



# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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## ABC, SCDA, Sickle Cell Disease Coalition Recognize National Sickle Cell Disease Awareness Month

America’s Blood Centers (ABC) issued a [news release](#) this week in recognition of September as National Sickle Cell Awareness Month. In the release, ABC, the Sickle Cell Disease Association of America (SCDAA), and the Sickle Cell Disease Coalition called for increased diversity among blood donors to best meet patient needs. “Now is the time during Sickle Cell Disease Awareness Month to stand up and take action for people with sickle cell disease, a blood condition that affects more than 100,000 Americans,” said Regina Hartfield, president and chief executive officer (CEO) of the Sickle Cell Disease Association of America. “One of the most important ways we can help is by giving blood. Blood transfusions are crucial to people with sickle cell disease, so I ask you to show up this month, give blood and save a life.” Tessa Youngner, sickle cell disease programs specialist at the Sickle Cell Disease Coalition, added in the news release, “[t]here are so many ways to support the sickle cell community, but donating blood is one of the most immediate and impactful. Individuals living with sickle cell disease urgently need a safe and reliable blood supply to manage their health year-round. However, many Americans are unaware of this need, and of the fact that the genealogy and ethnicity of donors affects the success of blood transfusions delivered to people living with sickle cell. National Sickle Cell Awareness Month is a powerful opportunity to spread awareness and inspire new, more diverse blood donors to lend an arm and join the fight to conquer sickle cell.”

In addition to the news release, several resources are available to ABC members to assist with any initiatives honoring National Sickle Cell Disease Awareness Month and blood donor diversity including:

- social media [graphics](#) and a video developed last year by the ADRP Public Awareness Committee;
- the Georgia Health Policy [website](#) which includes a blood donor diversity toolkit; and
- resources, graphics, and handouts from the National Institutes of Health’s [National Heart, Lung, and Blood Institute](#).

President Biden issued a [proclamation](#) on August 31<sup>st</sup> in recognition of National Sickle Cell Awareness Month.

(Source: MCN 22-076, 8/31/22) 💧

## FDA Publishes Communication for HCT/P Establishments Regarding Monkeypox Virus

The U.S. Food and Drug Administration (FDA) [issued](#) a communication on August 29<sup>th</sup> titled “Important Information for Human Cell, Tissue, and Cellular and Tissue-based Product (HCT/P) Establishments Regarding Monkeypox Virus and HCT/P Donation.” In the communication, the agency stated that “[w]orldwide, there have been no reports of transmission of monkeypox virus through use of human cells, tissues, or cellular or tissue-based products (HCT/Ps); therefore, the risk of infection transmitted by implantation, transplantation, infusion, or transfer of HCT/Ps remains theoretical. Monkeypox virus nucleic acid has been detected in tissues and secretions of infected humans, such as in skin, semen, and placenta; however, the levels of infectious virus in human cells and tissues have not been well characterized. Routine screening measures, for the purposes of making a donor eligibility determination, are already in place for evaluating risk factors and conditions as well as clinical evidence and physical evidence of infection in HCT/P donors.”

The FDA added that it “does not recommend using laboratory diagnostic tests to screen HCT/P donors for monkeypox virus. The HCT/P establishment’s responsible person (21 CFR 1271.3(t)) must determine and document the eligibility of a cell or tissue donor (21 CFR 1271.50). Based on information available at this time, establishments may wish to consider, whether, in the 21 days prior to HCT/P recovery, the donor:

- “was diagnosed with or was suspected of having a monkeypox infection;
- had close contact with a person or an animal diagnosed with or suspected of having monkeypox infection regardless of the donor’s vaccination status; or
- developed a rash or other symptoms suggestive of monkeypox infection.”

(Source: FDA [Communication](#), 8/29/22) ♦

## WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) “[amended](#) the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination.” According to the agency announcement, “the bivalent vaccines, [or] ‘updated boosters,’ contain two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2...Individuals 18 years of age and older are eligible for a single booster dose of the Moderna COVID-19 Vaccine, Bivalent if it has been at least two months since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine. Individuals 12 years of age and older are eligible for a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent if it has been at least two months since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.” FDA Commissioner Robert Califf MD stated in the news release, “[t]he COVID-19 vaccines, including boosters, continue to save countless lives and prevent the most serious outcomes (hospitalization and death) of COVID-19. As we head into fall and begin to spend more time indoors, we strongly encourage anyone who is eligible to consider receiving a booster dose with a bivalent COVID-19 vaccine to provide better protection against currently circulating variants.” The Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky, MD, MPH, also “[endorsed](#) the CDC Advisory Committee on Immunization Practices’ (ACIP) recommendations for use of updated COVID-19 boosters from Pfizer-BioNTech for people ages 12 years and older and from Moderna for people ages 18 years and older.”

