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NEWSLETTER

A weekly chronicle of events and issues impacting the blood community

2026 Issue #33 November 10, 2026

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FDA Issues Safety and Availability Communication Regarding FDA Reporting of Septic Transfusion Reactions from Bacterial Contamination of Platelets

The U.S. Food and Drug Administration (FDA) has published a "2026 Safety and Availability Communication" for blood establishments, transfusion services, and device manufacturers "Regarding FDA Reporting of Septic Transfusion Reactions from Bacterial Contamination of Platelets." In the communication, the agency explained that, "FDA reminds transfusion services that septic reactions to platelet transfusion can occur despite pathogen reduction or bacterial testing, and suspected transfusion reactions should be reported immediately to the blood supplier. Blood establishments and transfusion services, as appropriate, must conduct and record a thorough investigation of suspected septic transfusion reactions (21 CFR 606.170(a)). When a complication of transfusion is confirmed to be fatal, FDA must be notified as soon as possible (21 CFR 606.170 (b)). FDA encourages blood establishments and transfusion services to voluntarily report nonfatal septic transfusion reactions to FDA via MedWatch. Device manufacturers are required to report to FDA when they become aware of information that their device may have caused or contributed to a death or serious injury (21 CFR Part 803)."

The agency also noted in the communication that, "FDA continues to receive reports of septic transfusion reactions after transfusion of apheresis platelets. Since May 2025, FDA received reports of septic transfusion reactions, including two fatalities, following transfusion of pathogen-reduced platelets, and two fatalities following transfusion of apheresis platelets prepared with other bacteria mitigation strategies. FDA is issuing this safety communication to remind blood establishments and transfusion services to maintain a high suspicion for bacterial contamination to recognize the residual risk of sepsis after platelet transfusion. Bacterial contamination of platelets may occur despite the use of bacterial control strategies, including pathogen reduction and bacterial testing. [Suspected septic] transfusion reactions should be immediately reported to the transfusion service and blood supplier. Further, each septic transfusion reaction must be thoroughly investigated (Ref. 2, 21 CFR 606.170(a)). A thorough investigation is necessary to identify the root cause of the bacterial contamination. You should not rely on the conclusions of past investigations and should not assume the cause of bacterial contamination to be related to previously reported causes. To ensure a thorough investigation, you should consider retaining the implicated bacterial isolate and contacting FDA at CBEROBRRBPBInquiries@fda.hhs.gov."

(Source: FDA Communication, 11/5/26)

Transfusion-transmitted Malaria Risk and Blood Safety Policies Examined in *Vox Sanguinis*

Authors of a review in *Vox Sanguinis* sought to, "contextualize the residual risk of transfusion-transmitted malaria (TTM) and to critically appraise current and past preventive strategies considering available evidence, with particular attention to policy implications." They analyzed confirmed cases of TTM in North American and Europe from 2005 to 2024 and performed a narrative literature review limited, "to non-endemic countries in Europe and North America, including the European Union (EU), the United States and Canada, in order to assess the potential impact of the specific preventive strategies in these regions."

The paper defined confirmed cases as those in which, "sufficient donor information was available to reasonably attribute malaria transmission to blood component transfusion, including documented donor exposure history, an appropriate temporal relationship, laboratory-confirmed *Plasmodium* infection in the recipient and exclusion of alternative transmission routes. Donors were classified as trave[l]ers if they had resided for less than six consecutive months in malaria-endemic countries, and as residents if they were born in, or had resided for more than six consecutive months in endemic areas."

The researchers found, "18 confirmed cases of TTM were reported by scientific literature in Europe and North America, all linked to packed red blood cell (RBC) transfusion. Eleven cases were caused by *P. falciparum*, six by *P. malariae* and one by *Plasmodium ovale*. No cases due to *Plasmodium vivax* or *Plasmodium knowlesi* were reported. One additional case was excluded from the analysis because no information on the blood donor was available. There were three TTM fatal cases caused by *P. falciparum*, whereas no fatal outcomes were reported among *P. malariae* or *P. ovale* cases. With two exceptions, all cases were linked to donors born or long-term residents in malaria-endemic regions. All *P. falciparum* cases were associated with either former residents or trave[l]ers coming from sub-Saharan Africa (SSA)."

Additionally, the authors noted that, "[i]mmunological tests failed to identify infected donors in 4 cases out of 15. Three of these involved *P. malariae* infections, and one involved *P. falciparum*. Among 15 PCR tests performed on donor blood (i.e., RBC-containing) samples, 4 failed to detect parasitemia, including 3 *P. falciparum* cases. [Among the 11] cases that were reported between 2010 and 2022, fresh donor follow-up samples were available in 9 cases, and 8 were PCR-positive; the single PCR-negative follow-up sample tested positive on the corresponding stored sample. Of the two additional cases for which only stored samples were available, both were PCR-negative."

