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NEWSLETTER

A weekly chronicle of events and issues impacting the blood community

2026 #15 May 19, 2026

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Study in *NEJM* Explores Prehospital Type O Whole Blood Use in Trauma Patients

Researchers in paper published in *The New England Journal of Medicine* report on the findings of the "Type O Whole Blood and Assessment of Age during Prehospital Resuscitation (TOWAR) trial." Specifically, the authors aimed to, "evaluate the safety and efficacy of prehospital transfusion with low-titer group O whole blood as compared with blood components, as well as to characterize differences in outcome associated with the storage age of whole blood, in patients with severe injuries that warranted transfusion owing to risk of hemorrhagic shock."

The stated hypothesis of the investigators was that, "prehospital transfusion with low-titer group O whole blood would lead to lower 30-day mortality than transfusion with blood components." The trial included patients between the ages of 18 and 90 who were, "transferred from the scene of injury or a referring emergency department to a participating trauma center; [these individuals] were eligible for enrollment in the trial if they had had at least one episode of hypotension (defined as a systolic blood pressure of ≤90 mm Hg) and tachycardia (defined as a heart rate of ≥108 beats per minute) or if they had had severe hypotension (defined as a systolic blood pressure of ≤70 mm Hg) without tachycardia." The trial used a, "single-stage cluster randomization scheme in which participating air medical bases were assigned in a 2:1 ratio to use whole blood or component therapy for transfusion for fixed one-month blocks; the assignment for the initial block was randomly determined." Additionally, the paper noted that, "[a]ir medical bases assigned to use whole blood for a given month were stocked with two units of group O blood with anti-A and anti-B titers of less than 256 and a shelf life of up to 21 days. Eligible patients received up to two units of whole blood, with administration of the second unit guided by clinical status and site protocols."

The stated primary outcome of the trial was, "death from any cause within 30 days after randomization. Additional prespecified secondary outcomes included death within three, six, and 24 hours after arrival at the participating trauma center; death in the hospital; death attributable to hemorrhage or brain injury; the amount of blood products transfused during the first 24 hours after arrival; multiple organ failure; nosocomial infection; acute respiratory distress syndrome; allergic or transfusion-related reactions; time to hemostasis; and coagulation measurements."

The trial enrolled 1,020 patients from May 2022 to June 2025 as, "715 were transported by air bases that had been randomly assigned to the whole-blood group, and 305 were transported by bases assigned to the component group." The authors highlighted that primary outcome data was available for 972 patients. The study found that, "[a]t 30 days after randomization, overall mortality was 24.3 percent, with 180

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NEJM Paper Explores Prehospital Type O Whole Blood Use in Trauma Patients (continued from page 1)

deaths in the whole blood group and 61 deaths in the component group. Mortality at 30 days was 25.9 percent in the whole-blood group and 20.5 percent in the component group after imputation and adjustment for clustering and imbalance (adjusted odds ratio, 1.24; 95 percent confidence interval [CI], 0.87 to 1.76; P=0.24). [Additionally, mortality] at three, six, and 24 hours and in-hospital mortality appeared to be similar in the whole blood and component groups. No apparent differences between groups were noted with respect to the number of units of blood products transfused within 24 hours or the incidence of multiple organ failure, nosocomial infection, or acute respiratory distress syndrome."

The investigators noted that, "[t]he storage age of whole blood did not appear to be associated with substantial differences in 30-day mortality between the two groups (27.1 percent vs. 26.4 percent; adjusted odds ratio, 0.99; 95 percent CI, 0.74 to 1.32) or in other secondary outcomes. [The results] of the analysis of 30-day mortality according to the storage age of whole blood in the seven prespecified subgroups suggested no apparent differences."

The paper concluded that, "30-day mortality did not differ significantly between the trial groups, nor were apparent between-group differences observed with respect to secondary outcomes, including units of blood products transfused within 24 hours after arrival at the hospital, multiple organ failure, nosocomial infection, acute respiratory distress syndrome, coagulation measurements, and platelet function measurements. [In patients at risk] for hemorrhagic shock who underwent blood transfusion, the use of whole blood did not result in lower 30-day mortality than the use of blood components. The storage age of whole blood through 21 days from donation was not associated with apparent differences in outcomes." Acknowledged limitations of the study included, "[b]lood product crossover between trial groups occurred. Blood transfusion before randomization was not a criterion for trial exclusion, which potentially limited differences between the trial groups. The overall transfusion volume provided in the prehospital phase of care was low as compared with the volume of products provided in the hospital. Some patients in the component group received both plasma and red cells, which may have resulted in similar resuscitation characteristics in the two trial groups. Similarly, some patients in the whole-blood group received additional transfusion with blood components. The number of units of blood products transfused in the prehospital environment was not addressed in the protocol. The intervention could not be masked, which leaves the potential for treatment bias. Measurements of coagulation and platelet function were limited by missing data and potential spectrum bias. The analyses of primary and secondary outcomes may be limited by unmeasured or unknown confounders."

