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

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2025 #26 **August 18, 2025**

INSIDE:

Please Note: The *ABC Newsletter* will not be published on August 25th. We will resume regular publication on Tuesday, September 2nd. Thank you for your continued interest.

Potential Differences in Risk Phenotypes of Onsite VVRS Explored

Researchers in Denmark recently published a paper in *Vox Sanguinis* that sought, "to characterize the risk of phenotypes and genotypes of onsite vasovagal reactions (VVRs) alone, [classified] as syncope or near-fainting reactions, to investigate whether risk stratification based on subtype could be meaningful in donor vigilance." They examined, "lifestyle characteristics as well as mental and physical health, which in the future would allow [for the development of] a risk stratification tool that can be applied before the donor enters the donation facility."

Individuals participating in the study included whole blood, plasmapheresis, and platelet apheresis donors who completed a health questionnaire upon enrolling. The authors noted that, "[p]henotype data were available for 40,543 donors. A total of 1,453 experienced at least one near-fainting episode and 136 at least one syncopal reaction. Across all three groups (no adverse reactions (ARs), syncope, and near-fainting), there was a difference in sex distribution, age at inclusion, number of donations before and after inclusion, height and blood volume (BV), donation type at inclusion, smoking status, pain at donation, and mental component score (MCS)."

The study found that, "[n]ear-fainting cases were younger than in the other two groups (no reaction and syncope) and had lower height and BV). [Additionally,] near-fainting cases had fewer donations before inclusion compared to controls. Near-fainting cases also reported higher pain levels during donation than controls and had lower MCS compared to both syncope cases and controls…The near-fainting group also included a higher proportion of female donors. [There were no] significant differences in red blood cell count, white blood cell count, or h[e]matocrit across the groups."

The researchers also explained that, "[f]or both VVR types, the risk was increased by apheresis donation and warmer season, whereas donation after lunch appeared to be protective. For near-fainting, the risk was reduced by donation experience and increasing height. Older age also showed a tendency towards a significant protective effect." The paper noted that, "[n]o syncope-specific risk factors were identified. No significant interaction between sex and age was found for any of the VVR types. Modelling was performed first with height and then later with BV.

(continued on page 2)

Potential Differences in Risk Phenotypes of Onsite VVRS Explored (continued from page 1)

Increasing BV significantly reduced the risk of near-fainting (odds ratio [OR] 0.67, 95 percent CI: 0.52–0.86, p=0.002) but not syncope (OR 0.54, 95 percent CI: 0.18–1.62, p=0.274). Platelet counts or h[e]matocrit had no effect on either near-fainting or syncope risk. [The authors found] no association between genetic predisposition and the risk of near-fainting or syncope, both in the univariate and fully adjusted logistic models."

The researchers concluded that, "we found important differences in risk phenotypes for onsite VVRs with and without loss of consciousness (LOC). Whereas near-fainting risk is partly mediated by donation experience and height/BV, syncope risks appear to be entirely mediated through donation-specific characteristics. We furthermore found that genetic predisposition of syncope, anxiety, neuroticism, or coronary artery disease does not appear to have any effect on the risk of onsite near-fainting. The results highlight that current VVR research is significantly limited by the practice of combining syncope and near-fainting into a single entity, rendering it ineffective for predicting syncope."

The researchers acknowledged that limitations of the study included, "[t]he relatively small number of cases, especially for syncope, was the main limitation as well as the reason for not sex-stratifying the analysis. For the same reason, we were not able to investigate the impact of genetic predisposition on the risk of syncope or potential differences in risk factors across different donation types. In addition, a larger sample is needed to investigate all four types of VVR: onsite and offsite reactions with and without LOC. Another important limitation is that all participants had at least one donation prior to inclusion, as first-time donor status is a known important risk factor."

Citation: Mikkelsen, C., Sørensen, B.S., Aagaard, B., *et al*. "Onsite vasovagal reactions with and without loss of consciousness are distinct outcomes with different risk factors." *Vox Sanguins*. 2025.

WORD IN WASHINGTON

The National Institutes of Health (NIH) has announced a new policy regarding artificial intelligence (AI) use in research applications. The communication explains that NIH has, "noticed that some Principal Investigators (PIs) have been submitting a large number of research applications that far exceed the numbers we traditionally expect and may have been prepared using AI tools. While AI may be a helpful tool in preparing applications, the rapid submission of large numbers of research applications from a single PI may undermine the fairness and originality of the research application process and unfairly strain NIH's application review processes." NIH stressed that, "it is important to remember that applicants may use AI in limited aspects to reduce administrative burden while preparing applications. However, applicants should be mindful of the concerns around research misconduct or lack of originality when using such tools. Remember, NIH peer reviewers are prohibited from using AI for their critiques. To address these issues, the new policy is effective for the September 25th, 2025, receipt date and beyond [and it includes:]

- "[a]pplications that are either substantially developed by AI or containing sections substantially developed by AI are not considered the original ideas of applicants and will not be considered by NIH; [and]
- NIH will also only accept up to six new, renewal, resubmission, or revision applications from an individual PD/PI (Program Director/Principal Investigator) or Multiple Principal Investigator for all council rounds in a calendar year. For more details on applicability, investigator roles, and impacted application types, please see these new FAQs."

