America's Blood Centers
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NEWSLETTER

A weekly chronicle of events and issues impacting the blood community

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FDA Releases Buffy Coat Method Final Guidance for Blood Components

The U.S. Food and Drug Administration (FDA) has published the final guidance titled "Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method." The agency explained that the purpose of the guidance is to, "provide recommendations on the development of blood collection, processing, and storage systems (e.g., blood bags with anticoagulant and additive solutions, empty bags for platelet pooling) intended for the manufacture of blood and blood components for transfusion using the buffy coat (BC) method and on regulatory submissions to FDA for such products. This guidance is intended for manufacturers of blood collection, processing, and storage systems. The recommendations in this guidance do not apply to devices used to manufacture platelet rich plasma or similar products used for therapeutic purposes other than transfusion. The recommendations also do not apply to blood establishments that intend to manufacture blood and blood components using the BC method with approved or cleared collection, processing, and storage systems."

The final guidance included several key recommendations previously advanced in America's Blood Centers' (ABC) advocacy efforts:

- the FDA guidance acknowledged the transition to DEHP-free systems noting, "[w]e support efforts to develop blood collection, processing, and storage systems that do not contain DEHP and the introduction of additive solutions that are currently not approved by FDA and we encourage manufacturers to contact FDA to discuss their supporting data and planned submissions;"
- the agency included language in the final guidance, "recogniz[ing] that donor-related factors may result in variable degrees of hemolysis and potential failure to meet the acceptance criteria. Failures during testing should be investigated and described in the submission. FDA will consider the reason for the failure (e.g., donor-related factors), if identified, during our review of the submission;" and
- FDA recognized, "that some blood collection, processing, and storage systems entail holding whole blood for up to 24 hours before separation (overnight hold). Note that FDA regulations [for red blood cells, platelets, and plasma] do not restrict the timeframe for separation of the component from whole blood. Rather, the timeframe for separation must be as specified in the directions for use of the blood collection, processing and storage system. Manufacturers should include data that supports the timeframe for separation from whole blood (e.g., 4, 8, 24 hours) using the BC method."

(Source: FDA Final Guidance, 9/17/26)

BRIEFLY NOTED

The Governing Body of Jehovah's Witnesses have announced that, "the decision to accept red cells, white cells, plasma or platelets from another person's blood is a matter of personal conscience. Likewise, each Witness must decide whether or not to donate blood for the clearly expressed purpose of providing components or fractions for use by another person. The long-standing refusal of whole-blood transfusions on religious grounds, a core teaching based on the command to 'abstain from blood' (Acts 15:20), is unchanged." The announcement further noted that, "[t]he adjustment follows earlier updates regarding blood fractions and the use of one's own blood during medical procedures. Since the Bible does not comment on such decisions, they are a matter of individual conscience. That same reasoning has now been extended to the four main components of blood. Jehovah's Witnesses love life and want the best available medical care. They do not practice faith healing, and they seek out doctors who can provide effective treatment in accord with their wishes, values and beliefs." A spokesperson for the organization added in the announcement that, "[b]lood remains sacred to Jehovah's Witnesses, who continue to regard life and blood as precious gifts from God. We recognize that medical decisions involving blood components are a matter of conscience between each Witness and their God, Jehovah."

(Source: Jehovah's Witnesses Governing Body Announcement, 9/18/26)

WORD IN WASHINGTON

The Centers for Medicare & Medicaid Services (CMS) has published a news release stating that the Trump Administration is investing $169.6 million to, "expand specialty care, strengthen emergency services, and bring lifesaving blood transfusions closer to Colorado patients." The announcement explained that, "[the funding will expand] access to lifesaving whole-blood transfusions before patients reach the hospital, including training rural EMS providers across a network reaching 39 Colorado counties. [Specifically, the investment will strengthen] emergency medical services and emergency care [by expanding] emergency and transport capacity, regional training and coordination, workforce development, and access to lifesaving equipment, including efforts to expand the availability of whole-blood transfusions before patients reach the hospital."