Citation: Sperry, J.L., Guyette, F.X., Cotton, B.A., *et al*. "Prehospital Resuscitation with Type O Whole Blood for Trauma and Hemorrhage." *NEJM*. 2026.

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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.

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REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has published a notice in the *Federal Register* announcing that the Blood Products Advisory Committee (BPAC) has been renewed. According to the May 7th notice, "[t]he Commissioner has determined that it is in the public interest to renew the Blood Products Advisory Committee for an additional two years beyond the charter expiration date. The new charter will be in effect until the May 13th, 2028, expiration date." BPAC is a, "discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises and informs the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drug and biological products for human use, as well as, when required, any other product under the regulatory authority of FDA. The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and as required, any other products for which FDA has regulatory responsibility. The Committee also advises [the Commissioner] of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses. The Committee may consider the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner."

(Source: *Federal Register* Notice, 5/7/26)

The FDA announced on May 6th that, "it is piloting one-day inspectional assessments, as part of a broader initiative to make its inspectional resources more targeted and efficient. As part of this pilot, which launched in April 2026, the agency is conducting shorter, focused screening assessments to complement standard FDA inspections." The agency announcement explained that, "[o]ne-day inspectional assessments also support the development of more robust risk models across FDA programs. Data gathered through these assessments—such as recurring compliance themes, facility-specific risk scores, and discrepancies between registered and actual operations—can be used to better target future oversight activities. The pilot is being conducted across multiple FDA inspectorates, including human and animal foods, biologics, medical products, and clinical research programs. Facilities are selected using risk-based criteria such as product type, prior inspection outcomes, and operational characteristics." These assessments are not, "intended to replace standard FDA inspections. Instead, they serve as an additional tool to complement the agency's existing approach. Investigators retain authority to expand the scope or duration of an assessment if warranted. The pilot does not represent a change in enforcement policy and does not apply to higher-risk or more complex facilities that require more comprehensive inspectional coverage." FDA anticipates continuing the pilot, "[t]hrough fiscal year 2026, with additional assessments planned across inspectorates. The FDA is developing evaluation metrics to assess effectiveness, including inspection duration, escalation rates, and the utility of findings in informing risk-based decision-making."

(Source: FDA Announcement, 5/6/26)

Martin Makary, MD, MPH has resigned as commissioner of the FDA. Dr. Makary was confirmed as the 27th commissioner of the agency in March 2025. Kyle Diamantas, JD has been named Acting FDA Commissioner as of May 12th. He joined the agency in February 2025 as a special assistant to the Commissioner prior to assuming the role of Acting Deputy Commissioner for Human Foods. In February 2026, he began serving as senior counselor to the FDA at the U.S. Department of Health and Human Services (HHS).

Karim Mikhail, MS has been named Acting Director of the FDA's Center for Biologics Evaluation and Research (CBER). He joined FDA in 2025 as a senior advisor in the Office of the Commissioner.

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REGULATORY NEWS (continued from page 3)

Michael Davis, MD, PhD has become Acting Director of the FDA's Center for Drug Evaluation and Research (CDER). He succeeds Tracy Beth Høeg, MD, PhD. Dr. Davis most recently served as the agency's deputy director since 2025.

INFECTIOUS DISEASES UPDATE

DENGUE

The U.S. Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* (*MMWR*) published a paper titled, "Increase in Travel-Associated and Locally Acquired Dengue Cases—United States, 2024." The authors described that, "[d]uring 2024, a total of 3,798 dengue cases, including 2,252 (59.3 percent) confirmed and 1,546 (40.7 percent) probable cases, were reported to CDC from the 50 U.S. states and the District of Columbia (DC). These represent a 359 percent increase above the annual average of 828 cases per year during 2010–2023. Among these cases, 3,693 (97.2 percent) were travel associated, and 105 (2.8 percent) were locally acquired. Overall, 1,581 (41.6 percent) of all travel-associated and locally-acquired cases occurred during the summer months, including 509 (13.4 percent) in July, 602 (15.9 percent) in August, and 470 (12.4 percent) in September." Additionally, the paper highlighted that, "[a]mong the 3,693 persons with travel-associated dengue, 3,259 (88.2 percent) reported international travel (outside U.S. states and territories), and 246 (6.7 percent) reported travel to a U.S. state or territory. Most of the 246 cases among travelers to U.S. jurisdictions occurred in Puerto Rico (76.4 percent) or the U.S. Virgin Islands (22.0 percent); 1.6 percent occurred in Florida. Among the 3,505 (94.9 percent) persons with travel-associated dengue and known exposure location, the most frequent destinations were Mexico (892; 25.4 percent), Cuba (633; 18.1 percent), and India (225; 6.4 percent). Among all travel-associated cases, the most frequently visited regions were the Caribbean (including Puerto Rico and the U.S. Virgin Islands [34.1 percent]), North America (Mexico and the United States) (24.3 percent), Central America (15.6 percent), and Asia (10.1 percent). Trends varied by month, with more cases occurring in persons returning from South America during January–May and more in persons returning from the Caribbean, North America, Central America, and Asia during July–November." The investigators concluded that, "[t]he 2024 increase was primarily caused by an increase in travel-associated cases (97.2 percent of reported dengue cases) and reflects the sharp global surge in dengue cases observed in 2024. Worldwide, dengue cases reached 14.1 million in 2024, including approximately 13 million cases in the region of the Americas, an increase of approximately 8 million cases compared with 2023. [Locally acquired cases in Florida,] California, and Texas were reported from multiple counties within each state, suggesting multiple introduction events rather than extensive ongoing transmission in one location. Although these introductions did not lead to larger outbreaks in the continental United States, they indicate an increasing risk for locally-acquired cases, underscoring the need for enhanced surveillance, vector control, and public health preparedness and response efforts in areas with competent mosquito vectors. *Aedes aegypti* and *Aedes albopictus* mosquitoes are present in many counties in both the eastern and western United States and pose an ongoing risk for DENV transmission in new areas. [Although no dengue vaccines] are currently approved for U.S. travelers who are visiting but not living in dengue-endemic areas, persons can protect themselves by preventing mosquito bites during travel to and after returning from areas with dengue risk where competent mosquito vectors are present to reduce the risk and potential for local transmission."