The paper concluded that, "[a]cross 2005–2024, 10 TTM cases were reported in the United States and Canada and 8 in Europe. Based on publicly available data on blood utilization, the residual risk can be estimated at approximately one case per 27 million RBC units transfused in the United States and Canada, and one case per 52 million units in Europe. These figures should nonetheless be interpreted with caution, as the denominators are derived from heterogeneous data sources [and] under-reporting in the medical literature cannot be entirely excluded, and continued vigilance remains warranted. Importantly, all donor selection strategies in non-endemic countries rely primarily on the accuracy of travel and medical histories, which, like all anamnestic information, may be incompletely reported or inadvertently overlooked during donor assessment. The recent fatal case reported in Europe is a tragic illustration of this limitation. [E]pidemiological evidence from 2005 to 2024 indicates that, in Europe, combining donor history, deferral and selective immunological testing has been highly effective in preventing TTM, and particularly for *P. falciparum*, with only one case attributable to test failure. Deferral-only-based strategies, as applied in North America, were also effective in mitigating malaria transmission, but failed in five cases caused by long-term asymptomatic chronic *P. falciparum* carriers. High-sensitivity NAT may represent a valuable alternative, in particular contexts where blood availability is a concern. Although no TTM transmission other than through RBC concentrates has been reported during the last decades, pathogen reduction technologies for

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Transfusion-transmitted Malaria Risk & Blood Safety Policies Examined (continued from page 2)

platelets and plasma may provide additional risk mitigation. Enhanced hemovigilance and systematic reporting of TTM cases would improve risk estimates and inform policy decisions. Future policies should continue to balance transfusion safety, donor equity, and sustainability within a global health framework."

Citation: La Raja, M., Rastvorceva, R. M. G., Fontana, S., *et al*. "Transfusion-transmitted malaria in Europe and North America: Epidemiology, residual risk and implications for blood safety policies." *Vox Sanguinis*. 2026.

WORD IN WASHINGTON

The U.S. Cybersecurity and Infrastructure Security Agency (CISA), Federal Bureau of Investigation (FBI), Health and Human Services (HHS), U.S. Department of Agriculture (USDA), and the Department of Transportation (DoT) have published a fact sheet titled, "U.S. Government Partners Urge Hardening Industrial Refrigeration and Cold Chain Monitoring Systems." An announcement explained that, "'the authoring organizations'—are aware of malicious cyber activity targeting industrial refrigeration and cold chain monitoring systems globally. Organizations in the Healthcare and Public Health, Chemical, Food and Agriculture, and Transportation Systems Sectors widely use these systems, including in refrigerated transport services, for automated and remote monitoring of temperatures, continuous temperature logging, defrost cycle management, and energy optimization. The authoring organizations urge owners and operators to defend against this activity by using strong authentication, keeping systems updated, identifying any systems that are accessible from the internet, removing unnecessary remote access, and securing any necessary remote access."

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

HHS, through the Centers for Medicare & Medicaid Services (CMS) has announced, "$10 billion in awards to all 50 states for the second year of the Rural Health Transformation Program (RHTP), advancing President Trump's historic $50 billion investment to transform rural healthcare across America." An agency news release highlighted that, "[w]ith implementation underway in every state, the second year of funding will help states build on early progress and deliver lasting improvements in access, quality, and health outcomes for rural Americans. In the second year, states will build on this momentum by advancing initiatives from their approved state-developed transformation plans. Depending on each state's priorities, these initiatives may include efforts to improve prevention and chronic disease management, create sustainable access to care, strengthen the rural health workforce, advance innovative care and payment models, and put modern technology and data to work for rural patients and providers. Today's

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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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funding will help states deepen implementation and build the capacity needed to sustain improvements over the long term. [The RHTP] recognizes that meaningful transformation takes time and that states and rural communities begin from different starting points. The program's five-year structure gives states the opportunity to build, test, refine, and scale approaches capable of delivering sustainable improvements beyond the life of the program."

(Source: HHS News Release, 11/9/26)

Safi Biotherapeutics recently announced, "a $4.7 million non-dilutive award extension from the Defense Department, Defense Health Program, Combat Casualty Care portfolio, through the Medical Technology Enterprise Consortium (MTEC)." A news release noted that, "[t]he award extension funds core activities needed to carry the biomanufactured stem-cell-derived, human red blood cells (mRBCs) through to a planned Investigational New Drug (IND) submission for acute blood loss in 2027. The new funding enables Safi to enter the clinic, its next major milestone, while continuing to support the development of a readily transfusable, cryopreserved mRBC formulation. The funding is provided by the U.S. government through MTEC, under Other Transaction Number W81XWH-15-9-0001, Military Prototype Advancement Initiative (MPAI). With this $4.7 million Defense Department award, Safi has now received over $27 million in non-dilutive government funding to date."

(Source: Safi Biotherapeutics News Release, 11/3/26)

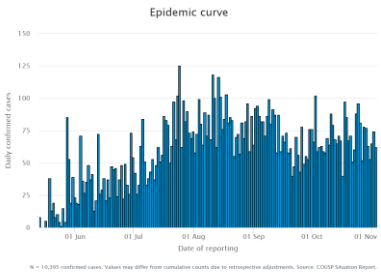
The U.S. Food and Drug Administration (FDA) has issued a "2026 Safety and Availability Communications" regarding the agency "Investigating Serious Risk of Malignancy Linked to Zolgensma Gene Therapy." The communication explained that, "FDA has received postmarketing adverse event reports of malignancies in patients treated with Zolgensma, an adeno-associated virus (AAV) vector-based gene therapy, for spinal muscular atrophy (SMA), including confirmed reports of product-related insertional oncogenesis involving the GLI1 (Glioma-Associated Oncogene Homolog 1) gene. GLI1 is an oncogene that has the potential to cause cancer when overexpressed or abnormally activated. Postmarketing reports of tumor formation (neoplasia) include tumors of the central and peripheral nervous systems, spinal/paraspinal regions, and kidney. Importantly, three cases involved tumors associated with the GLI1 oncogene. In two of those cases, molecular analysis of tumor tissue demonstrated Zolgensma AAV vector DNA integration into the host genome, with the promoter region of the onasemnogene abeparvovec construct inserted upstream of or within the GLI1 oncogene. FDA has determined that the risk of neoplasia, including malignancy, is applicable to both onasemnogene abeparvovec products, Zolgensma (administered via intravenous infusion; indicated for the treatment of pediatric patients less than 2 years of age with SMA) and Itvisma (administered via intrathecal injection; indicated for the treatment of SMA in adult and pediatric patients 2 years of age and older) as the two products contain the same vector and construct. FDA is closely monitoring the risk of neoplasia, including malignancy, in other similar AAV vector-based gene therapy programs. The overall benefits of Zolgensma and Itvisma continue to outweigh their potential risks for their approved uses."