(Source: NIH Announcement, 7/31/25)

(continued on page 3)

WORD IN WASHINGTON (continued from page 2)

On August 5th, the U.S. Government Accountability Office (GAO) published its decision and a report of findings regarding the U.S., "Department of Health and Human Services (HHS) — NIH — Application of Impoundment Control Act to Availability of Funds for Grants." The report noted that, "Congress appropriated amounts to the NIH to carry out various research objectives for fiscal year 2025. In accordance with several executive orders, the HHS and its agencies, including NIH, began canceling existing grants. HHS also issued a memorandum directing its agencies to cease the publication of grant review meeting notices in the *Federal Register*, a key step in NIH's grant review process. As a result, NIH reduced its awarding of new grants. NIH's actions to carry out these executive directives, coupled with publicly available data showing a decline in NIH's obligations and expenditures, establishes that NIH intended to withhold budget authority from obligation and expenditure without regard to the process provided for by the Impoundment Control Act of 1974 (ICA)." GAO concluded in its decision that, "[our] institutional role is to support Congress, including in Congress's exercise of its constitutional power of the purse. This includes GAO's responsibilities under the ICA, such as reviewing special messages and reporting impoundments the President has not reported. Our analysis and conclusions regarding NIH help ensure compliance with the ICA and appropriations law…HHS indicated that the pause relating to the publication of *Federal Register* notice submissions has been lifted. However, HHS's response does not include information regarding current obligations of NIH funds for fiscal year 2025. We have become aware of public statements that on or around July 29th, 2025, the Office of Management and Budget (OMB) directed NIH officials to pause the issuing of grants, research contracts, and training. We have also become aware of public statements that OMB later reversed this pause. We have asked HHS for information to confirm the Administration's actions related to the pause and the lifting of the pause, including requesting the apportionment schedules or any related documentation. HHS did not provide us with the requested information or documents noting the apportionments were in OMB's possession. The burden to justify a withholding of budget authority rests with the executive branch, and GAO has a statutory duty to report impoundments to Congress. Despite our requests for information and documentation, HHS has not provided the information nor justified its actions. Thus, we are left with the evidence of the pause and lower rates of obligation without justification as is required by the ICA. If the executive branch wishes to make changes to the appropriation provided to NIH, it must propose funds for rescission or otherwise propose legislation to make changes to the law for consideration by Congress."

(Source: GAO Report, 8/5/25)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors.
ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the health care system; promote partnerships, policies, and programs that increase awareness about the need for blood donation; and serve as a thought leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

America's Blood Centers
Chief Executive Officer: Kate Fry
Chief Medical Officer: Jed Gorlin
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: $420

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

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

INSIDE ABC

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

Register Today for the *Rise & Lead Workshop* November 13th-14th

Rise & Lead
A WOMEN'S LEADERSHIP WORKSHOP

America's Blood Centers (ABC) is excited to announce that registration is open for the 2025 ABC Women's Executive Leadership Community (WELC) *Rise & Lead Workshop* taking place November 13th-14th in San Antonio, Texas at the Westin Riverwalk. Book now to secure the discounted rate. Check out the schedule as this workshop is designed for women in leadership positions, emerging leaders, and professionals seeking personal and career growth. It also welcomes individuals who want to cultivate diverse perspectives. Attendees will engage in an intimate, engaging, and interactive environment focused on networking, mentorship, and meaningful discussions on leadership and growth. Please contact us with questions.

Register for the ABC WELC Webinar: "Recommitting to Transformative Leadership: A WELC Community Experience"

Registration is open for the ABC WELC Webinar: "Recommitting to Transformative Leadership: A WELC Community Experience" taking place on Tuesday, August 26th at 2 p.m. EDT. This virtual event will reignite your leadership journey with a powerful reconnection to the core principles that have shaped your growth. The engaging and interactive session will help you revisit key themes from past WELC webinars — Authentic Leadership, Lessons from Leadership, Taming the Tyranny of the Urgent, and The Art of Listening and Facilitation. Attendees will be able to choose a breakout room focused on the topic that resonates most. Dive deep into meaningful conversations with fellow members of WELC, share how you're working to integrate these concepts into your daily life, and brainstorm ways to overcome roadblocks. Additional information a link to registration are available to ABC members here.

ABC Workforce Trends Survey Closes in 2 Weeks

ABC has launched its Workforce Trends Survey. Instructions regarding how to access the survey have been distributed to authorized individuals. This valuable benchmarking survey is the most comprehensive source of information available on workforce trends at blood centers. We encourage all members to participate. The survey analyzes overall trends in compensation, benefits, and human resources (HR) policies and provides specific data for 74 different blood center employee roles. It also provides insights into employee turnover and retention for the preceding calendar year, analyzing trends overall as well as by department and length of service. The survey combines the previous Compensation & Benefits and Employee Turnover & Retention surveys. Please contact us with any questions or to add/change authorized individuals. This survey closes on August 31st.

ABC Offers Stop the Bleed Virtual Trainings for Members

ABC is pleased to announce an opportunity to help certify ABC members as Stop the Bleed Trainers. As part of a national partnership between ABC and Stop the Bleed, ABC will host the final virtual training

(continued on page 5)

INSIDE ABC (continued from 4)

sessions taking place on August 21st at 2 p.m. EDT. Registration is open to ABC members. Additional information and links to register for the training are available here. During these training sessions, Stop the Bleed Senior Manager Jimm Dodd, MPAS, MA, U.S. Army (Ret.), will spend the first 30 minutes covering new marketing resources available to blood centers. He will also discuss the rollout of a new Stop the Bleed portal, including instructions for logging into the portal, navigating the system, and guidance through the instructor registration process, before leading a training session. Participants are asked to complete the online pre-training activity prior to attending a virtual session. Please contact us with questions.

Register for the SMT Journal Club Webinar on August 29th

Registration is open for the next ABC Scientific, Medical, and Technical (SMT) Journal Club webinar on August 29th at 12 p.m. EDT. The webinar is complimentary for all ABC members as this virtual event will review two scientific/medical articles followed by open discussion by participants, presenters, and article authors. The articles to be reviewed are listed below:

- Fatal hemolytic disease of the newborn due to anti-B isohemagglutinin: An unfamiliar presentation of a familiar disease (*Transfusion*); and
- Food and inhaled allergens may play a more prominent role in allergic transfusion reactions than previously recognized (*Transfusion*).

A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars upon completion of the activity and evaluation. Additional information and a link to registration are available to ABC members here. Please contact us with any questions.