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INFECTIOUS DISEASES UPDATE (continued from page 4)

EBOLA

On May 17th, the World Health Organization (WHO) declared the Ebola disease outbreak in the Democratic Republic of the Congo and Uganda caused by Bundibugyo virus a, "public health emergency of international concern (PHEIC), but does not meet the criteria of pandemic emergency, as defined in the International Health Regulations (2005) (IHR)." As of May 16th, "eight laboratory-confirmed cases, 246 suspected cases, and 80 suspected deaths have been reported in Ituri Province of the Democratic Republic of the Congo across at least three health zones, including Bunia, Rwampara, and Mongbwalu." The agency explained that, "[u]nusual clusters of community deaths with symptoms compatible with Bundibugyo virus disease (BVD) have been reported across several health zones in Ituri, and suspected cases have been reported across Ituri and North Kivu. [There] are significant uncertainties to the true number of infected persons and geographic spread associated with this event at the present time. In addition, there is limited understanding of the epidemiological links with known or suspected cases. [The event constitutes] a public health risk [through] the international spread of disease. International spread has already been documented, with two confirmed cases reported in Kampala, Uganda on May 15th-16th following travel from the Democratic Republic of the Congo."

The U.S. Centers for Disease Control and Prevention (CDC) published an update on May 19th stating that the U.S. has, "implemented enhanced travel screening, entry restrictions, and public health measures to prevent Ebola virus disease from entering the United States amid ongoing outbreaks in East and Central Africa." CDC also noted that the agency is, "monitoring an outbreak of Ebola disease in remote areas of the Democratic Republic of the Congo (DRC) and Uganda. To date, no cases of Ebola disease have been confirmed in the United States because of this outbreak. The overall risk to the American public and travelers remains low." The CDC has not classified the affected region as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that, "in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2)."

(Source: WHO Update, 5/17/26; CDC Update, 5/19/26)

PEOPLE



Gulf Coast Blood has announced the promotion of **Kevin Shipley** to the role of vice president of Donor and Community Engagement. He most recently served as associate vice president of Community Engagement. Mr. Shipley will now, "oversee collections operations and donor recruitment, aligning donor engagement strategies with collection needs to support a more consistent and responsive blood supply," according to a blood center announcement. He began his career in healthcare in 2005 and has worked as a blood drive recruiter, building his career, "leading and scaling donor-focused programs, guiding high-performing teams, and supporting the coordination of thousands of blood drives each year to meet the region's critical needs." Mr. Shipley is also a member of the ADRP Advisory Board.

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PEOPLE (continued from page 5)



Marc Lewis has been named vice president of Blood Supply Chain Operations at Gulf Coast Blood. In this role, he will, "oversee manufacturing, inventory, and logistics for all blood products. His focus will be on centralizing expertise and advancing performance across the supply chain to ensure timely, reliable product availability for healthcare partners," according to a blood center announcement. [Mr. Lewis] began his career with Gulf Coast Blood in 1992 as a hospital services representative and quickly advanced through leadership roles within the department. His dedication to patient safety and operational excellence led to his promotion to director of Hospital Services in 2004, where he managed the regional blood supply and strengthened service to hospitals across the Gulf Coast region. His responsibilities expanded in 2008 when he became director of Production Management. [In 2016, his leadership scope] expanded further to include Production Management, Neighborhood Donor Centers, and Regional Operations. [Mr. Lewis was promoted] to vice president of Operations in 2017, assuming additional responsibility for business development."