(Source: FDA Communication, 11/6/26)



INFECTIOUS DISEASES UPDATE

EBOLA



On November 6th, the World Health Organization (WHO) updated the status of the Ebola disease outbreak in the Democratic Republic of the Congo (DRC). As of November 3rd, "the outbreak has expanded geographically in the DRC. While some areas have seen a slight decline in cases, sustained, high-level transmission continues overall in the DRC." On November 3rd, the WHO noted that, "[a total] of 10,668 confirmed cases, including 5,198 deaths (crude case fatality ratio: 48.7%), have been reported across 67 health zones in eight provinces, with active transmission ongoing in 51 health zones. The high proportion of deaths occurring in communities, especially among young children, continues to highlight challenges in early case detection and timely access to appropriate care. Of the 512 deaths reported since October 21st, 335 occurred in communities and 177 in treatment cent[ers]. Since the last Disease Outbreak News, no new cases have been reported from Kenya or Nigeria. However, the high-level transmission in the DRC indicates a continued need for readiness in the region, including cross-border surveillance, points of entry monitoring, timely case detection and coordinated preparedness and response measures. No new country has reported cases since the last Disease Outbreak News was published; however, two countries have medically evacuated confirmed cases among citizens: Switzerland and the United Kingdom of Great Britain and Northern Ireland." In May, the WHO declared the Ebola disease outbreak in the DRC and Uganda caused by Bundibugyo virus a, "public health emergency of international concern (PHEIC), but [noted that it] does not meet the criteria of pandemic emergency, as defined in the International Health Regulations (2005) (IHR)." The U.S. Centers for Disease Control and Prevention (CDC) published an update on November 10th stating that the U.S. "is responding to an outbreak of Ebola disease in remote areas of the DRC. 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." On May 18th, the CDC announced that it had, "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." 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 Food and Drug Administration (FDA) updated its guidance document on June 29th and published a communication explaining that"[b]ecause of the severity of [Ebola disease] and the potential risk of transmission by blood and blood components, Ebola disease meets the definition of transfusion-transmitted infection 21 CFR 630.3(l); however, transmission of Ebola disease by blood transfusion has not been reported. Routine measures used to screen every blood donor effectively prevent individuals with symptomatic Ebola disease from donating blood. [Considering] the current Ebola disease outbreak in the DRC and Uganda, we refer blood establishments to the recommendations in our guidance document to update their donor eligibility processes accordingly, including asking donors about residency or travel to DRC and Uganda."

(Source: WHO Update, 11/6/26; CDC Update, 11/10/26)



INSIDE ABC

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

ABC *Blood Bulletin* Member Survey Responses Due November 11th

America's Blood Centers (ABC) is reminding members to take part in the 2026 ABC *Blood Bulletin* Member Survey by the November 11th deadline. *Blood Bulletin* is a resource for timely scientific and technical information on transfusion medicine meant to educate hospitals and blood center staff. Your feedback will help guide future updates and topics for this publication. ABC members can find additional information and a link to complete the brief survey here. Please contact us with any questions.

ABC Prehospital Blood Utilization Survey Responses Due November 12th

ABC is encouraging members to participate in the annual ABC Prehospital Blood Utilization Survey by the November 12th deadline. Your input will help guide and strengthen our national advocacy efforts to expand access to prehospital blood transfusions. As part of ABC's Advocacy Agenda, we are committed to supporting our members' prehospital blood initiatives. The survey data collected each year provides valuable insights into utilization trends, helps identify emerging opportunities and challenges, and enables us to measure progress over time. The survey takes approximately 10 minutes to complete. All information submitted will be kept confidential and reported only in aggregate. Additional information and a link to the survey are available here. Please contact us with any questions.

Nominations Are Open for the ABC Board of Directors

ABC is now accepting nominations for the ABC Board of Directors until Friday, November 13th. Individuals can self-nominate or nominate other ABC members. ABC is committed to an inclusive, transparent nominations process. Individuals may submit nominations here. Please contact us with any questions.

Register for the November ABC Webinar: "Risk Assessment for Blood Centers"

The ABC Educational Webinar Committee is hosting a November 17th webinar at 3 p.m. EST titled "Risk Assessment for Blood Centers." Registration is open and ABC members can find additional information including a link to register here. Featured speakers include:

- Loretta Olamigoke, PhD, CLS Quality Assurance Manager at Gulf Coast Blood; and
- Dana Knight, Director of Quality Assurance at Versiti.