(Source: CMS News Release, 9/28/26)



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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the health care system; promote partnerships, policies, and programs that increase awareness about the need for blood donation; and serve as a thought leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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REGULATORY NEWS

The Association for the Advancement of Blood & Biotherapies (AABB) has published Association Bulletin #26-05 regarding "B-Cell-Depleting Monoclonal Antibody Therapy and Blood Safety." The document:

- "was developed in response to new information shared by Centers for Disease Control and Prevention (CDC) representatives to the Transfusion Transmitted Diseases (TTD) Committee and the Donor History Task Force (DHTF). Consistent with AABB's close working relationship with CDC on blood safety, the TTD Committee, the DHTF, and an *ad hoc* working group of AABB members with relevant expertise in transfusion medicine and donor screening reviewed the information and developed this bulletin.;
- [d]escribes an update to blood donor screening practices based on new information related to donors undergoing B-cell-depleting monoclonal antibody therapies for non-deferral medical conditions and the potential impact on blood and blood component recipients;
- [a]dds a new medication(s) and an associated donor deferral to the AABB Medication Deferral List version 4.0 (MDL v4.0);
- [c]larifies that the current edition of *Standards for Blood Banks and Transfusion Services* (*BBTS Standards*) requires accredited facilities to implement the updated version of the MDL within six months of the effective date of the MDL (*BBTS* Reference Standard 5.4.1A – Requirements for Allogeneic Donor Qualification, #10); [and]
- [d]oes not establish a new *BBTS* standard."

(Source: AABB Association Bulletin #26-05, 9/16/26)

PEOPLE



Dr. Chaffin

LifeStream has announced that **Joe Chaffin, MD** and **Minh-Ha Tran, DO** have joined the blood center's medical leadership team. According to the announcement, "Dr. Chaffin previously served as LifeStream's Chief Medical Officer from 2014–2021. Board-certified in Anatomic and Clinical Pathology and Blood Banking/Transfusion Medicine, he has held leadership and clinical roles in both hospitals and blood centers and recently concluded his role as a Transfusion Medicine educator at Loma Linda University. He is also the founder of the Blood Bank Guy website (www.BBGuy.org), which he created in 1998 to teach the essentials of transfusion medicine. Through the site, the Blood Bank Guy Essentials Podcast, and decades of live teaching, Dr. Chaffin has helped make complex transfusion medicine topics accessible and practical for pathologists, patient-facing physicians, laboratorians, and nurses worldwide."



Dr. Tran

Dr. Tran is, "professor of Pathology and Laboratory Medicine at the University of California, Irvine (UCI). After [finishing] internal medicine training, he completed a Blood Banking/Transfusion Medicine fellowship at the National Institutes of Health. At UCI, his work includes medical direction of transfusion services, development of the UCI blood donor center, therapeutic apheresis, complex immunohematology consultation, and cellular therapy collections. He is also a co-author of AABB's Concise Guide to Transfusion Medicine. The new medical team will focus on strengthening LifeStream's clinical partnership with the hospitals it serves. Dr. Chaffin will be readily available to hospital physicians, transfusion services, laboratory leaders, and transfusion committees for consultation and to help partners interpret and apply the latest evidence and recommendations in transfusion medicine. Dr. Tran, while retaining his primary responsibilities at UCI, will provide additional medical expertise and assist with on-call issues."

(Source: LifeStream News Release, 9/16/26)