(Source: Gulf Coast Blood Announcement, 5/6/26)

MEMBER NEWS



Rep. Kat Cammack (R-Fla.) visited **LifeSouth Community Blood Centers** earlier this month in Gainesville, Fla. During her visit, Congresswoman Cammack, "discuss[ed] the importance of blood donation and the lifesaving impact donors make in the communities serve[d]" by LifeSouth. A Facebook post also noted that, Rep. Cammack learned more about the blood needs of local hospitals and saw firsthand how blood products are supplied to EMS organizations to help provide on-site transfusions during emergency response situations."

(Source: LifeSouth Community Blood Centers Announcement, 5/8/26)



New York Blood Center (NYBC) recently welcomed the Amazin' Mets Foundation to its Queens Donor Center to honor the Foundation for its $150,000 grant in support of the donor center. A blood center announcement noted that the grant, "was used to enhance donor equipment needed to collect red blood cells, platelets, and plasma. This special acknowledgment was hosted at NYBC's new Queens Donor Center, where members of NYBC leadership and the Amazin' Mets Foundation unveiled an honorary plaque to represent the Foundation's generous contribution. The Queens Donor Center, which opened in late 2025, marks NYBC's sixth donor center in New York City." The Amazin' Mets Foundation is the "philanthropic arm" of Major League Baseball's New York Mets franchise.

(Source: NYBC Announcement, 5/5/26)

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MEMBER NEWS (continued from page 6)



SunCoast Blood Centers hosted a May 2nd blood drive at the home of blood center Chief Executive Officer Scott Bush. The Kentucky Derby themed blood drive resulted in the collection of 38 units. The event also featured a photo opportunity for prospective donors in the "Winner's Circle" with one of Mr. Bush's horses in addition to food and Mint Julep mocktails. Last year, Mr. Bush also held a blood drive at his home and explained in a blood center announcement that the decision to host the event was to, "demonstrate his commitment to saving lives and expanding SunCoast's reach [and to set an example of] what can be accomplished when leadership becomes directly involved in frontline community efforts."

(Source: SunCoast Blood Centers Announcement, 5/4/26)

BRIEFLY NOTED

An article published in *EMS World* noted that, "[a] released report from the National Emergency Medical Services Information System (NEMSIS) provides a comprehensive national snapshot of blood product administration in prehospital care, underscoring a significant shift in how emergency medical services (EMS) agencies manage hemorrhage and shock in the field." The news organization explained that the report, "analyze[s] data from 2024–2025 [as] the report documents more than 48,000 EMS blood transfusions nationwide, including more than 22,000 administered during ground ambulance responses. The findings reflect continued momentum in the adoption of prehospital blood programs, particularly among agencies seeking to improve outcomes for patients experiencing severe trauma or medical bleeding."

(Source: *EMS World*, "New NEMSIS Report Highlights Rapid Growth of Prehospital Blood Transfusion in EMS Systems Nationwide," 5/5/26)

The National Conference of State Legislatures' (NCSL) "Our American States Podcast" has published an episode titled, "The Lifesaving Potential of Prehospital Blood." The podcast features National Highway Traffic Safety Administration Administrator Jonathan Morrison, "discuss[ing] the importance of prehospital blood programs that allow emergency responders to administer blood at the scene to trauma victims. He's joined by a former military trauma nurse with deep experience in the field and a policy expert from NCSL. [Mr. Morrison explained] why these programs are a priority for NHTSA and how these programs could reduce the approximately 40,000 traffic crash fatalities in the U.S. each year. [Randi Schaefer, a former career Army trauma nurse] reviewed some of the challenges in setting up prehospital blood programs and the role state lawmakers can play [and] Aneesa Turbovsky, who tracks EMS-related legislation for NCSL, went into detail on the steps legislatures are taking to make it possible for paramedics to administer blood and how lawmakers can bring together the various parties needed to make these programs work."

(Source: NCSL Podcast, 4/12/26)

WORD IN WASHINGTON

The National Highway Traffic Safety Administration's (NHSTA) Office of Emergency Medical Services (EMS) is currently celebrating EMS Week May 17th-23rd. Over the course of this week, the agency is honoring, "the entire EMS profession for all [they] do to protect our health and safety. This year's theme, 'Improving Outcomes, Together,' is an opportunity to focus on the many ways EMS professionals work together and across disciplines—with 911, healthcare, public health, fire service, law enforcement, and

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WORD IN WASHINGTON (continued from page 7)

others—in the best interests of patients," according to an NHTSA announcement. Of interest to blood community, the agency noted that, "EMS Week [2026] highlights an advanced post-crash care intervention that's quickly expanding across the country: prehospital blood transfusion—the delivery of blood products to patients injured in a motor vehicle crash, helping to save lives and prevent injury. EMS Week is a good time to engage with the community—to host a blood drive to boost the blood supply in your community. Even if an EMS agency doesn't have a prehospital blood transfusion program, this community outreach event can help raise awareness about this life-saving intervention. For more information, access the EMS Blood Drive Toolkit; we hope you'll consider participating."