The event will provide attendees with:

- valuable perspectives on the importance of having a robust risk assessment program;
- help exploring challenges and opportunities; and
- the opportunity to connect with subject-matter experts to ask questions and exchange ideas.

Please contact us with questions.

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The Results are In: ABC Workforce Trends Survey

The results for this year's Workforce Trends Survey are now available. This valuable benchmarking survey is the most comprehensive source of information available on workforce trends at blood centers. The survey analyzes overall trends in compensation, benefits, and HR policies and provides specific data for 74 different blood center employee roles. The survey 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. Those ABC member blood centers who participated in the Workforce Trends Survey can purchase the report at a discounted price (code required and has been emailed to authorized individuals) of $450 while non-participating blood centers can purchase the report at the full price of $900. Please contact us with any questions to access the results or to identify the authorized individual at your blood center who received the discount code.

ABC Executive Fellows Program Call for Applicants Extended

Apply to participate in the 2027-2028 America's Blood Centers (ABC) Executive Fellows Program (EFP) by December 14th. ABC is partnering with Vanderbilt University's Owen School of Management. This groundbreaking initiative offers industry-specific, best-in-class leadership training to blood community executives, elevating individuals, organizations, and the nation's blood supply. The program will accept an annual cohort of up to 25 fellows who will participate in:

- "a week-long leadership residency at Vanderbilt;
- three additional in-person learning immersions;
- virtual seminars taught by Vanderbilt faculty;
- a 360-leadership assessment;
- individual executive coaching; and
- a capstone project presented at the 2028 ABC Annual Meeting."

The EFP strives to accept participants from a wide variety of backgrounds and leadership roles. Final selections for the 2027-2028 cohort will occur by December 2026. An independent selection committee is responsible for choosing each year's cohort. Senior leaders from ABC member blood centers, hospital-associate members, affiliate organizations, and industry partners are encouraged to apply. The Foundation for America's Blood Centers (FABC) is pleased to announce a limited number of partial scholarships available for individuals employed by ABC active member blood centers. Additional information regarding tuition rates is available here.

September *Blood Bulletin* Is Available

The latest edition of *Blood Bulletin*, titled "Platelet Products in Clinical Practice: Manufacturing, Dose, and Safety Considerations" has been published. This issue of *Blood Bulletin* was written by: Theresa Nester, MD, Co-Chief Medical Officer at Bloodworks Northwest; Kirsten Alcorn, MD, Co-Chief Medical Officer at Bloodworks Northwest; Roni J. Bollag, MD, PhD, Laboratory Medical Director, National Blood Testing Collaborative and Augusta University Blood Bank; Ruchika Goel, MD, MPH, CABP, Medical Director, Research, Carter BloodCare; Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Courtney Hopkins, DO, Vice President, Corporate Medical Director, Vitalant; Kathleen Hopping, MS, Senior Director Regulatory Affairs, Vitalant; Cyril Jacquot, MD, PhD, Medical Director, Children's National Hospital; and D. Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center. The authors of this publication disclosed no conflicts. *Blood Bulletin* is reviewed and edited by the ABC Scientific, Medical, and Technical Publications Committee.

MEMBER NEWS

Results from an **Our Blood Institute** pilot study on "Home-based transfusions in hospice patients with hematologic malignancies" has been published in *eClinicalMedicine*, part of *The Lancet Discovery Science*. The authors of the paper aimed to, "describe the initial experience with a Home-Based Transfusion (HBT) program for patients with hematologic malignancies (HM) receiving home hospice services. [They] hypothesized that providing transfusions for hospice recipients would increase patients' duration and quality of hospice care (HC). Furthermore, [the authors] hypothesized that a home-based, symptom-driven approach could allow for the safe administration of products, preserved quality of life (QOL), and improved probability for patients to receive end of life (EOL) care at home rather than in a hospital-based setting. By establishing and studying the first HBT pilot study in the U.S. for individuals with HM, these findings will aid in addressing future efforts to enhance EOL care delivery and outcomes for this population." The paper described, "primary feasibility and safety outcomes [as] recruitment, [and the] ability to administer indicated transfusions, and transfusion reactions." The study found that, "the HBT strategy in patients with HM receiving home hospice services was safe and feasible. The opportunity for transfusions at home represents a strategy to help increase appropriate hospice usage, as 100% of the eligible patients approached for our study enrolled. The feasibility of symptom-triggered transfusions minimized the complexity of transfusion support and maximized patient-centered care. [The] study confirmed previous work primarily done in Europe, suggesting a low risk of transfusion reactions." The authors concluded that, "[o]ur study represents the first to document that HBT provides a feasible and safe option for patients with HM receiving hospice. This work also demonstrates that HBTs can be symptom-driven in this population, limiting the need for interaction with the healthcare system. This study contributes to improving HC for patients with HM by providing data supporting the integration of HBT and economic analyses demonstrating minimal cost implications. Considering the limited use of transfusions in hospice, further advocacy for the inclusion of this low-cost therapy could be considered as an adjunct to future hospice models. The cost savings of allowing patients to comfortably receive EOL care at home are both patient-centered and potentially cost-effective. Ultimately, findings from this work provide a framework for further clinical trial investigations focused on the utility and effectiveness of incorporating HBT care models for patients with HM."

Citation: Saleem, R., Glover, J., Vesely, S.K., *et al*. "Home-based transfusions in hospice patients with hematologic malignancies: a pilot study." *eClinicalMedicine*, part of *The Lancet Discovery Science*. 2026.