RESEARCH IN BRIEF

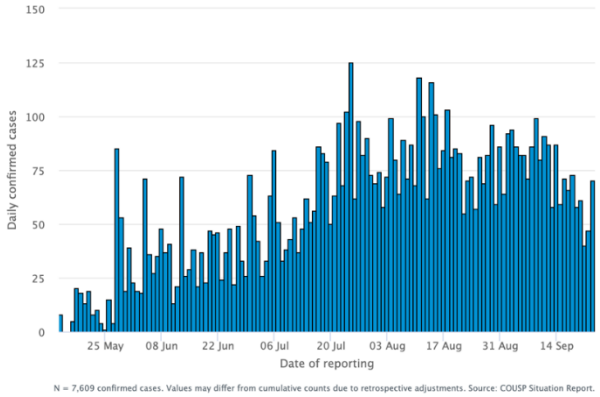
ABO Nonidentical Transfusions Associated with Increased Mortality in Patients Undergoing Massive Transfusion Protocol? Authors of a "Research Letter" published in *JAMA Surgery* aimed to, "investigat[e] whether receipt of ABO nonidentical transfusions while on massive transfusion protocol was associated with increased mortality at a level I trauma center." For their cross-sectional study, they analyzed, "24-hour and hospital mortality in patients requiring activation of massive transfusion protocol at a level I trauma center from 2008 to 2020. The delay in final analysis (performed September to December 2025) was primarily due to changing transfusion practice during the intervening years; this was prior to implementation of A plasma and low-titer group O whole blood. All massive transfusion protocol activations were included. Patient ABO blood group, quantity of ABO nonidentical transfusions, and total transfusions were analyzed." The study included 403 individuals. The study found that, "[p]atients alive at 24 hours (275 patients [68%]) and at discharge (213 patients [53%]) did not differ by ABO group (group O, 192 patients; group A, 143 patients; group B, 51 patients; group AB, 17 patients). Receipt of 1 to 4 ABO nonidentical components (73 patients) was not associated with inferior survival vs. receipt of 1 to 4 ABO identical component transfusions (288 patients; 24-hour survival: 55 patients [75%] vs. 199 patients [69%]; overall survival: 47 patients [65%] vs. 153 patients [53%]). Transfusion of 5 or more ABO nonidentical components (mostly red blood cells [RBCs]; 42 patients) was associated with inferior survival at both 24 hours (20 patients [48%]; P = .006) and at hospital discharge (13 patients [31%]; p = .002) compared with patients receiving 0 to 4 ABO nonidentical transfusions. [Additionally, patients] receiving similar numbers of transfused components experienced inferior survival if receiving ABO mismatched blood when compared with patients receiving only ABO identical components. Among the 24-hour survivors, group O individuals (129 patients) experienced reduced hospital deaths (23 patients [18%]) compared with those of groups AB, A, and B (146 patients [27%]) (p = .05). Deaths among 24-hour non–group O survivors were highest in group AB (14 patients [43%]), followed by group A (101 patients [28%]), and were lowest in group B (31 patients [16%]) (p = .06). The presence of A antigen on the cells of the recipients was associated with greater hospital mortality among those surviving 24 hours (34 deaths of 115 survivors [30%]) than those not having A antigen (28 deaths of 160 survivors [18%]) (p = .02)." The authors concluded that, "ABO nonidentical transfusions were associated with increased mortality compared with recipients of only ABO identical transfusion. Mortality rates were approximately twice as high with receipt of ABO mismatched component transfusions when 6 to 15 transfusions were given. Group AB and A patients had higher rates of death among those who survived 24 hours. We hypothesize that the overall superior survival of type O and B patients contrasted with type A and AB patients may be in part due to latter receiving ABO mismatched transfusions containing anti-A. One possible benefit of using low-titer group O whole blood in some patient cohorts may be the fact that it is ABO identical with almost one-half of recipients. [These results] do suggest that determining the patient's ABO type as soon as feasible and administering ABO identical components as a policy might improve outcomes in some instances. Future studies of resuscitation with blood transfusion should consider the patient's ABO type and receipt of ABO nonidentical transfusions in assessments of efficacy and safety." A limitation of the study acknowledged by the authors was that, "few transfusion services prioritize use of ABO identical platelets and cryoprecipitate, as we did in our study; this may make it difficult to confirm these results."

Citation: Blumberg, N., Heinrichs, K., Masel, D., *et al*. "ABO Nonidentical Transfusions and Mortality in Patients Undergoing Massive Transfusion Protocol." *JAMA Surgery*. 2026.



INFECTIOUS DISEASES UPDATE

EBOLA



On September 25th, the World Health Organization (WHO) updated the status of the Ebola disease outbreak in the Democratic Republic of the Congo (DRC). As of September 23rd, "the outbreak has spread to 63 health zones [in the region] across 7 of 26 provinces of the country." On September 23rd, the WHO noted that, "[a total] of 7,890 confirmed cases, including 3,799 deaths, have been reported corresponding to a crude case fatality ratio (CFR) of 48.1 percent. At the national level, the number of new cases reported each day remains high. However, the situation varies across the country, with some provinces and health zones experiencing much higher levels of transmission than others. The continuously high CFR, and especially the continuous high rate of deaths occurring in communities, highlights the seriousness of the disease and the persistent challenges in timely case detection and access to early and adequate patient care. These delays can contribute to preventable illness and deaths among people in affected and newly affected areas, while also allowing transmission to continue within households, communities, and healthcare settings." 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 September 29th stating that the U.S. "is responding to an outbreak of Ebola disease in remote areas of the (DRC and Uganda.) To date, no cases of Ebola disease have been confirmed in the United States because of this outbreak. The overall risk to the American public and travelers remains low." 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, 9/25/26; CDC Update, 9/29/26)



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 Executive Fellows Program Call for Applicants Is Open

Apply to participate in the 2027-2028 America's Blood Centers (ABC) Executive Fellows Program (EFP) before November 7th. 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.