(Sources: FDA [News Release](#), 8/31/22; CDC [News Release](#), 9/1/22) ♦



## RESEARCH IN BRIEF

**A National Survey of Outpatient Platelet Transfusion Therapy.** A study published in the *American Journal of Clinical Pathology* sought “to determine the current state of platelet transfusion practice in the outpatient setting in the United States.” The investigators explained that a “survey was distributed to 735 AABB members in September and October 2021 [and] completed by 317 individuals, for a 43 percent response rate from 44 states...The majority of respondents were managers of their institution’s blood bank (77 percent) [and] 85 percent [had] 16 or more years of experience...Half of the respondents’ institutions have formal outpatient platelet transfusion guidelines in place: 51 percent use less than 10,000/ $\mu$ L for transfusing platelets to stable, afebrile outpatients, with 29 percent using less than 20,000/ $\mu$ L.” The study found that “[w]hen asked for their outpatient platelet transfusion threshold in clinical practice (regardless of formal guidelines), the most common answers [from respondents] were less than 10,000/ $\mu$ L (49 percent), less than 20,000/ $\mu$ L (31 percent), and less than 50,000/ $\mu$ L (14 percent)...Forty-five percent monitored outpatient platelet use through both prospective and retrospective audits, with retrospective audits only [at] 25 percent, followed by 10 percent monitoring prospectively...Actions taken when requests for outpatient transfusion did not meet institutional guidelines [included] 75 percent report[ing] that communication occurs between the ordering provider and either the transfusion service or, the transfusion committee; some respondents took both actions...In 13 percent of cases, the blood bank refused to release the platelets if the request did not meet institutional guidelines...Another 8 percent of respondents indicated that there were no consequences for providers ordering outside of established guidelines...When queried about requests that do not meet guidelines patient-specific indications included distance patient lives from the clinic or hospital, recent bleed or a history of bleeding, petechiae/mucosal bleeding, qualitative platelet disorder, periprocedural outpatient platelet transfusion, recent hematopoietic stem cell transplantation, coexisting coagulopathy, graft-vs-host disease, and bleeding.” The authors noted that while “[t]he number of platelet transfusions increased in the United States by almost 16 percent between 2017 and 2019, [there] [u]nfortunately has not been a similar increase in donations, creating frequent platelet shortages...[O]utpatient platelet transfusions are occurring with increasing frequency.” The study concluded that “this survey demonstrated that opportunities exist to improve the establishment and enforcement of platelet transfusion guidelines for outpatient platelet transfusion.”

**Citation:** O’Brien, K., Bakhtary, S., Benson, K., Stephens, L., Lu, W. [A National Survey of Outpatient Platelet Transfusion Practice](#). *Am J Clin Pathol*. 2022.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 



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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the 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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**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 staff only, unless otherwise specified.*

### **ABC Webinar: Navigating HIPAA and PHI in Community Blood Donor Centers**

America's Blood Centers' (ABC) will host a webinar on September 13<sup>th</sup> titled "Navigating HIPAA and PHI in Community Blood Donor Centers." The webinar will take place from 3-4 pm EDT and will feature Roxanne Tata, MT(ASCP) SBB, CQA (ASQ), vice president of Regulatory Affairs and Corporate Quality Services at Vitalant. She will share her expertise in differentiating and protecting HIPAA and PHI (Protected Health Information) at community blood donor centers as well as the impact of electronic devices use on securing the information. P.A.C.E credits will be available as well as a webinar recording. This is the first in a two-part series as Richard Dunn, CISM, ISACA, manager of Security and Resilience at Gulf Coast Regional Blood Center will present on an ABC webinar on September 20<sup>th</sup> from 3-4 pm EDT on: "Navigating Cybersecurity in Community Blood Centers." More information on this webinar will be coming soon. Additional details including a link to join the first webinar are available to ABC members in MCN 22-075. Contact [us](#) to receive a copy of the MCN.

(Source: MCN 22-075, 8/30/22)

### **ABC Launches 2022 Benchmarking Survey for Service Fees**

ABC recently launched its annual benchmarking survey for member service fees. All ABC member blood centers are encouraged to participate. The results of this survey are an important part of ABC's advocacy efforts for better CMS reimbursements for blood products. The data from the report will aggregated and no individual member data will be shown. Members are asked to complete the survey by September 23<sup>rd</sup>. A link to the survey and a PDF version are available to ABC members in MCN 22-073. Please [contact](#) ABC Director of Regulatory Affairs Jill Mastin with any questions.