ADVANCED THERAPIES NEWS

Northwest Biotherapeutics and NHS Blood and Transplant (NHSBT) have announced a partnership to, "support production of its experimental cancer vaccine DCVax®-L." A Northwest Biotherapeutics (NWBio) news release explained that, "the agreement is the culmination of months of joint work between the organizations. DCVax®-L is a personalized dendritic cell-based therapy being developed for glioblastoma (GBM), the most aggressive form of primary brain cancer. Because each dose is made for an individual patient, production starts with collecting the patient's own immune cells. Working with NWBio and Advent Bioservices, two NHSBT teams are supporting key manufacturing stages:

- Therapeutic Apheresis Services (TAS): performs leukapheresis to collect the immune cell starting material for each patient's treatment. Leukapheresis is an established procedure in which blood is collected and separated to obtain specific white blood cells, with the remaining blood components returned to the patient.
- Cellular and Molecular Therapies (CMT): provides specialist processing and handling of the cellular material.

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ADVANCED THERAPIES NEWS (continued from page 8)

The collaboration initially involves NHSBT's sites in Leeds and Oxford. NHSBT, NWBio, and Advent Bioservices are exploring a phased expansion to additional NHSBT locations across England. NWBio [has] completed a 331-patient Phase III trial of DCVax®-L for GBM, published the results in *JAMA Oncology*, and submitted a marketing authorization application (MAA) for commercial approval in the UK, which is currently under review. The company has also developed DCVax®-Direct for inoperable solid tumors, completing a 40-patient Phase I trial, and previously conducted a Phase I/II trial of DCVax-L in advanced ovarian cancer with the University of Pennsylvania."

(Source: Northwest Biotherapeutics News Release, 10/8/26)

GLOBAL NEWS

***SVT Nyheter* is reporting that "[a] new collaboration between northern Sweden, Norway, and Finland will ensure that blood is always available in emergency situations, such as during a crisis or war."** The news organization explained in an article that, "the Nordic Blood Supply Project, in collaboration with Norway and Finland, will ensure that the regions of the Arctic can help each other in an emergency. [Since 2003,] Sweden has been part of the Nordic Health Preparedness Agreement, which regulates cooperation between the Nordic countries in times of crisis or war. However, until now, there has been a lack of a protocol for blood supply. '[The goal is [to] be able to exchange blood between countries. This is something that is difficult today, and this is partly due to the fact that there are different rules and legislation in the participating countries,'" stated Henrik Brännholm, chief emergency physician in Region Norrbotten, to the publication.

(Source: *SVT Nyheter*, "New Nordic cooperation will secure blood in times of crisis and war," 10/27/26)

The World Health Organization has announced that it is, "strengthening Ukraine's blood service by investing in laboratory capacity, biosafety, quality management systems and the professional development of laboratory specialists across the country." A news release from the WHO noted that, "[t]o help standardize the processing of donated blood, WHO has provided modern blood bank centrifuges to 17 regional blood cent[ers]. Also, WHO is supporting the launch and future operation of Ukraine's National Reference Laboratory, contributing to improving national health security. With financial support from the Swedish International Development Cooperation Agency (Sida), WHO is helping Ukraine maintain safe and essential blood services under the continued pressures of war, while also strengthening the foundations of a modern and resilient blood system, aligned with international standards. [WHO is] investing in laboratory quality management systems, improving biosafety practices, and helping laboratory professionals maintain reliable services even under challenging conditions. As part of this cooperation, WHO has provided essential reagents to the blood cent[er] in the Ternopil region to ensure that testing for hepatitis B and C, HIV, and syphilis can continue for the coming six months. In response to a request from Ukraine's Ministry of Health, WHO has also provided blood collection containers to all 24 regional blood cent[ers], together with biosafety supplies that can support operations over the coming years. WHO has [also] supported the professional development of laboratory specialists across Ukraine through a comprehensive training progra[m] covering PCR testing, biosafety, and laboratory quality management. More than 1,500 specialists have participated, including staff from all blood cent[ers], cent[ers] for disease control and prevention, and a number of hospitals involved in blood transfusion. [The cooperation] between WHO and Sida goes beyond the provision of equipment and supplies. It is helping Ukraine strengthen the system and skills needed to ensure that blood services remain safe."

(Source: WHO Announcement, 11/4/26)

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GLOBAL NEWS (continued from page 9)