Share Your Input: 2027-2029 ABC Advocacy Agenda Survey

The deadline is approaching to complete the 2027-2029 ABC Advocacy Agenda Survey. Your participation is needed before the October 2nd deadline. ABC's Advocacy Agenda defines the federal legislative and regulatory issues that matter most to community blood centers. New this year, the advocacy cycle is moving to a two-year agenda rather than a single-year agenda. The survey will take up to 15 minutes to complete. We encourage you to share this survey widely within your center as input from every role makes the final agenda stronger. If you have questions, please do not hesitate to contact us.

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

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INSIDE ABC (continued from page 6)

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.

ABC Executive Compensation Survey Is Open

ABC has launched the Executive Compensation Survey. Authorized individuals from ABC member blood centers have received an email with additional details and instructions for accessing the survey. The deadline to complete a submission is October 30th. The Executive Compensation Survey serves as a resource for blood center chief executive officers (CEOs) and their boards in setting executive salaries/benefits, as well as meeting the Internal Revenue Service (IRS) Form 990 requirements to demonstrate comparability of executive compensation. Please contact us with any questions.

Registration Is Open for the ABC Quality Regulatory Forum

Register for the Fall 2026 ABC Quality Regulatory Forum. This event will take place on October 13th at 1 p.m. EDT. Join us for this engaging and interactive session that will focus on "Quality Department Challenges Facing Blood Centers Today." Speakers include:

- Megan McShea, Manager of Regulatory at Versiti Blood Health, Inc.; and
- Rebecca L. Thornton, Director of Quality Assurance and Regulatory Affairs at OneBlood.

Take part in discussions that will address:

- key changes in FDA inspections over the last several years and approaches to address unanticipated questions; and
- quality resilience during internal/external business disruptions or major changes.

Attendees will also have the opportunity to ask questions, share perspectives, and join the discussion in a collaborative setting. This forum is designed to be both informative and interactive as the second part of the session is dedicated to open discussion and audience-driven topics. Don't miss this opportunity to gain practical knowledge, connect with your peers, and be part of the conversation! Please contact us with any questions.

Registration Is Open for the Rise & Lead Workshop

Register for the ABC Women's Executive Leadership Community (WELC) Rise & Lead Workshop taking place in San Antonio, Texas November 5th-6th at The Westin Riverwalk, San Antonio. Join blood community professionals and industry partners for a dynamic leadership experience focused on Executive Presence and Personal Brand to develop the skills needed to increase your visibility, strengthen your influence, and confidently communicate your value while building meaningful connections with peers and industry leaders. For chief executive officers (CEOs) seeking a more intimate leadership experience, an optional CEO Retreat on November 4th offers a dedicated opportunity to connect with fellow executives, discuss shared challenges, and engage in meaningful peer-to-peer conversations before the workshop begins. WELC empowers leaders throughout the blood community through networking and professional development. Whether you are an emerging leader, experienced manager, or seasoned executive, the workshop creates space for meaningful conversations, shared learning, and the development of lasting professional relationships. Please contact us with any questions.

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Nominations Are Open for the ABC Medical & Scientific Emerging Leader Award

America's Blood Centers (ABC) is encouraging member blood centers to recognize an early to mid-career medical and scientific professionals (individuals who are within 20 years of having completed their training) with the ABC Medical & Scientific Emerging Leader Award. The deadline to submit a nomination is September 30th. This award honors individuals who demonstrate leadership, innovation, and commitment to advancing blood banking and transfusion medicine. The award recipient will receive:

- complimentary meeting registration and travel support to the 2027 ABC Annual Meeting in Atlanta, Ga.;
- an opportunity to deliver a featured 60-minute lecture during the 2027 ABC Annual Meeting; and
- recognition as an emerging leader in the field.

