based on experiences of agencies currently conducting programs."

(Source: PHBTIC <u>News Release</u>, 9/13/23)

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 <u>calendar of events</u> includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

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PEOPLE

ABC Newsletter

Kristy Shrewsbury has been named vice president of Quality Assurance and Regulatory Affairs at The Community Blood Center (CBC) in Appleton, Wis. According to a news release, Ms. Shrewsbury "has more than 10 years of blood center experience and has served in both quality assurance and operational support leadership roles. Most recently, she has been focused on process improvement and quality validation in the pharmaceutical field." In her new role at CBC, she will focus on "continuous process improvement as well as the enhancement of what is already a comprehensive quality assurance plan. In addition, Shrewsbury will serve as the corporate contact for all regulatory and accreditation agencies." CBC President and Chief Executive Officer (CEO) John Hagins added in the news release, "[t]his is a key position in aligning and



supporting the achievement of organizational objectives at CBC. Our team is looking forward to seeing all Kristy accomplishes at CBC, the direction of this position, and her work as a part of the senior leadership team."

(Source: CBC News Release, 9/22/23)



Garry D. Allison Jr. is the new senior vice president of Operations at Blood Assurance (Chattanooga, Tenn.). In this role, Mr. Allison will "oversee the nonprofit's collections, community development, marketing, and recruitment efforts. He brings 20 years [of] experience in blood banking [to Blood Assurance], and [previously worked in] the Alabama-Mississippi-Tennessee Region of the American Red Cross, where he most recently served as regional donor services executive for four years. He has held various other positions within the American Red Cross, including director of donor recruitment, and director of blood collections," according to a news release. Blood

Assurance CEO J.B. Gaskins added in the news release, "Garry brings a wealth of knowledge to Blood Assurance. He has a strong commitment to community, and a passion for increasing blood collections in our service area. We are lucky to have him, and look forward to seeing the organization's operations thrive under his leadership." Mr. Allison stated in the news release, "[o]ver the past two decades, I've had the good fortune of serving hospitals, blood drive sponsors, and their donors. I've seen first-hand how these donations save lives. I'm honored to join Blood Assurance, and look forward to ensuring blood products continue to be available for our local patients."

(Source: Blood Assurance News Release, 9/19/23) •

MEMBER NEWS



Rep. Earl L. "Buddy" Carter (R-Ga.) recently visited **The Blood Connection**'s Savannah, Ga. location. On Monday, September 11th, Rep. Carter participated in the nationwide September 11th Day of Service by donating blood in his district. In a news release, he also informed his constituents on the importance of donating blood and shared The Blood Connection's need for increased blood donors following the recent local impacts of Hurricane Idalia. "In times of need, giving blood is a selfless act that allows each of us to do our part for our community. I can think of no better way to mark the solemn anniversary of 9/11 than by raising awareness for the lifesaving act of donating blood," said Rep. Carter.

(Source: The Blood Connection Announcement, 9/20/23)

Contributed by James Wooten, Media & Events Coordinator at The Blood Connection 🌢



GLOBAL NEWS

ABC Newsletter

A Dispatch published in the Centers for Disease Control and Prevention's Emerging Infectious Diseases journal describes, "a report [of] Listeria monocytogenes infection in a patient in Italy who was transfused with pooled platelet concentrate." The authors explained that, "[a] Genomic analysis revealed that L. monocytogenes isolates from the donor blood unit, the transfused platelets, and the patient's blood culture were genetically closely related, confirming transfusion transmission." They stated that, "[a]lthough the source of the contamination was unclear, one explanation could be environmental contamination of the donated blood unit. Several cases of contamination of transfusion products by environmental bacteria have been described. L. monocytogenes is widespread in the environment and could have entered the blood unit via undetected defects or damages in the storage container. Another explanation could be a transient bacteremia experienced by the donor who was asymptomatic at the time of donation, such as in a previously described case. Questionnaires administered to assess blood donors' health and medical history are not useful to identify L. monocytogenes infection because healthy persons will generally be asymptomatic. Indeed, persons with transient asymptomatic bacteremia, or who are in the recovery phase of an infection, still can qualify as blood donors." They concluded that, "bacterial contamination of donated blood and blood components still represents a major public health issue globally. This case highlights the need to improve safety in transfusion medicine by implementing surveillance activities and additional measures, such as secondary testing and pathogen-reduction technology."

Citation: Gori, M, Bolzoni, L., Scaltriti, E., *et al.* "Listeria monocytogenes Transmission from Donated Blood to Platelet Transfusion Recipient, Italy." *Emerging Infectious Diseases.* 2023.

The University of New South Wales Sydney's Kirby Institute and the Australian Red Cross Lifeblood have been <u>awarded</u> a \$1.5 million grant by the National Health and Medical Research Council (NHMRC). According to the announcement, the partnership grant is geared towards, "research aimed at protecting Australia's blood supply." Professor John Kaldor added in the news release, "[w]e welcome this renewed funding from the NHMRC. The Kirby Institute brings strengths in a range of key research disciplines, [including] epidemiological evaluation, mathematical modelling, health economics, and social science. Our research will investigate community attitudes to blood donation and its eligibility criteria and evaluate how changes in policy may impact blood safety and supply. A new element in our collaboration will be research aimed at making optimal use of blood donations for monitoring emerging infectious pathogens in the community."