Registration Is Open for the August ADRP Webinar: "Building Lifesavers: Internal Preparedness and External Engagement for High School Donors"

Register for the Wednesday, August 27th at 1 p.m. EDT titled: "Building Lifesavers: Internal Preparedness and External Engagement for High School Donors." Don't miss the chance to explore insights and tips for, "educating and empowering both internal team members as well as external partners in the high school blood donation journey. Learn how to enhance staff readiness, support coordinators, and guide young donors through the process with confidence." The webinar also will feature a review of ABC's & ADRP's *Vein to Vein* program, a powerful tool to enrich donor education and engagement. Please contact us with questions.

Full Schedule Available for 2025 ADRP Master Class September 24th-25th

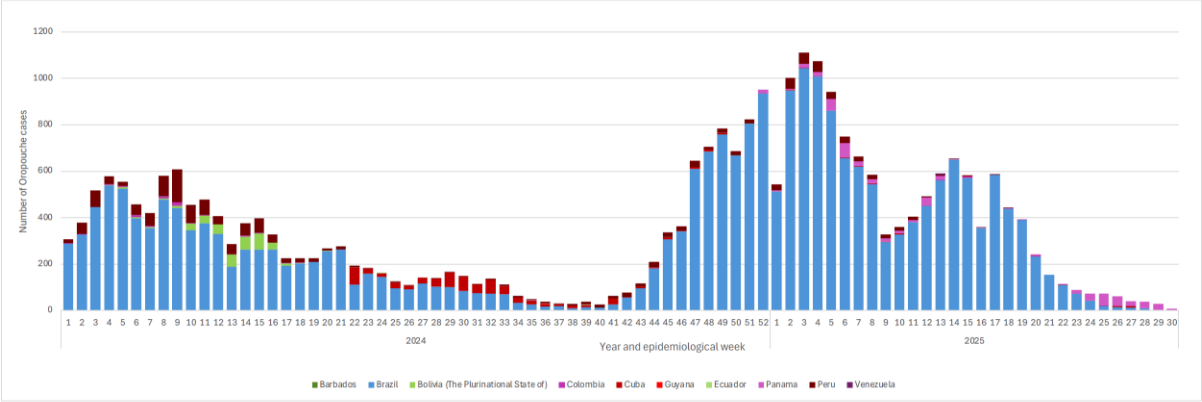
Register for the 2025 ADRP Master Class taking place September 24th-25th. The complete two-day schedule has now been released. This year's theme is "Building Brighter Experiences: Empowering Customers, Engaging Employees." See why you should attend. In today's competitive market, organizations that prioritize both employee and customer experience gain a significant edge. A motivated and engaged workforce leads to improved customer interactions, higher satisfaction, and long-term brand loyalty. The customer experience starts with the employee experience. Don't miss keynote speakers Janice Honeycutt Hering and Dave Murray help attendees identify the components of a culture that promotes satisfaction and engagement, while discussing and sharing insights for taking small steps to make your donor experience the most significant competitive advantage for your organization. Please contact us with questions.

INFECTIOUS DISEASE UPDATES

OROPOUCHE

The Pan American Health Organization (PAHO) has published an update on Oropouche fever in the Americas. The latest data from PAHO noted that, "[s]o far in 2025, 12,786 confirmed cases have been reported across 11 countries — seven with local transmission and four with imported cases — reflecting the growing spread of this virus, primarily transmitted by the *Culicoides paraensis* (midge). From January 1st to July 27th, 2025, confirmed cases are distributed as follows: Brazil (11,888 cases), Panama (501), Peru (330), Cuba (28), Colombia (26), Venezuela (5), and Guyana (1). Imported cases have been reported in Uruguay (3), Chile (2), Canada (1), and the U.S. (1). In 2024, the region recorded 16,239 cases across 11 countries and one territory, including four deaths." According to PAHO, "Oropouche fever typically causes high fever, severe headaches, and muscle and joint pain, with most patients recovering in two to three weeks, though up to 60 percent may experience relapses. In rare cases, it can lead to meningitis or encephalitis, and in pregnant women, there are concerns about potential fetal risks…[PAHO's update] emphasize[d] the need for stronger epidemiological surveillance and vector control to curb the disease, which currently has no vaccine or specific antiviral treatment." In September 2024, the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) issued a communication titled, "Important Information for Blood Establishments Regarding the Oropouche Virus and Blood Donation" that stated, "[w]orldwide, there have been no reports of trans-mission of Oropouche virus by transfusion of blood or blood components. [Taking into] consideration the existing safeguards for blood safety, the current small number of Oropouche virus disease cases among U.S. travelers, and no reports of Oropouche virus transmission by blood and blood components, screening donors by asking them specific questions about exposure to Oropouche virus or travel to areas with Oropouche virus outbreaks is not warranted at this time. A screening test for Oropouche virus is not available."

Figure 1. Number of confirmed autochthonous cases of Oropouche by country and epidemiological week (EW) of symptom onset, Americas Region, 2024–2025.



Source: Adapted from data provided by the respective countries and reproduced by PAHO/WHO *(1-16)*.

(Source: PAHO Oropouche Update, 8/14/25)

CHIKUNGUNYA

The United Kingdom Health Security Agency (UKHSA) has announced an uptick in travel-associated chikungunya cases in England. An agency communication explained that, "[a] total of 73 cases were reported between January and June 2025. The same period in 2024 saw 27 cases. 2025 has the highest number of cases recorded in this period to date." Most of the cases reported included, "travel to Sri Lanka, India, and Mauritius [and are] linked with ongoing local outbreaks in countries in the Indian Ocean region. All

(continued on page 7)

INFECTIOUS DISEASE UPDATES (continued from 6)

cases were reported in England, with the majority in London." According to UKHSA, "chikungunya is a mosquito-borne infection [with symptoms] including a sudden onset of fever usually accompanied by joint pain. While most people recover fully within 1 to 2 weeks, the joint pain can persist for months or even years. Up to 12 percent of patients still experiencing discomfort three years after infection…There are two chikungunya vaccines that have recently been approved for use in the UK based on The Joint Committee on Vaccination and Immunisation (JCVI) [recommendations:]

- "Ixchiq® is available for individuals aged 18 to 59 years old; [and]
- Vimkunya® is available for individuals 12 years and older."