Additional criteria details and more information are available on the ABC website. Please contact us with any questions.

Economic Outlook Survey Report Available

America's Blood Centers (ABC) recently announced that the ABC Economic Outlook Survey Report has been released. The report is complimentary to participants and instructions on accessing it have been distributed to the designated contact. Non-participating ABC members may purchase the report. The ABC Economic Outlook Survey provides a comprehensive look at blood center finances, including 19 of the most frequently used ratios for benchmarking the financial health of an organization as well as median service fees for 30 different blood products and blood center procedures. Please contact us with questions.

MEMBER NEWS



Vitalant has announced that the Vitalant Foundation has, "[surpassed the] initial $1 million fundraising goal for the Dr. Michael P. Busch First Response Fund." A special event took place on July 24th celebrating the achievement and honored the, "remarkable career of one of the world's leading blood safety researchers. The event, generously underwritten by Vitalant and the University of California San Francisco Department of Laboratory Medicine, [featured Nobel Laureate Dr. Harvey J. Alter delivered an inspiring keynote tribute before more than 140 distinguished colleagues, collaborators, donors, family and friends gathered. Honoring Dr. Busch's four decades of groundbreaking scientific leadership, the Dr. Michael P. Busch First Response Fund will provide annual support for rapid-response pilot projects at Vitalant Research Institute (VRI), advance key scientific priorities, support trainees and collaborators, and help establish the foundation for larger research initiatives funded by national and international partners." Vitalant Chief Executive Officer Dave Green added in the announcement, "Dr. Busch's extraordinary 40-year career has transformed Vitalant and leaves an indelible mark on the field of transfusion medicine, driving advances that continue to benefit patients and save lives around the world. The Dr. Michael Busch Legacy Fund is a fitting tribute to a career defined by innovation, leadership and service." The announcement also noted that Dr. Busch is, "[o]ne of the world's foremost experts in blood safety and infectious disease research [and] helped lead the development of universal HIV and West Nile virus screening for blood donations and was a founding leader of the National Institutes of Health's Recipient Epidemiology and Donor Evaluation Study (REDS) program. Throughout his career, he has authored more than 750 peer-reviewed scientific publications and played key roles in dozens of large-scale research studies that have advanced blood safety worldwide."

(Source: Vitalant Announcement, 9/22/26)

ADVANCED THERAPIES NEWS

The U.S. Food and Drug Administration (FDA) has published a notice in the *Federal Register* titled "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing." The agency explained in the notice that, "a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995." The total number of annual responses being estimated is 17,818 and the total number of hours being estimated is 34,191.

(Source: *Federal Register* Notice, 9/16/26)

Orca Bio recently announced findings, "from a retrospective analysis which suggests a three-year overall survival (OS) benefit with TREGZITM, in patients with hematologic malignancies." The company noted in the, "retrospective analysis evaluated data from the Precision-T phase 1b multicenter study comparing TREGZI + tacrolimus (Tac) to a CIBMTR-NMDP registry cohort of patients receiving conventional allo-HSCT + PTCy based GVHD prophylaxis. The findings, featured in the journal *Transplantation and Cellular Therapy*, showed improved survival outcomes for patients treated with TREGZI compared to similar patients treated with PTCy in the myeloablative setting. [The data revealed that the] TREGZI arm was associated with higher OS over a three-year follow-up period compared to PTCy arm (HR=0.41; log-rank p=0.003). Overall survival at one, two, and three years for patients receiving TREGZI (n=76) was 96% (95% CI: 88%-99%), 86% (76%-92%), and 83% (73%-90%), respectively. For patients included in the PTCy cohort (n=360), OS at one, two, and three years was 81% (95% CI:77%-85%), 72% (67%-77%), and 66% (60%-71%), respectively. Historically, a drug cocktail of Tacrolimus/methotrexate (tac/MTX) was the predominant standard of care to prevent GVHD for patients following alloHSCT. However, there has been increased adoption of different approaches to GVHD prevention such as, PTCy-based regimens and the recently approved high-precision cell therapy, TREGZI. In clinical studies, both TREGZI + Tac and allo-HSCT + PTCy have demonstrated the reduced cumulative incidence of GVHD relative to Tac/MTX."