(Source: MCN 22-073, 8/24/22) ◆

## **PEOPLE**



**Amanda Farrell** has joined The Blood Connection as the senior director of Donor Resources. According to a news release from the blood center, "[i]n this role, she will be responsible for improving efficiency in the donor recruitment process, along with working closely with [the blood center's] strategic partnerships. [Ms. Farrell] will also help lead the charge on TBC's implementation of the America's Blood Centers (ABC) initiative, "Vein to Vein: The Science of Blood Donation": a groundbreaking high school education program that helps educators craft lesson plans to develop student leadership skills and a lifelong interest in supporting our nation's blood supply." She previously served as the senior director of Donor Recruitment and Experience at ConnectLife, where she "was responsible for oversight of blood donor recruitment across approximately 900 partnering organizations, along with four donation centers. While there, Ms. Farrell lead a blood donor recruitment team that saw more than 15 percent growth among blood donors over the last two years." She also currently serves as the current president-elect of ADRP, an International division of ABC. Ms. Farrell

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earned her B.S. in Human Development and B.A. in Psychology from Binghamton University. “I’m thrilled to be working with Amanda again,” said Marie Forrestal, vice president of Donor Recruitment at The Blood Connection in the news release. “She’s truly one of the superstars in donor recruitment and retention. Amanda is a unique visionary who is also able to strategize on details and move projects forward.” Ms. Farrell added, “I’m very fortunate to have the opportunity to join The Blood Connection team. I look forward to supporting the organization’s incredible mission, while helping to ensure there is a stable blood supply in our communities.”

(Source: The Blood Connection News Release, 9/1/22) ♦

**MEMBER NEWS**

**The Blood Connection** recently “broke ground” on a new blood donation [site](#) in Anderson, S.C. According to a report from the *Upstate Business Journal*, the 4,000 square foot facility will “serve AnMed Health, which closed its blood donor center in 2018 and has been using The Blood Connection as its sole blood provider.” The donor center will have 10 donor beds and is “expected to be complete[d] and open by [the] spring [of] 2023.” The Blood Connection President and Chief Executive Officer Delisa English told the publication, “[The Blood Connection] has been a part of the Anderson community for a long time thanks to loyal donors here and our friends at AnMed — it’s only fitting that we should finally put down roots here and continue to grow with and support Anderson.”



*Photo courtesy of the Upstate Business Journal*

(Sources *Upstate Business Journal*, [The Blood Connection breaks ground on new Anderson blood donation center](#), 8/24/22) ♦

**GLOBAL NEWS**

**Sanquin Health Solutions, the commercial subsidiary of the Sanquin Blood Supply Foundation, the organization that provides the blood supply in the Netherlands, has [agreed](#) to sell “its reagents branch to the Dutch Gilde Healthcare according to a news release from the organization.** “We are very pleased with this announcement,” said Hugo de Bruin, a partner at Gilde Healthcare, in the news release. “We invest in companies that enable better care at lower costs. The strong [research and development] into new reagents that Sanquin Reagents has built up fits in with this investment philosophy. We see many opportunities to expand the unique research and manufacturing capabilities and develop new reagents. This will provide more affordable products with a wider global reach.” The news release noted that the “acquisition, which is still subject to the usual approval under the Works Councils Act, is expected to be completed in the coming months...Sanquin Health Solutions Reagents division produces and sells blood group and immune reagents, materials needed for, among other things, diagnostic research and drug development.”

(Source: Sanquin [News Release](#), 8/29/22)

**The World Health Organization (WHO) has published an [updated](#) “Vaccines and immunization for monkeypox interim guidance” developed “with advice and support” from the Strategic Advisory Group of Experts (SAGE) Ad-hoc Working Group on smallpox and monkeypox vaccines.** The recommendations in the updated interim guidance include:

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- “[m]ass vaccination is not required nor recommended for monkeypox at this time;
- [f]or contacts of cases, post-exposure preventive vaccination (PEPV) is recommended with an appropriate second- or third-generation vaccine, ideally within four days of first exposure to prevent onset of disease;
- [p]rimary preventive vaccination (PPV) is recommended for persons at high risk of exposure, including but not limited to gay or bisexual men who have sex with men or other persons with multiple sex partners, health workers at risk, laboratory personnel working with orthopoxviruses, clinical laboratory staff performing diagnostic testing for monkeypox, and others who may be at risk, as per national policy;
- [v]accination program[s] must be backed by thorough surveillance and contact-tracing, and accompanied by a strong information campaign, robust pharmacovigilance, ideally in the context of collaborative vaccine effectiveness studies with standardized protocols and data collection tools; [and]
- [d]ecisions on use of smallpox or monkeypox vaccines should be based on a full assessment of risks and benefits on a case-by-case basis.”