In conjunction with EMS Week, NHTSA will also host a webinar on Thursday, May 21st at 11 a.m. EDT titled: "Blood on Board: The New Standard of Care Panel." Registration for this virtual event is open. It will be, "moderated by Jonathan Morrison, administrator of the NHTSA. [This webinar] will feature a panel discussion on prehospital blood transfusion hosted by NHTSA in partnership with Federal Interagency Committee on Emergency Medical Services (FICEMS). [Hear] how EMS systems are implementing prehospital blood transfusion programs, the partnerships making it possible and progress underway to expand access and improve patient outcomes. Panelists include:

- "Emily Coberly, MD, Divisional Chief Medical Officer, American Red Cross;
- Matthew Levy, DO, MSc, FACEP, FEMS, NRP, Professor of Emergency Medicine, The Johns Hopkins School of Medicine; Chief Medical Officer, Howard County Fire and Rescue; [and]
- David Long, MA, Executive Director, Tidewater EMS Council."

(Sources: NHSTA EMS Week Announcement, 4/8/26; NHSTA Webinar Announcement, 5/15/26)

ADVANCED THERAPIES NEWS

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has published a May 5th final guidance titled "Chemistry, Manufacturing, and Controls Flexibilities for Developing Human Cellular and Gene Therapy Products for a Biologics License Application." The final guidance details, "information on when chemistry, manufacturing, and Controls (CMC) flexibilities may be appropriate for the development of human cellular and gene therapy (CGT) products and does not comprehensively address the CMC information and data necessary to support CGT product licensure under section 351 of the Public Health Service Act (42 U.S.C. 262)." The agency explained in the document that, "[c]onsistent with the statutory and regulatory requirements for biological products, FDA uses a flexible approach to ensuring applicable CMC requirements are met for CGT products. FDA's flexible approach serves to help expedite development, review, and patient access to safe and effective CGT products to treat serious or life-threatening conditions that represent significant unmet medical needs. FDA has issued several guidances that provide CMC recommendations to sponsors developing CGT products. Sponsors developing CGT products should consider the CMC recommendations in this guidance in addition to those guidances for industry, as applicable."

(Source: FDA Final Guidance, 5/5/26)

Terumo Blood and Cell Technologies (Terumo BCT) and Steminent Biotherapeutics Inc. have announced a "strategic collaboration" that aims to, "accelerate late-stage manufacturing readiness for mesenchymal stem cell (MSC) therapies, addressing one of the key barriers to clinical scale-up and commercialization in regenerative medicine." Specifically, the partnership will focus on, "optimizing automated cell expansion for clinical development and future commercial production of Steminent's late-stage MSC-based therapy. [Upon successful completion] of development milestones, Steminent plans to

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ADVANCED THERAPIES NEWS (continued from page 8)

expand usage of Quantum Flex, leveraging the system to support broader clinical translation and commercialization plans. This collaboration aligns with Terumo BCT's APAC Ecosystem Blueprint—a practical, collaborative framework designed to support cell and gene therapy developers in the Asia-Pacific region as they transition from early development to scalable, repeatable manufacturing and delivery."

(Source: Terumo BCT News Release, 5/13/26)

Eli Lilly and Company has committed, "[an] additional $4.5 billion investment across two of its three Lebanon sites," which will include Lilly Lebanon Advanced Therapies, its first dedicated genetic medicine manufacturing facility [that opened on May 6th.]" The company described the advanced therapies facility as being designed to, "support both clinical and commercial production of advanced therapies that target disease at the genetic level and will include a full spectrum of genetic medicine modalities from research-stage development through large-scale commercial supply. Designing and building for these modalities required developing new manufacturing processes without established commercial precedent."

(Source: Eli Lilly and Company News Release, 4/29/26)

The United Kingdom's (UK) regulatory authority, Medicines and Healthcare products Regulatory Agency (MHRA), in collaboration with the Department of Health in Northern Ireland have, "launched a consultation calling to update the legal definition of gene therapy medicinal products (GTMPs) in the UK." The proposed changes seek to, "ensure UK regulation keeps up with advances in gene therapy, synthetic biology, and gene editing technologies." The agency explained that the updated definitions, "will not alter the approval process for gene therapies, the regulatory classification of products already licensed, or change any existing safety, quality, or efficacy standards. The proposed amendments intend to: [p]rovide greater certainty for developers working on gene therapy products; [e]nsure consistent regulation across all gene therapy products, whether these are created biologically or synthetically; [s]upport innovation across the sector, giving researchers and companies a future-proof regulatory framework; [and maintain] high standards of patient safety and regulatory oversight."