(Source: Orca Bio News Release, 9/17/26) ♦

GLOBAL NEWS

Sanquin, the national blood provider for the Netherlands, has begun testing all blood donations for West Nile virus, according to a report from the *NL* Times. The news comes in the wake of a death of a person, "who received West Nile-infected blood from a Sanquin donor." The news organization noted in an article that, "[t]he donor was infected by a mosquito. It is unclear if the person that died was killed by the virus or if they already had existing health complications. Following the deadly transfusion, the donation unit was shut down, so no one else reportedly received the infected blood." The *NL* Times also recently reported that, "[a]nother person in the Netherlands has died after being infected with West Nile virus, while the number of new cases has risen slightly." The news agency explained that, "five people who were confirmed to have contracted West Nile virus have died in the Netherlands this year. However, the virus is not necessarily considered the direct cause of their deaths. The National Institute for Public Health and the Environment (RIVM) reported 16 new infections over the past week. All of those patients contracted the virus after being bitten by an infected mosquito, according to the RIVM." Last month, the RIVM previously reported that, "[a] West Nile virus infection had been confirmed in a blood donor in the Netherlands. This occurred in August 2026 during a Sanquin study among blood donors from areas where the West Nile virus had previously been detected in humans, horses, birds, or mosquitoes. A laboratory test (PCR) detected the

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GLOBAL NEWS (continued from page 9)

virus in the donor, who had no symptoms and is still not showing any." The agency further noted that, "[this was] the first confirmed case of a human infection in 2026 that originated in the Netherlands. The last time people contracted a West Nile virus infection in the Netherlands was in 2020." West Nile virus is a mosquito-borne illness that is transfusion-transmissible. "The disease caused by the West Nile virus is called West Nile fever. 80 percent of people with West Nile fever have no symptoms, 19 percent have flu-like symptoms and 1 percent may develop neurological symptoms. People over 50 and people with weakened immune systems due to illness or medication have a higher risk of becoming very ill from West Nile fever."

(Sources: *NL Times*, "Blood bank to test all donations in 9 provinces after West Nile transfusion death," 9/18/26; "Fifth West Nile virus death reported in Netherlands as 16 new cases confirmed," 9/24/26; "Two more deaths linked to West Nile virus in the Netherlands; Infections double to 18," 9/10/26; RIVM Announcement, 8/17/26) ♦

China is revising its blood donor eligibility criteria. *Caixin Global* is reporting that the country is, "raising the [upper] age limit and shortening the [interval] between donations as the nation faces a widening blood supply shortage. The National Health Commission is revising the 1998 Blood Donation Law to ease the strain of dwindling donor numbers and rising clinical demand fueled by an aging population."

(Source: *Caixin Global*, "China Overhauls Blood Donation Law to Avert Supply Crisis," 9/15/26)

Canada's regulatory authority (Health Canada) has suspended the license of the Grifols plasma collection facility on Taylor Avenue in Winnipeg, according to a report from *Reuters*. The license suspension comes as, "the regulator expressed concerns about its quality management system following a donor's death last year, Canada's *Globe and Mail* reported." *Reuters* noted that Grifols responded to the move by stating, "[a]t no point has the safety of donors, patients or the quality and safety of plasma collected at the Taylor Avenue cent[er], or any of our other Canadian centers been compromised." The company added that, "operations would be unaffected because the company had already voluntarily suspended plasma collection at the facility. [They are] already working with the regulator on a re-opening plan, after Health Canada's inspection of the cent[er]. *CBC News* reported earlier this year that two people had died in October 2025 and January 2026 after donating plasma at Grifols clinics in Winnipeg, including the Taylor Avenue location."

(Source: *Reuters*, "Grifols says Canada plasma license suspension has no impact on ongoing operations," 9/24/26)

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK), has announced, "for the first time, an urgent response plan to address a significant and accelerating decline in organ donation and transplantation across the UK." The organization added in the announcement that, "[d]eceased donation rates have declined sharply in recent months and are currently trending at 9% below this time last year. Meanwhile, the UK transplant waiting list continues to rise, with over 8,700 people currently waiting for a lifesaving transplant. New figures [released], reveal that over 700 potential donations did not go ahead in the period between April 2021 and March 2026, because families did not know for certain what their loved one would have wanted. On average, each deceased donor will donate three organs, resulting in around 2,127 missed opportunities for transplant. Only 1% of people in the UK die in circumstances where donation is possible and the pool of eligible donors has reduced by around 20% since 2019/20. At the same time, family consent rates have dropped from 67% in 2020/21 to 57% last year, resulting in hundreds of missed opportunities for transplants. Families support donation 90% of the time when they know their loved one's decision, but this falls to around 50% when no decision is known."