Transfusion-transmission of chikungunya has not been described and any risk to the blood supply is believed to be theoretical.

(Source: UKHSA Announcement, 8/14/25)

BRIEFLY NOTED

The Texas Medical Association (TMA) recently reported that the state's legislature has allocated $10 million for, "a pilot program to support administering whole blood in the field to patients with extreme blood loss due to trauma, maternal hemorrhage, or other significant medical conditions." According to the TMA, the association collaborated with the, "Governor's EMS and Trauma Advisory Council (GETAC) Whole Blood Task Force, the Texas EMS Alliance and other stakeholders to campaign for a $4 million state budget rider to facilitate prehospital whole blood, which can be prohibitively costly, especially for rural, volunteer agencies that might transport patients over great distances from small hospitals to Level I trauma centers." TMA further explained that next steps include, "[t]he Texas Department of State Health Services (DSHS) [defining] the structure, process, and funding distribution for the statewide program. In consultation with regional advisory councils, DSHS will determine the most cost-effective method for securing the required resources for EMS agencies to operate whole blood programs."

(Source: TMA Announcement, 7/29/25)

MEMBER NEWS

Lifeline Blood Services and Magnolia Regional Health Center (MRHC) have announced a partnership. As part of the collaboration, Lifeline Blood Services will, "host regular mobile blood drives throughout the Corinth area and plans to launch expanded donor outreach efforts, local partnerships, and educational programs to promote the importance of blood donation." John B. Miller, MBA, chief executive officer (CEO) of Lifeline Blood Services added in the announcement, "[w]e are honored to welcome Magnolia Regional Health Center into the Lifeline service area. This partnership allows us to further our mission of ensuring that every hospital and every patient has access to the blood products they need. Corinth and the surrounding communities can be proud that their donations will directly support their neighbors and loved ones."

(Source: MRHC Announcement, 8/4/25)

ImpactLife recently announced that its donors have, "contributed more than $30,000 to nonprofit causes through the blood center's 'Good Giving' program so far this year." According to a blood center news release, "Good Giving is a component of the blood center's Donor For Life rewards program. After each donation, blood donors receive an email with the subject line 'Your Recent Donation' within 48 hours. The message includes a link to order a thank you gift, which can come in the form of an electronic gift card, points to use in the Donor Rewards Store, or the opportunity to make a charitable donation. Donors who

(continued on page 8)

MEMBER NEWS (continued from 7)

select the Good Giving option receive information on how to select their charity. All 501(c)(3) organizations are available to choose, and the amount of the donor's contribution is based on donation frequency." Katie Marchik, chief operating officer at ImpactLife, stated in the news release, "[o]ne way that ImpactLife celebrates our fellow nonprofit organizations is to encourage blood donors to direct their donor rewards to the nonprofit of their choice through our Good Giving program. This is a powerful way for donors to double the impact of their donation — blood products for their community members and a financial donation to their favorite charity."

(Source: ImpactLife News Release, 8/17/25)

GLOBAL NEWS

Canadian Blood Services has published a statement further describing its agreement with Grifols to, "manufacture immunoglobulins for patients in Canada." The August 13th communication highlighted that:

- "[n]one of the plasma collected at Canadian Blood Services' donation cent[ers] is being used to make medicine that is being sold in other countries — including albumin;
- [e]very drop of blood and plasma that is collected by Canadian Blood Services is used exclusively for Canadian patients;
- [t]here is a global shortage of immunoglobulins, a lifesaving medicine for thousands of Canadian patients, that is made from plasma. Canadian Blood Services is working to ensure a consistent and reliable supply of this critical medicine. Through our agreement with Grifols, we are creating Canada's first-ever domestic supply chain for immunoglobulins, exclusively for patients in this country;
- [a]ll immunoglobulins manufactured from plasma collected by Canadian Blood Services, as well as by Grifols, who collects plasma on our behalf, must remain in Canada for Canadian patients — boosting our domestic sufficiency;
- [w]ith any plasma manufactured into immunoglobulins, there are byproducts leftover that can be used to make another kind of medicine called albumin. There is no global shortage of albumin and Canada has a sufficient supply thanks to the generosity of Canadian Blood Services' plasma donors;
- Grifols operates their own plasma donation cent[ers], and the excess byproducts from the manufacturing of immunoglobulins from their plasma donors is being used to make albumin that is then being sold to other countries;
- [g]iven we have plenty of albumin already in Canada, these byproducts would be otherwise wasted. But there is a need for this lifesaving medicine for patients in other countries; [and]
- [o]ur agreement with Grifols allows for these otherwise wasted byproducts to help patients in other countries as well as offset the cost of manufacturing immunoglobulins for Canadian patients."

The statement from Canadian Blood Services comes in the wake of a report from *The Globe and Mail* that, "members of Parliament (MPs) are calling for a parliamentary investigation into [Grifols'] use of Canadian-donated blood plasma to make medicines for sale abroad. The call follows [an investigation from the news outlet] that [allegedly found that] Canadian Blood Services is selling some blood components to Grifols to manufacture a product called albumin, as part of a complex arrangement between [Grifols and Canadian Blood Services] to collect and process blood plasma." In September 2022, Grifols and Canadian Blood Services announced a partnership aimed to "accelerate" the self-sufficiency of immunoglobulins for Canada to, "ensure Canadian plasma is processed into immunoglobulin medicines on Canadian soil for the

(continued on page 9)

GLOBAL NEWS (continued from 8)

exclusive needs of the thousands of patients in the country who critically depend on these lifesaving therapies."