The Ministry of Health in Mexico has published a standard (NOM-253-SSA1-2025) in the *Federal Official Gazette* on October 12th that, "update[es] the sanitary rules for obtaining, processing, storing, testing, and transfusing human blood and its components," according to a report from *Mexico Business News*. The publication explained that the standard, "closes a regulatory update that began with a draft published on November 8th, 2024. Its central changes are the incorporation of nucleic acid amplification testing (NAT) for HIV and hepatitis B and C, formal hemovigilance and traceability procedures, and a defined calendar for compliance. The standard defines hemovigilance as a set of procedures to monitor adverse and unexpected reactions in donors or recipients, with the aim of preventing these events and reducing their recurrence through recording, analysis, and follow-up. The previous standard had governed the therapeutic use of blood in Mexico since December 2012. The 2025 version is mandatory nationwide for professional, technical, auxiliary, and administrative staff at public, social, and private establishments involved in the therapeutic use of blood. Its scope covers every stage of the transfusion chain, from donor selection to clinical use. The standard's text assigns specific functions to blood banks, collection centers, processing centers, distribution centers, biological qualification centers, and hospital transfusion services. Biological qualification centers are authorized to perform immunohematology, nucleic acid amplification, infectious agent detection, and related quality control analyses. The regulated areas include donor evaluation, information, and consent; blood extraction and component processing; storage and transport under product-specific technical conditions; laboratory determinations; and the supply and clinical application of units, including identification and compatibility procedures. The update aligns with COFEPRIS' broader institutional agenda. In August 2026, the agency set priorities for the Federal Sanitary System focused on harmonizing technical criteria, strengthening risk-based sanitary surveillance, and participating in the WHO Global Benchmarking Tool, according to *Mexico Business News*. That meeting included state public health laboratories, which form part of the surveillance network that oversees sanitary establishments. Beyond NAT for HIV and hepatitis B and C, the standard requires screening for other transfusion-transmissible agents, including *Treponema pallidum*, the bacterium that causes syphilis, and *Trypanosoma cruzi*, the parasite that causes Chagas disease, along with the immunohematological determinations needed to ensure component safety. [The final text] establishes that blood services will have 180 additional calendar days after the standard enters into force to comply with the provisions on NAT and irregular antibody screening. Based on the April 10, 2027, entry-into-force date, that window extends into October 2027."

(Source: *Mexico Business News*, "Mexico Publishes New Blood Bank Rules, Effective April 2027," 10/14/26)

England recently opened its largest donor center and the first that collects blood, plasma, and platelet donations "under one roof." The Reading Blood Donor Cent[er] spans close to, "11,000 sq ft and is the first of its kind for the organi[z]ation, featuring 16 plasma chairs, three blood chairs, three platelet chairs, and three additional chairs to support blood collection during periods of high demand. Plasma collection began on October 12th, whole blood donations started on October 19th, with platelet collections due to follow before the end of the year. By bringing all three donation types together in one location, NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK), is making it easier than ever for people in and around Reading to start or continue donating."

(Source: NHSBT News Release, 10/20/26)

The World Health Organization's (WHO) Director-General Dr. Tedros Adhanom Ghebreyesus and the K-pop group ENHYPEN recently met in Seoul to celebrate the, "success of their collaboration for World Blood Donor Day 2026 and recognize the group's role in inspiring young people around the world to donate blood and save lives. The collaboration between WHO and ENHYPEN started on

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GLOBAL NEWS (continued from page 10)

World Blood Donor Day, bringing together the power of music, social media, and the group's global fan community, known as ENGENE, to promote voluntary, unpaid blood donation," explained a WHO news release. "Through a series of social media videos and digital content developed with WHO, ENHYPEN encouraged their millions of fans to learn about the importance of safe blood, [to] make a pledge to donate and take action in their own communities. ENHYPEN highlighted the global participation from ENGENE and their hope to continue creating meaningful change together with their fans, saying [in the WHO news release, '[w]e launched this campaign hoping our fans would join us, and we're grateful to see ENGENEs from all around the world taking part. We hope to continue creating meaningful change together with our fans.' The group led by example by visiting a Korean Red Cross blood donation cent[er] in Seoul, where all members underwent donor eligibility screening and members Jay and Jungwon donated plasma. [Their message] resonated far beyond the Republic of Korea. Fans from countries including Indonesia, the Philippines, Germany, and the United States shared photographs and personal stories of donating blood, transforming an online campaign into real-world participation. WHO's 2026 'Drop Your Drop' global blood donation campaign had received more than 9,000 pledges from people across 177 countries, including over 3,250 participants identifying themselves as ENGENE."

(Source: WHO News Release, 10/23/26)

COMPANY NEWS

The U.S. Food and Drug Administration (FDA) recently provided supplement approval to **Grifols Diagnostics Solutions Inc.** to update the "'Instructions for Use' written instructions for the manual lysis mix. According to the FDA letter, additional minor edits included, "[revisions] to the homogenization step and endogenous substances wording, the removal of specific RLU values from the results interpretation presentation (RLU values are set by the Procleix Panther System software) and additional minor editorial updates that are required for the following biological products:

- "BL 125673/37 Procleix® Babesia Assay;
- BL 125862/1 Procleix® Plasmodium Assay."

(Source: FDA Letter,10/6/26)

Hemanext Inc. has announced partnerships with LifeSouth Community Blood Centers, Hoxworth Blood Center, and Mississippi Blood Services expanding its, "U.S. patient services and commercial reach after three major independent, non-profit U.S. blood centers signed supply agreements for the Company's patented and FDA cleared Hemanext ONE® Red Blood Cell Processing and Storage System." According to a company news release, the agreements come in the wake of, "Hemanext Inc.'s recently announced strategic production partnership with OneBlood and Vitalant. [Hemanext ONE® is] a first-in-class oxygen-controlled (hypoxic) processing and storage system designed to improve the quality of stored red blood cells by reducing oxygen exposure, a primary driver of oxidative damage during storage. The system is intended to process and store whole blood- or apheresis-derived leukocyte-reduced red blood cells collected in CP2D/AS-3 or apheresis-derived LR-RBC in ACD-A/AS-3. Hemanext ONE has received U.S. Food and Drug Administration authorization and is CE marked for commercial distribution in the European Economic Area and the United Kingdom."