(Source: Kirby Institute <u>News Release</u>, 8/24/23)

COMPANY NEWS

Hemanext Inc. <u>announced</u> this week that the U.S. Food and Drug Administration (FDA) has, "granted marketing authorization for commercial distribution for the company's Hemanext One blood processing and storage system," via the agency's De Novo pathway. According to a company news release, the Hemanext One system, "creates hypoxic red blood cells (RBCs) that have been processed to reduce oxygen and carbon dioxide content of RBCs and to maintain this level throughout storage up to 42 days. Hypoxic RBCs have demonstrated positive impacts on multiple in vitro metrics of RBC quality in preclinical studies."

(Source: Hemanext, Inc. News Release, 9/21/23)

Terumo Blood and Cell Technologies (BCT) has <u>partnered</u> with **MCQ Instruments**. Through the collaboration, "makers of advanced [cell] therapies now have an alternative for manufacturing spaces that cannot accommodate pre-mixed gas tanks," according to a news release. The companies will offer Terumo BCT's Quantum Flex Cell Expansion System with the MCQ Nano 3, "creating options for a critical step in the



<u>COMPANY NEWS</u> (continued from page 6)

process to expand cells in a range of facilities. The combination enables a straightforward workflow from existing facility gas lines through to Quantum Flex, which uses hollow-fiber perfusion technology to enable continuous gas exchange, ensuring optimal conditions for cell expansion." The product is currently available in Europe, the Middle East and Africa stated Terumo BCT in the news release.

(Source: Terumo BCT <u>News Release</u>, 9/21/23) ♦

Upcoming ABC Webinars & Virtual Events – Don't Miss Out!

- ABC Women's Executive Leadership Community (WELC) Webinar Oct. 26. More information available here.
- ADRP International Showcase Nov 15. <u>Registration</u> is open. More information available <u>here</u>.





CALENDAR

ABC Newsletter

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

Sept. 26-29. Centers for Disease Control and Prevention (CDC) Sickle Cell Data Collection Summit (Virtual). <u>Registration</u> is open. More information available <u>here</u>.

Oct. 9-11. Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif. <u>Registration</u> is open. More information available <u>here</u>.

Oct. 14-17. AABB Annual Meeting, Nashville, Tenn. Registration is open. More information available here.

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

Oct. 26. America's Blood Centers (ABC) Women's Executive Leadership Community (WELC) Webinar. More information available <u>here</u>.

Oct. 31. U.S. Food and Drug Administration (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee Meeting (Virtual). More information available <u>here</u>.

Nov 15. ADRP, The Association for Blood Donor Professionals International Showcase (Virtual). <u>Registration</u> is open. More information available <u>here</u>.

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<u>CALENDAR</u> (continued from page 7)

Nov. 18-21. ISBT Regional Congress, Cape Town, South Africa. <u>Registration</u> is open. More information available <u>here</u>.

2024

Feb.7-8. International Plasma and Fractionation Association & EBA Symposium on Plasma Collection and Supply. Leiden, Netherlands. More information available <u>here</u>.

Mar. 4-6. ABC Annual Meeting, Arlington, Va. More information available here.

May 14-16. 2024 ADRP Annual Conference, St. Louis, Mo. 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

EQUIPMENT AVAILABLE

For Sale. Two refurbished Aurora Plasmapheresis System devices with Certificate of Compliance for each device. Both devices have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email <u>latrinamorman@lifelinebloodserv.org</u>.

For Sale. Two NEW Aurora Plasmapheresis System devices with Certificate of Compliance. NEVER USED. Currently, both have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email <u>latrinamorman@lifelinebloodserv.org</u>.

POSITIONS

Director, Public Relations and Marketing. Mississippi Blood Services (MBS) is seeking the right candidate for the highly visible position of Director of Public Relations & Marketing. We are looking for an individual with flexible skills who can oversee our Communications and Public Relations efforts to ensure we are able to collect and distribute the much-needed resource of blood donations! As the face of the company, the ideal candidate will be responsible for all aspects of Public Relations and Marketing, which includes recruitment of blood drives and telerecruitment. This individual will work with Public Relations, Marketing Representatives, Telerecruitment manager, and other managers to coordinate and organize ample daily collections of whole blood, double red cells, apheresis platelets, and plasma collections for the organization. They will also work in conjunction with other MBS management to set strategic goals and objectives for the company. Must have a bachelor's degree (BA) from a four-year college or university; three to five years' related experience; or equivalent combination of education and experience. Visit www.msblood.com to apply online.

Assistant Manager - Product Quality Control (Carter BloodCare). Principal Accountability: The Assistant Manager Product Quality Control reports to the Manager of Product Quality Control and will be responsible for all

daily, routine departmental activities and operations, consulting with the Manager, as needed. This position will oversee strict fiscal adherence to the budget and other administrative activities for the department, as assigned by the Manager, Technical Director, or Medical Director. The Assistant Manager is able and willing to perform any departmental task, as needed, to ensure efficient workflow within the department. Education: Bachelor of Science Degree and Minimum MT/MLS ASCP, or equivalent, required. Experience: Working knowledge of Product Quality Control instrumentation and parameters associated with donor collections. Strong working knowledge of blood bank policies and procedures. Comprehensive problem-solving skills. Good written and verbal communication skills. Excellent interpersonal and conflict resolution skills. Very strong customer service practices. Advanced computer skills. Comprehensive knowledge of administrative functions, including budget activities. Effective organizational skills, to include the ability to organize and prioritize workload, attention to detail, and consistently follow through with a commitment to excellence. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job Assistant Manager Product Quality Control.

<u>POSITIONS</u> (continued from page 8)

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 apply <u>here</u>!