(Sources: Canadian Blood Services Statement, 8/13/25; *The Globe and Mail*, "Conservatives call for investigation of Spanish drugmaker's use of Canadian-donated blood plasma," 8/14/25)

The New Zealand Blood Service (NZBS) and Northern Rescue Helicopter Limited are collaborating as part of the Study of Whole Blood in Frontline Trauma (SWiFT) Aotearoa trial. According to an article published by *Scoop Business*, the SWiFT trial, "like those in the United Kingdom and Canada, will follow the learnings of military combat medicine, where the use of platelet rich whole blood transfusions has improved health outcomes for soldiers with severe trauma and blood loss. [It will] determine whether the inclusion of platelets in pre-hospital transfusion allows for earlier control of bleeding, potentially reducing the number of transfusions needed after arrival at the hospital and improving the probability of survival and recovery for patients. The randomi[z]ed controlled trial will investigate the feasibility of making and delivering platelet-rich O-negative whole blood compared to the current O-negative whole blood carried by Northern Rescue for pre-hospital transfusion. This trial aims to collect data on if platelet-rich whole blood might be more effective for patients with life-threatening bleeding due to trauma. Platelets aid with blood clotting to stop bleeding and studies suggest that the earlier bleeding is brought under control, the better it is for the patient."

(Source: *Scoop Business*, "Northern Rescue And New Zealand Blood Service Use Battlefield Insights To Take Partnership To New Heights," 8/15/25) ♦

COMPANY NEWS

Velico Medical, Inc. has finished its, "first-in-human phase I multi-center clinical trial of FrontlineODP™ Spray Dried Plasma in healthy volunteers." According to a company news release, "[t]he dose-escalation study with a randomized, crossover cohort demonstrated the safety of the spray dried plasma, with no serious adverse events or safety signals reported…FrontlineODP™ Spray Dried Plasma [is] shelf-stable for up to 24 months, ultra-lightweight for easy transport and rapid field deployment, and can be quickly reconstituted for immediate use in emergencies." Dr. Mark Popovsky, chief medical officer at Velico Medical, added in the news release, "[t]his trial marks the beginning of a new era in plasma therapy. A plasma product that's safe, portable, and transfusion-ready in just 2.5 minutes could transform how trauma is treated - both on the battlefield and in civilian emergencies."

(Source: Velico Medical, Inc. News Release, 8/14/25)

Beam Therapeutics Inc. has announced that the U.S. Food and Drug Administration (FDA) recently "granted" the Regenerative Medicine Advanced Therapy (RMAT) designation for its investigational advanced therapy to treat sickle cell disease (SCD). According to the company, the FDA's RMAT designation is, "designed to support the development and evaluation of regenerative medicines, including genetic therapies, with the intention of addressing serious or life-threatening diseases that have unmet medical needs. RMAT designation provides opportunities for early interactions with the FDA to discuss potential surrogate or intermediate endpoints to support accelerated approval, organizational commitment from senior staff at the agency, opportunities to participate in novel review and development programs, and the potential for a rolling review and priority review of a product's future biologics license application." Earlier this year, Beam Therapeutics received an orphan drug designation from the FDA for the investigational SCD advanced therapy. The investigational advanced therapy (BEAM-101) is a, "one-time therapy consist[ing] of autologous CD34+ hematopoietic stem and progenitor cells (HSPCs) that have been base-edited in the

(continued on page 10)

COMPANY NEWS (continued from 9)

promotor regions of the HBG1/2 genes and are administered via a hematopoietic stem cell transplant procedure. The [investigational therapy] is designed to inhibit the transcriptional repressor BCL11A from binding to the promoter without disrupting BCL11A expression, leading to increased production of non-sickling and anti-sickling fetal hemoglobin (HbF) and thus mimicking the effects of naturally occurring variants seen in hereditary persistence of fetal hemoglobin. [The safety and efficacy of the investigational therapy] is being evaluated in the ongoing BEACON Phase I/II study, an open-label, single-arm, multicenter trial in adult patients with SCD with severe vaso-occlusive crises (VOCs). [Updated data from 17 patients treated with BEAM-101 in the trial] demonstrated robust and durable increases in fetal hemoglobin (HbF) and reductions in sickle hemoglobin (HbS), rapid neutrophil and platelet engraftment, and normalized or improved markers of hemolysis and oxygen delivery. Patients required a median of one mobilization cycle. No VOCs were reported post-engraftment. BEAM-101 is manufactured using an advanced, largely automated process that has demonstrated consistently high yields and viability."

(Source: Beam Therapeutics Inc. News Release, 8/14/25)

Abbott and the **Big Ten Conference** have announced that Season 2 of the *We Give Blood* initiative will begin on August 27th and will include the release of, "[limited edition] Homefield designed T-shirts. Each Big Ten school has its own custom design" for donors throughout the competition while supplies last. An Abbott news release describing the *We Give Blood* initiative also explained that, "[l]ogging a donation for your Big Ten school of choice is easier than ever: anyone eligible to donate blood can do so at any blood center or drive across the country from August 27th to December 5th and text 'DONATE' to ABBOTT (222688) to log a donation for their Big Ten school. You can also submit your donation at www.BigTen.Org/Abbott, where you can find more information about eligibility, specifics around campus blood drives and a blood center locator tool. This year's competition will offer Big Ten fans more opportunities with the goal of inspiring first-time donors…Beginning with the first week of the Big Ten football season, Abbott and the Big Ten will host 12 *We Give Blood* Weekly One-Up Challenges. These mini competitions will pit two Big Ten schools against each other to see which can show up to donate the most blood during the week. Donors from the winning school will receive a chance to win select memorable campus experiences offered by the universities. The winner of the *We Give Blood* drive will be announced at the Big Ten Championship Football Game on December 6th in Indianapolis. That school will receive $1 million to advance student or community health. Donation totals will be tracked on a live leaderboard [throughout] the campaign" here.

Photo courtesy of Abbott and the Big Ten Conference.