(Source: Hemanext Inc., 11/5/26)

Moderna, Inc. and **Merck** recently shared, "detailed positive recurrence-free survival (RFS) and distant metastasis-free survival (DMFS) results from the Phase III INTerpath-001 trial evaluating intismeran autogene (intismeran; V940 or mRNA-4157), a novel investigational mRNA-based individualized neoantigen

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COMPANY NEWS (continued from page 11)

therapy (INT) being jointly developed by Merck and Moderna, in combination with KEYTRUDA ® (pembrolizumab), Merck's anti-PD-1 therapy, as adjuvant treatment for patients with completely resected stage IIB-IV melanoma." According to the news release, "[a]t the primary pre-specified analysis (intention-to-treat), after a median follow-up of 24.6 months, intismeran in combination with KEYTRUDA significantly reduced the risk of recurrence or death by 42% (HR=0.58 [95% CI, 0.45–0.75]; two-sided p<0.001). Intismeran plus KEYTRUDA also significantly reduced the risk of distant metastasis or death by 38% (HR=0.62 [95% CI, 0.45–0.85]; two-sided p=0.002) compared to KEYTRUDA alone. The improvements observed in RFS and DMFS were generally consistent across pre-specified patient subgroups. Overall survival (OS) data are not yet mature, but a favorable trend in OS with intismeran plus KEYTRUDA has been observed. The study remains ongoing to further evaluate OS and other key endpoints. The safety profile of intismeran plus KEYTRUDA was generally consistent with previously reported studies of the combination, and no new safety signals were observed. Based on these data, we are engaging with regulatory authorities. The efficacy of the intismeran immunization plus KEYTRUDA in the first six months was comparable with KEYTRUDA alone for risk of recurrence or death (HR=0.99 [95% CI, 0.66–1.49]) and risk of distant metastasis or death (HR=1.01 [95% CI, 0.58–1.79]). At six months, following the intismeran immunization regimen, a pre-specified sensitivity analysis of the primary endpoint showed the addition of intismeran plus KEYTRUDA reduced the risk of recurrence or death by 58% (HR=0.42 [95% CI, 0.30–0.58]) and reduced the risk of distant metastasis or death by half (HR=0.50 [95% CI, 0.34–0.73]) compared to KEYTRUDA alone. In a pre-specified sensitivity analysis of the modified intent-to-treat (mITT) population, which excluded participants who did not receive at least one dose of intismeran or placebo as planned, intismeran plus KEYTRUDA reduced the risk of recurrence or death by 49% (HR=0.51 [95% CI, 0.39–0.67]) and the risk of distant metastasis or death by 45% (HR=0.55 [95% CI, 0.40–0.77]) compared to KEYTRUDA alone. INTerpath-001 is a randomized, double-blind, placebo- and active-comparator-controlled global Phase 3 trial (ClinicalTrials.gov, NCT05933577) evaluating the safety and efficacy of intismeran in combination with KEYTRUDA compared to KEYTRUDA alone in patients with high-risk (stage IIB-IV) resected cutaneous melanoma. The trial enrolled 1,137 patients who, following complete surgical resection, were randomized 2:1 to receive intismeran (1 mg every three weeks for up to nine doses) and KEYTRUDA (400 mg every six weeks up to nine cycles [for approximately one year]) compared to placebo plus KEYTRUDA for approximately one year until disease recurrence or unacceptable toxicity, or for a total treatment duration of up to approximately 56 weeks, whichever was sooner. The primary endpoint is RFS, defined as the time from randomization to any disease recurrence (local, locoregional, regional or distant) as assessed by the investigator, or death due to any cause. Key secondary endpoints include DMFS, OS, safety, tolerability, and quality of life."

(Source: Moderna, Inc. and Merck News Release, 10/22/26)

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

November 17. **ABC Educational Committee Webinar: Risk Assessment for Blood Centers (Virtual).** ABC members can contact us for more information including a link to registration.

November 17. **NHTSA Office of EMS Prehospital Blood Transfusion Policies, Protocols Guidelines & Training Webinar (Virtual).** Registration is open. More information is available here.

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CALENDAR (continued from page 12)

November. 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.

December 10. **U.S. Food and Drug Administration (FDA) OTP Guidance Webinar: "Potency Assurance for Cellular and Gene Therapy Products" (Virtual).** Registration is open. More information is available here.

December 15. **NHTSA Office of EMS Prehospital Blood Transfusion: Tracking Success & Improvement Webinar (Virtual).** Registration is open. More information is available here.

2027

March 2-4. **Eugene Springfield Fire "Pacific Northwest Whole Blood Summit."** Eugene, Ore. Col. More information is available here.

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

April 20-21. **PPTA International Plasma Protein Congress (IPPC). Barcelona, Spain.** More information is available here.

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

May 12-13. **The International Plasma and Fractionation (IPFA)/Paul-Ehrlich Institut[e] (PEI) 33rd International Workshop on Surveillance and Screening of Blood-borne Pathogens. Edinburgh, Scotland.** Registration is open. More information available here.

September 15-16. **2027 ADRP: The Association for Blood Donor Professionals Master Class (Virtual).** More information is coming soon.