(Source: NHSBT Announcement, 9/21/26) ♦

COMPANY NEWS

The U.S. Food and Drug Administration has approved the supplemental New Drug Application (sNDA) from **Fenwal Inc.** for CPD, ADSOL Red Cell Preservation Solution, (PL 146) and/or SEPACELL Filter (Anticoagulant Citrate Phosphate Dextrose Solution (CPD)) and ADSOL Red Cell Preservation Solution (PL 2209) CPD and ADSOL and/or SEPACELL in PL 2209 (Anticoagulant Citrate Phosphate Dextrose Solution (CPD)). The agency explained in the supplement approval letter that, "these 'Changes Being Effected' sNDAs provide for an update to the product description for Composelect PQ610US in the approved Directions for Use label. We have completed our review of this application. It is approved, effective on the date of this letter (September 15th), for use as recommended in the agreed-upon labeling."

(Source: FDA Approval Letter, 9/15/26)

Terumo Blood and Cell Technologies (Terumo BCT), in partnership with **Wiley Health Learning**, has developed a CME-accredited e-learning module titled, "From Manual to Automated Platelet Production: Optimizing Supply, Safety, and Efficiency." According to the companies, the module explores, "the transition from traditional manual and apheresis-based collection methods to automated whole blood processing systems. Participants will gain insight into the impact of these technologies on platelet supply, operational efficiency, and product consistency, all while learning how emerging approaches may be applied in their own settings." Learning objectives are:

- "[d]escribe the historical evolution of platelet manufacturing, comparing manual whole blood component separation and apheresis collection in terms of process steps, product consistency, donor burden, and contribution to supply constraints;
- [a]nalyze clinical and operational outcome data from centers implementing newer platelet manufacturing approaches and determine how these changes could be applied in their own practice settings to improve efficiency, safety, and platelet availability; [and]
- [e]xplain the core principles and key features of automated whole blood processing systems (for example, single-spin, integrated component extraction) and compare their potential advantages and limitations relative to traditional manual and apheresis-based methods when making or influencing local transfusion practice decisions."

(Source: Terumo BCT Announcement, 9/24/26)

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

October 4-7. **Association for Advancing Tissue and Biologics (AATB) Congress 2026. San Francisco, Calf.** Registration is open. More information is available here.

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

October 13. **Fall 2026 America's Blood Centers (ABC) Quality Regulatory Forum (Virtual).** A link to registration and additional information are available to ABC members here.

October 14-15. **Biomedical Excellence for Safer Transfusion (BEST) Collaborative Member Meeting. Atlanta, Ga.** More information is available here.

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CALENDAR (continued from page 11)

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

November 3-4. **Plasma Protein Therapeutics Association (PPTA) Plasma Protein Forum Alexandria, Va.** Registration is open. More information is available here.

October 20. **NHTSA Office of EMS Paying for Your Prehospital Blood Program Webinar (Virtual).** Registration is open. More information is available here.

November 5-6. **2026 ABC Women's Executive Leadership Community (WELC) *Rise &* Lead Workshop. San Antonio, Texas.** Registration is open. More information is available here.

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

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 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.

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

Manager, Immunohematology Reference Lab (Gulf Coast Blood). Take your laboratory leadership career to the next level with Gulf Coast Blood, one of the nation's largest community blood centers serving more than 170 hospitals across Texas. In this impactful role, you'll lead the daily operations of the Immunohematology Reference Lab, ensuring the delivery of safe, accurate, and timely laboratory services while overseeing quality, regulatory compliance, staff development, and continuous improvement initiatives. This opportunity is ideal for experienced blood banking and transfusion medicine professionals who are passionate about mentoring teams, solving complex immunohematology challenges, and collaborating with hospitals, physicians, and laboratory leaders to support lifesaving patient care. **Required Qualifications:** Bachelor's degree in Medical Laboratory Science, Clinical Laboratory Science, Biomedical Science, Biology, or