(Source: Abbott News Release, 8/18/25)

The FDA has published a communication explaining that the agency has approved label changes for **bluebird bio, Inc.**'s Skysona (elivaldogene autotemcel). According to an agency announcement, FDA is requiring, "updates to the Boxed Warning, Indications and Usage, Warnings and Precautions, and Adverse Reactions – Clinical Trials Experience sections of the prescribing information and Medication Guide to

(continued on page 11)

COMPANY NEWS (continued from 10)

include new safety information on the increased risk of hematologic malignancy," for Skysona (elivaldogene autotemcel), a lentiviral autologous hematopoietic stem cell (HSC)-based gene therapy. The FDA noted that, "[we have] completed a review of the clinical trial data and [have] required updates to the Boxed Warning, Indications and Usage, Warnings and Precautions, and Adverse Reactions — Clinical Trials Experience sections of the prescribing information and Medication Guide to include new safety information on the increased risk of hematologic malignancy. Notably, the revised Indications and Usage restricts the indication to patients without an available human leukocyte antigen (HLA)-matched allogeneic hematopoietic stem cell (allo-HSC) donor. Therefore, Skysona should only be used in CALD patients without suitable alternative treatment options, given the increased risk of hematologic malignancy. The Limitations of Use section retains language emphasizing careful consideration of appropriateness and timing of treatment." The agency stated that, "[a]t the time of initial approval of Skysona in 2022, hematologic malignancy was identified as a serious risk, with MDS reported in 3 of 67 patients (4 percent) across clinical studies. Since initial approval, FDA has received seven additional reports from clinical trial participants, and as of July 2025, hematologic malignancies have been diagnosed in 10/67 (15 percent) clinical trial participants, more than tripling the previously reported incidence. Current reports suggest that the time to diagnosis of hematologic malignancy ranges from 14 months to 10 years after Skysona administration. Nine of the 10 patients have been treated with allo-HSCT (with or without chemotherapy) for the hematologic malignancy. The malignancies are life-threatening conditions, and one death related to treatment for malignancy has occurred. One patient developed recurrence of MDS after initial treatment, which required re-treatment. Importantly, some patients developed malignancy before Skysona had time to potentially provide therapeutic benefit for their CALD."

(Source: FDA Communication, 8/7/25) ♦

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.)*

2025

August 21. **ABC Stop the Bleed Training Session (Virtual).** A link to registration and more information are available to ABC members here.
August 26. **ABC Women's Executive Leadership Community (WELC) Webinar: Recommitting to Transformative Leadership: A WELC Community Experience (Virtual).** A link to registration and more information are available to ABC members here.

August 29. **ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar.** A link to registration and more information are available to ABC members here.

Sept. 10-12. **6th European Conference on Donor Health and Management (ECDHM). Wijk aan Zee, the Netherlands.** Registration is open. More information available here.

Sept. 17-19. **58th Annual Conference of the German Society for Transfusion Medicine and Immunohematology (DGTI). Manheim, Germany.** Registration is open. More information is available here.

Sept. 24-25. **2025 ADRP Master Class: "Building Brighter Experiences: Empowering Customers, Engaging Employees" (Virtual).** Registration is open. More information is available here.

(continued on page 12)

CALENDAR (continued from page 11)

Sept. 28. **U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Public Listening Meeting: "Leveraging Knowledge for Facilitating the Development and Review of Cell and Gene Therapies" (Virtual).** Registration is open. More information is available here.

Sept. 30-Oct. 1. **3rd Annual European Blood Alliance (EBA) and the International Society of Blood Transfusion (ISBT) Rare Blood Provision Workshop. Bilbao, Spain.** Registration is open. More information is available here.

Oct. 12-15. **American Association of Tissue Banks (AATB) Annual Meeting. Atlanta, Ga.** Registration is open. More information available here.

Oct. 14-15. **International Protein Forum. Old Town Alexandria, Va.** Registration is open. More information is available here.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** Registration is open. More information is available here.

Oct. 26-29. **Blood 2025 and the ISBT 36th Regional Congress. Perth, Australia.** More information available here.

Nov. 12. **2025 ADRP International Showcase.** More information is coming soon.

Nov. 13-14. **2025 ABC Women's Executive Leadership Community (WELC) *Rise & Lead Workshop*.** Registration is open. More information available here.

Nov. 13-14**. EBA Benchmarking Workshop. Amsterdam, Netherlands.** More information is coming soon.

Nov. 17-20. **American Society for Clinical Pathology (ASCP) Annual Meeting. Atlanta, Ga.** Registration is open. More information available here.

2026

Feb. 11-12. **4th Biennial International Plasma and Fractionation Association (IPFA) & EBA Symposium on Plasma Collection and Supply. Leuven, Belgium.** More information is available here.

Mar. 9-12. **2026 ABC Annual Meeting. Tucson, Ariz.** More information is coming soon.

May 12-14. **2026 ADRP Annual Conference. Minneapolis, Minn.** 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

Chief Information Officer. Carter BloodCare seeks a strategic and innovative Chief Information Officer (CIO). As CIO, you will shape and lead our technology vision, ensuring that our IT strategy aligns with organizational growth, operational excellence, and our lifesaving mission. As a member of the Senior Management team, you will act as a strategic liaison between technology and executive leadership to communicate IT needs and initiatives. The CIO provides quality and compliance, responsible for ensuring the integrity and efficiency of our information systems, administration, governance, data quality and the security of computer systems. The CIO oversees outsourced software, support services and the fulfillment of contractual obligations. The CIO provides necessary vision to each business entity, ensuring proper operational controls, compliance, business, and reporting procedures in support of our mission. Ideal candidates will have at least three years of management experience

(continued on page 13)

POSITIONS (continued from page 12)

in a strategic technology role, with an additional five years of experience in IT or data management. You will also have a proven track record of digital transformation and a passion for mentorship and team development. If you are ready to lead with vision, build with integrity, and innovate for a greater good, let's connect. Together, we can ensure technology plays a vital role in saving lives. Apply at https://www.carterbloodcare.org/who-we-are/careers/.