The WHO also stated that the goal “the global outbreak response for monkeypox is to stop human-to-human transmission of monkeypox, with a priority focus on communities at high risk of exposure which may differ according to context, and to effectively use strong public health measures to prevent onward spread of the disease. Judicious use of vaccines can support this response.”

(Source: WHO Interim [Guidance](#), 8/24/22)

**Takeda recently received [approval](#) for the company’s dengue vaccine from the Indonesia National Agency for Drug and Food Control.** The vaccine can now be used in the “prevention dengue disease caused by any serotype in individuals six years to 45 years of age...regardless of previous dengue exposure and without the need for pre-vaccination testing,” according to a company news release. The approval was “based on results through three years after vaccination from the ongoing Phase 3 Tetravalent Immunization against Dengue Efficacy [Study](#) (TIDES) trial that enrolled over 20,000 healthy children and adolescents ages four to 16 years living in dengue-endemic areas in Asia and Latin America. [The vaccine] demonstrated continued overall protection against dengue illness and hospitalization three years after vaccination, regardless of an individual’s previous dengue exposure. [It was] generally well tolerated, with no important safety risks identified in the TIDES trial, to date Takeda recently presented long-term safety and efficacy results from the TIDES trial through 54 months of follow-up, which further validated the vaccine’s efficacy and safety profile.”

(Source: Takeda [News Release](#), 8/22/22) 💧

## COMPANY NEWS

**Haemonetics Corporation** announced a [partnership](#) with **Epic** to “offer” Haemonetics’ transfusion management system to hospitals within Epic’s global network. “[Our transfusion management system] provides complete visibility of patients and blood products for blood banks across the care continuum,” said Haemonetics President of Global Hospital Stew Strong in a news release. “As staffing and blood supply shortages persist, we look forward to helping more hospitals within Epic’s network leverage [our system] for greater transfusion safety and efficiency.”

(Source: Haemonetics [News Release](#), 8/29/22) 💧

## CALENDAR

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

### 2022

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

Sept. 20-22. **2022 Center for Biologics Evaluation and Research (CBER) Science Symposium (Virtual).** Registration is [open](#). More information available [here](#).

Sept. 21-22. **28<sup>th</sup> 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 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.
- **ADRP vCJD Implementation – Soup to Nuts Webinar** – October 12 from 1-2 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](mailto: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](mailto:newsletter@americasblood.org)

## POSITIONS

**Manager of Technical Services.** The Blood Connection is looking for a Manager of Technical Services in Morrisville, NC. This is a new role that will be responsible for supervising and managing the daily operations of the technical departments: Hospital Services, Component Manufacturing/Biologics Processing and Immunohematology Reference Laboratory. We offer a generous benefits package including a great 401k match, tuition reimbursement, yearly increases, company bonus, cell phone stipend, and 30 days PTO. Join our team and help make an impact in your community today! Relocation assistance offered. 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 coverage. If you meet the above qualifications, please apply by sending your resume to: [mcannon@bbak.org](mailto:mcannon@bbak.org). For more information about the Blood Bank of Alaska, please visit our website at <https://www.bloodbankofalaska.org>.

**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.

**Divisional Director.** The Blood Connection, formerly Carolina-Georgia Blood Center, is expanding our operations into Augusta, Georgia! We are one of the fastest growing blood centers in the country and we are looking to hire a Divisional Director who will be responsible for our day-to-day operations and help direct our expansion of services into this new territory. The ideal candidate is a results-focused self-starter with progressive leadership experience and the drive to help fulfill the needs of our community partners. We offer a generous benefits package including a great 401k match, tuition reimbursement, yearly increases, company bonus, cell phone stipend, and 30 days PTO. Join our team and help make an impact in your community today! Click [here](#) 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

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POSITIONS (continued from page 8)

of four years of management/supervisory experience required; Equivalent combination of demonstrated work experience and education may be considered. Starting salary range is \$135,000 - \$150,000 annually. Click [here](#) to apply. ●