(Source: MHRA Announcement, 5/11/26)

GLOBAL NEWS

South Korea is raising the upper age limit for blood donor from 69 years of age to 75. According to a report from *Korea JoongAng Daily*, "[t]he government is pushing to raise the upper age limit for blood donation, currently capped at 69, to secure a stable supply amid low birthrates, an aging population and recurring seasonal declines in donations, according to the Ministry of Health and Welfare." The news organization further explained that, "[t]he Health Ministry said it had finalized and unveiled the second basic plan for blood management from 2026 to 2030 at a meeting of the blood management committee. The plan focuses on expanding participation in blood donation and building a more stable blood supply system. Under the plan, the government will review raising the upper age limit for blood donation, which has remained at 69 since it was increased from 64 through a revision to the Blood Management Act in 2008. A ministry-commissioned study released in December 2025, which analyzed donor screening standards and related issues, concluded that the upper age limit should be raised to 75. [Individuals in] their teens and 20s accounted for 55 percent of all donors in Korea, indicating a heavy reliance on younger age groups and a risk in managing supply as the younger population shrinks, while demand for blood among older adults continues to grow. The population of people in their teens and 20s fell from 11.6 million in 2020 to 10.6 million in 2024. Meanwhile, the number of transfusion recipients aged 50 and older increased from 347,000 in 2020 to 366,000 in 2024, with older adults accounting for the majority of transfusion cases."

(Source: *Korea JoongAng Daily*, "Gov't proposes raising blood donation age limit from 69 to 75 to bolster supply, 5/13/26)

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.

2026 ABC Advocacy Summit Less Than 3 Weeks Away — Register Today!

Register now for the 2026 America's Blood Centers (ABC) Advocacy Summit taking place in Washington, D.C. at The Dupont Circle (part of The Doyle Collection Hotels) June 8th-9th. View the schedule and don't miss the chance to let your voice be heard as this event connects the blood community with national leaders in public policy and advocacy including meetings with members of Congress and their staff. The 2026 ABC Advocacy Summit includes advocacy training and group preparations for meetings with congressional offices on June 8th before heading to Capitol Hill on June 9th for group meetings with members of Congress and their staff, advancing ABC's advocacy priorities. We will coordinate the scheduling of meetings on behalf of all attendees and conclude the day with a reception. Please contact us with questions.

Register for the AI for Blood Centers Webinar

The ABC Educational Webinar Committee will host a June 16th webinar titled "Artificial Intelligence (AI) for Blood Centers." Hear your peers share real-world experiences and insights on how AI is being deployed and implemented at their blood centers. Speakers include:

- Chris Ebert (SunCoast Blood Centers);
- Evan Arias Johnson (SunCoast Blood Centers);
- Andrea Sign (Carter BloodCare); [and]
- Niveditha Rameshbabu (Stanford Blood Center).

ABC members can contact us with questions or to receive a link to registration.

COMPANY NEWS

Biowy Corporation has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Biowy Multi-Chamber Freezing Bag Set. This product is, "intended for a single sequence of freezing, storage (in Liquid Nitrogen (-196°C)), and subsequent thawing (at +37°C) of hematopoietic progenitor cells."

(Source: FDA Letter, 4/29/26)

The American Society for Clinical Pathology (ASCP) has extended the deadline to Sunday, May 31st.for the 2026 Vacancy Survey. An announcement from the organization noted that the survey aims to, "determine the extent and distribution of workforce shortages within the nation's medical laboratories. All responses will be confidential, and data will only be reported in aggregate. Individual-level data will not be reported." ASCP asks all laboratory professionals to complete the survey and encourages individuals to forward the survey link to their peers.

(Source: ASCP Survey, 5/5/26)

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COMPANY NEWS (continued from page 10)

Blood Bank Computer Systems, Inc. (BBCS) recently announced that Kentucky Blood Center has implemented the BBCS' Forcyte Scheduling Platform™. According to a company news release, the platform, "delivers a modern, user-friendly solution designed to simplify and optimize the donor scheduling experience. With advanced tools for appointment management, mobile accessibility, and real-time updates." Kentucky Blood Center Chief Executive Officer (CEO) William Reed added in the news release, "[w]e are excited to partner with BBCS. [This] technology allows us to better serve our donors by making it easier than ever to schedule and manage appointments. Ultimately, it helps us fulfill our mission of providing a safe and adequate blood supply to the communities we serve."

(Source: BBCS News Release, 5/4/26)

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.)*

2026

May 19-20. **U.S. Food and Drug Administration (FDA) Regulatory Education for Industry (REdI) Annual Conference 2026: "Innovative Regulatory Strategies to Advance Medical Products" Silver Spring, Md. (Hybrid).** Registration is open. More information is available here.

May 20-21. **IPFA/Paul-Ehrlich Institut[e] (PEI) 32nd International Workshop on Surveillance and Screening of Blood-borne Pathogens. Bilbao, Spain.** Registration is open. More information available here.

May 21. **National Highway Traffic Safety Administration (NHTSA) Webinar: "Blood on Board: The New Standard of Care Panel (Virtual).** Registration is open and more information is available here.

June 4. **FDA CBER Office of Therapeutic Products (OTP) Virtual Town Hall: "Best Practices for Preparing BLA Submissions for Cell and Gene Therapy Products."** More information is available here.