Director of Marketing and Public Relations. This position leads all marketing, branding, communication, and public relations efforts for Central California Blood Center (CCBC). As a key member of CCBC's Senior Management Team, this position collaborates closely with internal departments and external partners to maintain and enhance CCBC's positive public image. This position plays a vital role in advancing awareness of the volunteer blood donor program and the need for a safe, stable blood supply throughout the Central Valley and surrounding communities. Skills: a proven track record in directing marketing best practices including creative and production needs; experience in community development and event management is required; knowledge of CRM, SEO and digital marketing platforms/strategies as well as a proven track record in staff development; and verbal/written and interpersonal communication skills (including public speaking/on camera appearances) are required. Learn more and apply here.

Medical Director. Central California Blood Center is seeking a Medical Director who shall work to promote the mission of Central California Blood Center (CCBC) while being responsible for overseeing the medical activities of the organization. This scope of duties will be accomplished within 20-25 hours per week remotely and/or in person at CCBC's headquarters in Fresno, Calif. The Medical Director oversees all processes and SOPs of CCBC relating to donor selection, eligibility, collection, processing, testing and distribution of blood products, donor safety and other roles guided or mandated by local, state, federal, and international regulatory agencies. Qualifications and skills: must be a Doctor of Medicine Degree or Doctor of Osteopathic Medicine Degree, with a license in good standing; must be licensed in the State of California with sub-specialty training in Hematology (IM) or Transfusion Medicine (Pathology); excellent verbal and written communication skills; must be proficient in Microsoft Office products and virtual meeting technology platforms; strong people skills; superior leadership skills; and superb judgment, problem-solving and cognitive skills. Learn more and apply here.

Director of Recruitment. For over 75 years, SunCoast Blood Centers has been the region's nonprofit community blood bank and the exclusive supplier of blood products to local hospitals. Located on Florida's beautiful Treasure Coast, we are committed to saving lives, advancing research, and supporting the health of our community. Take the lead in shaping the future of donor recruitment at SunCoast Blood Centers. Oversee our Contact Center, Mobile Recruitment, and Concierge Program teams, developing bold, innovative strategies that not only meet but surpass our blood collection goals. This high-impact role requires a Bachelor's degree (Master's preferred), 5+ years in recruitment or related fields with at least 3 years in leadership, and exceptional skills in leadership, public speaking, and project management. Click here to apply.

Clinical Services Apheresis LPN. For over 75 years, SunCoast Blood Centers has been the region's nonprofit community blood bank and the exclusive supplier of blood products to local hospitals. Located on Florida's beautiful Treasure Coast, we are committed to saving lives, advancing research, and supporting the health of our community. Join our Clinical Services and Research team in Sarasota and play a vital role in patient care and medical advancement. In this specialized position, you'll perform therapeutic apheresis procedures for hospital patients and contribute to groundbreaking research collections. Candidates must hold a current Florida LPN with IV certification, have 1–2 years of hospital patient care experience, and demonstrate proven expertise in apheresis. Click here to apply.

Quality Assurance and Compliance Specialist (San Diego Blood Bank). Make a Difference in Patients' Lives as a Quality Assurance and Compliance Specialist. The San Diego Blood Bank is seeking a Quality Assurance and Compliance Specialist II who will participate in maintaining a Quality Management System that supports the manufacture of FDA-regulated biologic blood, cell, and tissue products and other related regulatory activities. The Specialist ensures that the performance and quality of products conform to established standards and regulatory requirements. Reports to: Manager, Quality and Regulatory Affairs. Ideal candidates possess a bachelor's degree and at least four (4) years of experience in a Quality Assurance or Regulatory Affairs role that includes participation in FDA and State site inspections, experience with GMP requirements, application of quality assurance principles, and healthcare compliance within the biologics/pharmaceutical industry. **Click HERE for the full job description and to apply.**

Director of Technical Services (LIFELINE Blood Services). The Director of Technical Services manages and supervises technical staff including laboratory, distribution, and components. The Director of Technical Services must meet the regulatory responsibilities and demonstrate active involvement in the laboratory's operation and be available to the laboratory staff onsite, phone, or electronic consultation. The Director of Technical Services is

(continued on page 14)

POSITIONS (continued from page 13)

responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel. Even though there is the option to delegate some responsibilities, the Director is ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met. It is the responsibility of the Director of Technical Services to ensure that your laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable test results. Refer to Code of Federal Regulations Title 42 Part 493, Laboratory Requirements. Education: Medical Technologist with Bachelor's Degree in Medical Technology or chemical, physical, or biological science. Individual must hold a Current State of Tennessee Supervisor License. A Specialist in Blood Bank (SBB) certification is preferred. Experience: Five years of experience as a working Medical Technologist. Three years of Management or Supervisory experience. as a Specialist in Blood Bank preferred. Has a working knowledge of cGMP, AABB, CLIA and CFR blood banking requirements. Click here to view the full job description and apply.

Lead Quality Control Specialist. Gulf Coast Blood is seeking a Lead Quality Control Specialist! This key role supports quality assurance by preparing and testing blood component samples to ensure safety and effectiveness for patients and hospitals throughout the Texas Gulf Coast region. It's ideal for detail-driven individuals who uphold high standards and contribute meaningfully to patient outcomes. Showcase your expertise by performing advanced quality control testing, managing lab operations in the absence of supervisors, and responding to critical situations such as positive bacterial cultures. You'll initiate recall procedures, track and trend QC results, train new hires, coordinate workflow, and recommend process improvements, all while ensuring compliance with lab standards and supporting patient safety. **Why join us?** We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. **Qualifications:** MT/MLS certification (ASCP or equivalent) with at least two years of hematology experience. Flow cytometry experience is a plus. This role operates Monday through Friday, 7:00 AM to 3:00 PM. If you embody integrity, commitment, and respect, apply now and help make a difference!