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POSITIONS (continued from page 12)

a related scientific/healthcare field. Six to 10 years of progressive laboratory experience, preferably in blood banking, transfusion services, reference laboratories, or similar regulated environments. Demonstrated leadership or supervisory experience managing laboratory operations and personnel. Strong knowledge of laboratory quality systems, regulatory compliance, and accreditation standards. Current certification as a Specialist in Blood Banking (SBB) or international equivalent. Join a mission driven organization where your expertise directly contributes to saving and sustaining lives! Apply Now: Manager, Immunohematology Reference Lab - Gulf Coast Blood

Donor Services Collections Operations Manager (Ada, OK). Our Blood Institute is looking for a Donor Services Collections Operations Manager. This position will play a vital role in ensuring successful blood collection operations throughout our mobile blood drive program. In this leadership position, you'll guide and support supervisors and donor services staff while helping us achieve our collection, quality, financial, compliance, and customer service goals. This is an exciting opportunity for an experienced leader who enjoys working with people, using data to drive improvement, and creating efficient, high-performing teams-all while contributing to a mission that saves lives. This position requires a minimum of three (3) years of supervisory or management experience; blood banking experience preferred. **Salary Range:** Competitive compensation and comprehensive benefits package, including Health, Dental and Vision insurance, Life Insurance, Long-Term Disability, Flexible Spending Plan, 401(k) retirement plan, Paid Time Off, Holiday Pay, and Tuition Reimbursement along with tenure bonuses ($500 bonus after 6 months, $1,000 bonus after 1 year, and $1,500 bonus after 3 years). **How to apply:** https://ourbloodinstitute.org/about/careers/

Process Optimization Program Manager (Orlando, FL). OneBlood is seeking a Process Optimization Program Manager to lead initiatives that enhance efficiency, improve donor experience, and strengthen blood supply operations. In this highly visible role, you will partner with teams across Collections, Recruitment, Manufacturing, and Quality to identify opportunities, implement solutions, and drive measurable operational improvements. The ideal candidate is a strategic problem solver with expertise in process improvement, data analysis, and change management. You will lead cross-functional projects focused on reducing product waste, minimizing donor deferrals, improving collection accuracy, and aligning blood collections with organizational demand. Qualified candidates should have a bachelor's degree and relevant experience in business operations, industrial engineering, or process improvement, with knowledge of Lean Six Sigma and continuous improvement methodologies preferred. This is a hybrid position offering the opportunity to make a meaningful impact on OneBlood's mission to save lives. Apply Here.

Director of Quality Assurance. National Blood Testing Cooperative (NBTC) is seeking an experienced Director of Quality Assurance to lead the Quality Management System supporting testing services for more than 20 blood centers at **Stone Mountain, Georgia** laboratory. The Director of Quality Assurance is responsible for overseeing all quality management activities to ensure compliance with applicable FDA, CLIA, AABB, 21 CFR, OSHA, and other regulatory and accreditation requirements. This position provides strategic leadership for quality assurance, validation, auditing, document control, supplier qualification, occurrence management, CAPA, continuous process improvement, and inspection readiness. Working closely with onsite laboratory leadership, the Director develops, implements, and maintains quality policies and programs; supports operational excellence; and promotes a culture of quality and regulatory compliance. The position partners with laboratory managers on performance improvement, employee development, and strategic initiatives to ensure the laboratory consistently delivers safe, accurate, reliable, and timely testing services. **Qualifications:** Demonstrated experience in a blood center, blood banking, transfusion medicine, or related healthcare laboratory environment required. Bachelor's degree in science or an allied science discipline. Minimum five (5) years of Quality Assurance management experience. Medical Laboratory Scientist (MLS/ASCP) or Specialist in Blood Banking (SBB/ASCP) certification preferred. CMQ/OE or CQA certification through the American Society for Quality (ASQ) preferred. Strong leadership, communication, organizational, analytical, and problem-solving skills. Demonstrated ability to lead cross-functional quality initiatives and drive sustainable process improvement. This is an outstanding opportunity for a collaborative and strategic quality leader who is passionate about regulatory excellence, continuous improvement, and advancing the safety and reliability of the nation's blood supply. Click here to apply.