June 8-9. **2026 America's Blood Centers (ABC) Advocacy Summit. Washington, D.C.** Registration is open. More information is available here.

June 16. **ABC Webinar: Artificial Intelligence (AI) for Blood Centers (Virtual).** Please contact us for more information and a link to registration.

June 19. **Alliance for Regenerative Medicine (ARM) Workshop: "From Platform to Patient: Defining Market readiness for Genetic Medicines. Paris, France.** Registration is open. More information is available here.

June 20-24. **International Society of Blood Transfusion (ISBT) 39th International Congress. Kuala Lumpur, Malaysia.** Registration is open. More information available here.

June 25-26. **National Heart, Lung, and Blood Institute (NHLBI) and the Sickle Cell Disease Association of America, Inc. (SCDAA) "Research That Heals: Partnering with Patients to Transform SCD Care." Rockville, Md. (Hybrid).** More information is coming soon.

Sept. 16-17. **ADRP: The Association for Blood Donor Professionals Master Class (Virtual).** More information is coming soon.

Oct. 4-7. **Association for Advancing Tissue and Biologics (AATB) Annual Meeting. San Francisco, Calf.** More information available here.

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CALENDAR (continued from page 11)

Oct. 5-7. **ARM Cell & Gene Meeting on the Mesa. Phoenix, Ariz.** More information is available here.

Oct. 17-19. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Atlanta, Ga.** More information is coming soon.

Nov. 5-6. **2026 ABC Women's Executive Leadership Community *Rise* & Lead Workshop. San Antonio, Texas.** More information is coming soon.

Nov. 17-20. **American Society for Clinical Pathology (ASCP) and Canadian Association of Pathologists- Association Canadienne des Pathologistes (CAP-ACP) Joint Annual Meeting. Montreal, QC.** Registration is open. More information available here.

2027

March 8-11. **2027 ABC Annual Meeting. Atlanta, Ga.** More information is coming soon.

May 11-13. **2027 ADRP: The Association for Blood Donor Professionals Annual Conference Columbus, Ohio.** More information is coming soon.

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

Clinical Systems Analyst – Blood Center Services (BECS). Stanford Blood Center (SBC) in Palo Alto, CA, is seeking a specialized **Clinical Systems Analyst** to join our Blood Operations team. In this role, you will support blood collections, manufacturing, testing, and distribution by delivering technical solutions through BECS, LIS, and other core blood center applications. Key responsibilities include optimizing system configurations, writing test cases, executing validations, performing root cause analysis, and ensuring the ongoing maintenance of all SBC blood systems. Key Responsibilities: System Oversight: Administer and support blood operations applications. Compliance & Validation: Manage system updates, configurations, validation, and implementation. Workflow Integration: Collaborate with lab operations to optimize system interfaces and blood manufacturing/testing workflows. Technical Support: Implement and troubleshoot system functions for zero downtime operations. Minimum Qualifications: Experience: Minimum 3 years of systems analyst work experience in blood operations, BECS administration, and support. Domain Expertise: Minimum 3 years of experience with Blood Establishment Computer Systems (BECS), Laboratory Information Systems (LIS), or Data Innovations (DI) Instrument Manager. Education: Bachelor's degree in a related field or equivalent professional experience. About Stanford Blood Center - SBC is a world-class organization dedicated to connecting local donors to patients in need. We provide hope for healing through innovative research and clinical excellence. Join us in a role where your technical expertise directly impacts life-saving medical care. Visit us at www.stanfordbloodcenter.org. Apply here! For inquiries, contact: Miriam Garrido, mobile: 650-272-8412 SBC Talent Acquisition Consultant.

Medical Laboratory Scientist. LifeSouth Community Blood Centers is looking for experienced Medical Laboratory Scientists, with a passion for making a difference. Current openings: Gainesville, Florida (Multiple shifts available; rotating weekends and holidays), Jacksonville, FL (Overnight), and Atlanta, Georgia (Morning shift; rotating weekends and holidays). **Legal authorization to work in the United States is required. We do not provide visa sponsorship for these positions.** Shift differential applies to eligible evening and overnight hours; **sign-on and/or relocation bonuses** may also be offered to qualified candidates. Our Medical Laboratory Scientists work in a full-service, accredited immunohematology laboratory following established policies and procedures to resolve complex immunohematology and compatibility problems to provide the safest donor blood for patients in our community. Join us in our mission to make sure blood is available when it's needed most. Visit

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POSITIONS (continued from page 12)

our careers page to learn more about this position and apply today!