September 20-23. **Association for Advancing Tissue and Biologics (AATB) Congress 27. Montréal, Canada.** More information available here.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Executive Vice President (EVP). Bloodworks Northwest is seeking a strategic **Executive Vice President (EVP), Blood Operations** to lead the blood business of one of the country's leading independent blood centers, based in Seattle, Washington. Reporting to the President and Chief Executive Officer and serving on the executive leadership team, the EVP is responsible for the operational execution and financial performance of the blood business. This role leads the entire blood supply chain, from donor recruitment and collections through manufacturing, inventory, distribution, transportation, and hospital services. **Qualifications:** Bachelor's degree in business administration, healthcare administration, operations management, supply chain management, engineering, life sciences, or a related field required; advanced degree preferred. Minimum fifteen years of progressive leadership experience, including at least ten years leading large, complex operational functions. Must have demonstrated success with full P&L accountability for a substantial operating business. Experience leading geographically dispersed teams in healthcare, blood banking, biologics, manufacturing, logistics, life sciences, or another highly regulated environment. Proven record of strengthening reliability, productivity, customer service, and financial performance across multiple inter

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POSITIONS (continued from page 13)

dependent functions. Direct blood banking experience is welcome but not required when paired with strong operational leadership. Experience with partnerships, affiliations, or acquisitions is preferred. To express interest, please contact Andrew Ulrich at Korn Ferry, Bloodworks' executive search partner, at andrew.ulrich@kornferry.com.

Business Services Manager. LifeSouth Community Blood Centers is seeking an experienced, results-driven **Business Services Manager** to lead our Business Office operations at our headquarters in **Gainesville, FL**. This is an opportunity to put your financial expertise and leadership skills to work for a nonprofit organization with a lifesaving mission. **Position Highlights:** Lead and develop a team supporting essential financial and accounting operations. Oversee functions including payroll, accounts payable, revenue cycle, fixed assets, and expense reporting. Promote accuracy, accountability, operational efficiency, and exceptional service across the organization. Identify opportunities for process improvement and strengthen financial operations. **What We're Looking For:** Progressive accounting or finance experience with demonstrated supervisory experience. Strong knowledge of accounting principles, financial controls, and business operations. Proven leadership, organizational, and communication skills. Bachelor's degree in Accounting, Finance, or a related field (equivalent education, training, and experience may be considered). **Location:** Gainesville, FL (fully on-site). **Starting Salary:** Negotiable based on relevant experience and qualifications. **Interested?** Learn more about the position and apply using the link below. **To be considered for this opportunity, candidates must submit an application through LifeSouth's official careers website.** APPLY HERE

Chief Donor and Growth Officer. Carter BloodCare (Bedford, TX) seeks a strategic, mission-driven **Chief Donor and Growth Officer** to lead donor growth, collection operations, marketing and communications, donor experience, and community engagement. As an executive leadership team member, you will guide the complete donor journey, strengthen partnerships, and align innovation, resources, and operations to sustain a reliable blood supply for patients. **Required qualifications: Education** - Bachelor's degree in business administration, healthcare administration, marketing, communications, public health, life sciences, or a related discipline; **Experience** - Seven years leading executive-level customer, patient, community, or donor acquisition, retention, engagement, and experience strategies; five years in executive or senior leadership overseeing multiple functions or complex operations; experience in a regulated industry or mission-driven environment. Competitive compensation and comprehensive benefits package. Apply Here.

Divisional Director (Suffolk/Norfolk, VA). The Blood Connection seeks an experienced and strategic Divisional Director to provide leadership, administrative guidance, and operational direction across key departments within the organization. This leader will oversee critical functions that may include donor recruitment, blood collection operations, facilities, fleet, procurement and materials management, hospital services, component manufacturing, and laboratory services. The Divisional Director will oversee departmental budgets, staffing, performance, quality, and operational planning while ensuring compliance with current good manufacturing practices. This leader will also drive process improvements, support strategic initiatives, and partner with executive leadership as The Blood Connection expands services and enters new regions. Candidates must have a bachelor's degree in a related field, five years of experience in a technical or laboratory setting, including at least five years of progressive management experience, and a background in blood banking or another regulated biologics manufacturing environment. Strong analytical, organizational, communication, and leadership skills are essential, along with the ability to effectively manage priorities and collaborate across all levels of the organization. This is an opportunity to lead mission-critical operations that directly support The Blood Connection's continued growth and lifesaving work throughout the communities we serve. Apply today: https://jobs.dayforcehcm.com/enUS/tbc/CANDIDATEPORTAL/jobs/19089.

Finance Manager. LifeSouth Community Blood Centers is seeking an experienced **Finance Manager** to lead our Business Office operations at our headquarters in Gainesville, Florida. This is an opportunity to put your financial expertise and leadership skills to work for a nonprofit organization with a lifesaving mission. **Position Highlights:** Lead and develop a team supporting essential financial and accounting operations. Oversee functions including payroll, accounts payable, revenue cycle, fixed assets, and expense reporting. Promote accuracy, accountability, operational efficiency, and exceptional service across the organization. Identify opportunities for process improvement and strengthen financial operations. **What We're Looking For:** Progressive accounting or finance experience with demonstrated supervisory experience. Strong knowledge of accounting principles, financial controls, and business operations. Proven leadership, organizational, and communication skills. Bachelor's degree in Accounting, Finance, or a related field (equivalent education, training, and experience may be considered). **Location:** Gainesville, FL (fully on-site). Starting Salary: Negotiable based on relevant experience and qualifications. **Interested?** Learn more about the position and apply using the link below. **To be considered for this opportunity, candidates must submit an application through LifeSouth's official careers website.** APPLY HERE.