Consultation & Reference Lab Tech III – Weekend Shift. Gulf Coast Blood is seeking a Consultation & Reference Lab Tech III – Weekend Shift! This key role supports advanced testing and preparation of special blood components for patients and donors, serving over 170 hospitals across the Texas Gulf Coast region. Ideal for detail-oriented professionals who value precision, quality, and meaningful community impact. Showcase your expertise by performing advanced antibody identification, compatibility testing, and donor serological testing to support life-saving transfusions. You'll prepare consultation reports, process sample requests, maintain specialized blood component inventory, perform quality control, and ensure compliance with all lab standards, directly impacting patient care. **Why join us?** We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign-on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. **Qualifications:** MT/MLS certification (ASCP or equivalent) and at least two years of recent blood banking experience. New graduates are also encouraged to apply. This full-time role operates Friday through Sunday, from 7:00 a.m. to 7:00 p.m. If you embody integrity, commitment, and respect, we encourage you to apply now and help make a difference!

Consultation & Reference Lab Tech III – Night Shift. Gulf Coast Blood is seeking a Consultation & Reference Lab Tech III – Night Shift! This key role supports advanced testing and preparation of special blood components for patients and donors, serving over 170 hospitals across the Texas Gulf Coast region. Ideal for detail-oriented professionals who value precision, quality, and meaningful community impact. Showcase your expertise by performing advanced antibody identification, compatibility testing, and donor serological testing to support life-saving transfusions. You'll prepare consultation reports, process sample requests, maintain specialized blood component inventory, perform quality control, and ensure compliance with all lab standards, directly impacting patient care. **Why join us?** We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign-on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. **Qualifications:** MT/MLS certification (ASCP or equivalent) and at least two years of recent blood banking experience. New graduates are also encouraged to apply. This position operates Wednesday through Saturday, 10:00 p.m. to 8:00 a.m. If you embody integrity, commitment, and respect, we encourage you to apply now and help make a difference!

Consultation & Reference Lab Tech III – Evening Shift. Gulf Coast Blood is seeking a Consultation & Reference Lab Tech III – Evening Shift! This key role supports advanced testing and preparation of special blood components for patients and donors, serving over 170 hospitals across the Texas Gulf Coast region. Ideal for detail-oriented professionals who value precision, quality, and meaningful community impact. Showcase

(continued on page 15)

POSITIONS (continued from page 14)

your expertise by performing advanced antibody identification, compatibility testing, and donor serological testing to support life-saving transfusions. You'll prepare consultation reports, process sample requests, maintain specialized blood component inventory, perform quality control, and ensure compliance with all lab standards, directly impacting patient care. **Why join us?** We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign-on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. **Qualifications:** MT/MLS certification (ASCP or equivalent) and at least two years of recent blood banking experience. New graduates are also encouraged to apply. This full-time role operates from Sunday through Wednesday, 11:00 AM to 9:00 PM. If you embody integrity, commitment, and respect, we encourage you to apply now and help make a difference!

Manager, Regional Development. Be part of something bigger; change the world with us by joining **ImpactLife's team**. We are seeking a **Manager, Regional Development**, to lead donor engagement and blood drive development efforts across Central Illinois. In this key leadership role, you'll guide a dynamic regional team in growing our mission to connect donors and patients through life-saving blood collections. This role requires direct supervision of a regional team. This position can be located at our Peoria, Springfield, or Urbana, Illinois locations. For more information including job details, benefits, and compensation click here: Change the World With Us.

Cell Therapy Technologist (Carter BloodCare). The Cell Therapy Technologist 1 (CTT1) participates in activities in the Cellular Therapy Laboratory. These activities include, but may not be limited to, cellular therapy (CT) processing, performing and troubleshooting quality control of reagents and equipment, participating in educational instruction of students and new employees, familiarity and full compliance with all CT and general laboratory regulations, and participating in design and implementation of new methodology for processing CT products. A CTT1 ensures daily operations within the department meet and follow all established guidelines and provide excellence in service and patient care. Ability to work a flexible schedule, long and/or odd hours with little notice. Regular full-time attendance is required during normal working hours. This position requires a valid driver's license. **Education:** MT (ASCP), MLS(ASCP) or equivalent, or eligible with certification obtained within 90 days of hire. Bachelor of Science Degree in Clinical Laboratory Science, Medical Laboratory Science, Medical Technology, or a related field in laboratory science. **Experience:** Minimum of one year of experience as an MT/MLS. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job Cell Therapy Tech or Cell Therapy Technologist.

Instructor – Phlebotomy (Carter BloodCare). Under the direction of the Education Coordinator, the Instructor is responsible for the training and continuing education of the Collection Services staff in all procedures involved in the blood collection process (i.e., medical history, donor lookup, phlebotomy, quality control, apheresis, CPR). This position ensures trainees receive applicable clinical experience, safely perform all required skills, and successfully complete competency testing. The Instructor plans for and guides the learning process to help students achieve the objectives required within the allotted time. This position maintains open communication with supervisory staff and informs them of employee progress. This position creates schedules, inputs data, and runs reports. Adequate transportation is necessary to travel to and from all donor centers/mobile drives to perform competency evaluations and retraining in a timely and efficient manner. This position adheres to all regulations and requirements set forth by the Food and Drug Administration (FDA), American Association of Blood Banks (AABB), CBC, and departmental policies and procedures. This position must be available to work any shift, including nights and weekends. Regular full-time attendance is required during normal working hours. Education: High School Diploma or equivalent. Experience: Six (6) months of supervisory experience required. Minimum of one year of blood banking, preferred. Six (6) months of apheresis experience, preferred. Teaching experience (professional and informal), preferred. Equal Opportunity Employer: Disability/Veteran. www.carterbloodcare.org, click Careers & search for job #49098.