Laboratory Supervisor (Evenings). LifeSouth Community Blood Centers is looking for an experienced **Laboratory Supervisor** with a passion for making a difference to lead our evening shift Immunohematology Reference Laboratory team, in **Gainesville, FL**. Shift differential applies to eligible evening and overnight hours; sign-on and relocation bonuses may also be offered to qualified candidates. In this role, you'll oversee daily operations, ensure adherence to established policies and procedures, and support staff in resolving complex testing and compatibility challenges. You'll play a critical part in identifying and addressing issues that may impact test performance or result reporting, while mentoring and guiding team members to uphold the highest standards of quality and safety. Your leadership will help ensure the delivery of the safest donor blood for patients in our community. We are committed to excellence in customer service and patient care. Join us in our mission to make sure blood is available when it's needed most. Visit our careers page to learn more about this position and apply today!

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 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 here!

Program Manager, Blood Donor Engagement. The University of Texas MD Anderson Cancer Center's Program Manager, Blood Donor Engagement leads relationship-driven marketing and communications efforts to advance the institution's blood donor recruitment and engagement goals. This role leads a cross-functional Blood Bank Marketing and Communications team representing eight departments to ensure timely, coordinated implementation of outreach tactics. Serving as the Institutional Affairs liaison for Blood Bank leadership, the Program Manager provides a single point of contact to address communications needs, manage issues and risks, and elevate matters as appropriate. The position develops and drives a comprehensive blood donor engagement strategy, oversees marketing and communications planning, and provides strategic recommendations to support recruitment goals. The Program Manager strengthens partnerships across departments conducting outreach activities, ensures consistent use of MD Anderson's brand voice and English and Spanish editorial standards, and manages coordinated institutional communications during critical blood shortages. This role directly supports lifesaving patient care. **Education:** Bachelor's degree in communications, marketing, public health, business, or related field. **Experience:** Experience in program or project management with emphasis on marketing and communications; healthcare or blood banking experience preferred. Click here to apply.

Director Business Development. OneBlood is seeking an experienced **Director, Business Development** to lead strategic growth initiatives and build strong partnerships that support organizational objectives within a dynamic healthcare environment. This leadership role will drive business expansion, identify new opportunities, manage key relationships, and collaborate cross-functionally to support long-term operational success. Candidates should possess proven experience in business development, strategic planning, relationship management, and team leadership, along with strong communication and analytical skills. Healthcare, nonprofit, or regulated industry experience preferred. Bachelor's degree required; advanced degree a plus. This position is based in Orlando, Florida, and offers the opportunity to contribute to a mission-driven organization dedicated to saving lives across the communities it serves. Competitive compensation and comprehensive benefits package offered. Apply online through OneBlood Careers.

Chief Financial Officer. Blood Assurance is seeking a strategic, collaborative, and mission-focused **Chief Financial Officer (CFO)** to join our executive leadership team. The CFO serves as a key strategic partner to the CEO and Board of Directors, providing leadership and oversight of the organization's financial strategy, fiscal sustainability, and operational performance. This executive leader will guide long-term financial planning, ensure strong internal controls and compliance, and support strategic growth initiatives across the organization. The CFO will oversee Finance and Information Technology functions and play a critical role in aligning financial operations with Blood Assurance's life-saving mission. **Key Responsibilities:** Develop and execute long-term financial strategies aligned with organizational objectives. Lead capital planning, forecasting, and investment strategy. Identify and assess financial risks and opportunities. Oversee accounting, payroll, budgeting, forecasting, financial reporting, audit, and tax compliance. Ensure strong internal controls and regulatory compliance. Lead annual budgeting process and present financial updates to executive leadership and Board. Oversee financial systems, data integrity, and reporting tools. Oversee the Information Technology department. Support projects

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POSITIONS (continued from page 13)

and initiatives for the Information Technology department. **Required Qualifications:** Bachelor's degree in Accounting or Finance with CPA license. 10–15+ years of progressive experience in finance and accounting. Minimum 5 years in senior executive or leadership role with direct supervisory responsibility. Experience working closely with a Board of Directors. Demonstrated experience in strategic financial planning and organizational leadership. Qualified candidates are encouraged to email a cover letter and resume to Marly Stone at marlystone@bloodassurance.org.

Transfusion Lab Manager Needed! Join Florida's leading blood center, **OneBlood**, as a Blood Bank Lab Manager in Bay Pines, FL. Bring your leadership, technical expertise, and management experience to support the transfusion testing procedures on patient and/or donor samples. Qualified candidates should possess five (5) or more years' experience in a related field. A valid and current Florida Clinical Laboratory Supervisor license in Immunohematology required; SBB certification preferred. To apply and view a complete Job Description of this Lab Manager position, visit www.oneblood.org/careers. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Financial Services Manager. LifeSouth Community Blood Centers is seeking an experienced and detail-oriented **Financial Services Manager** to join our team, in **Gainesville, FL**. This position oversees core financial operations, manages staff, and ensures compliance with organizational policies and deadlines. It provides leadership across accounts payable/receivable, fixed assets, payroll, and revenue cycle functions, driving accuracy and efficiency while supporting the organization's mission to provide a safe blood supply and exceptional service to the community. The Financial Services Manager will work closely with leadership to analyze financial data, identify trends, and support strategic decision-making while maintaining compliance with company policies and regulatory standards. 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 here!