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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2025 #9 **March 17, 2025**

INSIDE:

Blood Community Malaria Guidance Comments to FDA

America's Blood Centers (ABC), the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross (ARC) have submitted joint comments to the U.S. Food and Drug Administration in response to the agency's Malaria Draft Guidance.

In the March 13th comments, the blood community requests:

- "an option to continue the present transfusion-transmitted malaria (TTM) risk reduction questioning without testing as reasonable given little to no expected reduction of the already exceedingly low residual risk under the proposed testing schema and already low numbers of ethnically diverse donor deferrals in many blood centers. [Additionally, ABC, AABB, and ARC asked FDA to] perform real world modeling studies to determine the sensitivity of available tests, including studies performed in malaria-endemic locations and including data on semi-immune donor populations, and ensure any testing burden, including costs, is justified by a commensurate increase in safety;
- reinstatement of the definition 'malaria-endemic area' along with a three-month travel deferral with no testing;
- a universal testing option [as difficulties] associated with the complexity of donor history questionnaire (DHQ) algorithms, donor recall, and response interpretation, sample tube management, and test ordering may make universal testing operationally more feasible for some centers should substantial testing volume be mandated [with] collectors implementing universal testing not be[ing] required to ask any malaria risk questions;
- clarify the details on how information on malaria symptoms should be elicited from the donor;
- maintain as-proposed testing of donors reporting a history of malaria at every presentation but continue to allow a three-month deferral without testing after travel to malarial areas for donors never residing in an endemic country (i.e., those not at risk for partial immunity);
- [a] limited period of every presentation testing of prior residents [since it] can identify whether intermittent hepatic reservoir parasitemia occurs in prior residents of endemic countries. This additional testing should be offset by removing the requirement to test travelers never residing in an endemic country, a large donor group from which only one TTM case has ever been reported;

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Blood Community Malaria Guidance Comments to FDA (continued from page 1)

- [s]hould FDA feel one-time testing is sufficient for residents of malaria-endemic countries, the [a]gency should clarify how a second period of residence in a malaria-endemic country triggering subsequent testing should be elicited from the donor. FDA should also address the logical inconsistency of only considering endemic area travel within the past 12 months as a reinfection risk in populations likely to be partially immune;
- that FDA better describe the number of cases required and geographical rules to be employed (how donors' home/work/travel zones impact the size of affected collection zones);
- that, when a donation tests reactive for malaria, and the testing was triggered due to travel or a local outbreak, that FDA shorten the lookback period to no longer than the time between the date on which the travel or local outbreak commenced, and the donation occurred; [and]
- [an] extended implementation period [as after the] final guidance [is published], many centers will require a long horizon (≥12 months) for implementation. FDA should commit to ≥12 months, currently listed as only one potential choice in the Guidance."

America's Blood Centers (ABC) previously submitted malaria testing recommendations in comments to the FDA Blood Products Advisory Committee (BPAC) in May 2024 that, "strongly recommended" that the agency delay publishing draft guidance until modeling studies are finished and additional malaria testing assays are approved and available. We will continue to provide updates as they become available. Please contact ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM with questions.

(Source: Blood Community Joint Comments, 3/13/25)

House Bill Introduced to Prevent "Overregulation" of Laboratory Developed Tests

Reps. Brad Finstad (R-Minn.) and Dan Crenshaw (R-Texas) have introduced H.R. 1463, the Freedom for Laboratory Innovation and Testing Act. The legislation would, "prevent any federal funding from being used to implement the Biden Administration's burdensome U.S. Food and Drug Administration's (FDA) rule that inhibits the innovation of and delays access to Laboratory Developed Tests (LDTs)," according to a news release.

The congressmen explained that the FDA LDT rule would:

- "[i]mpose regulatory burdens that hinder the development and deployment of new and improved lab-developed tests;
- [i]ncrease regulatory requirements that will lead to delays in patients' access to critical diagnostic tests;
- [p]otentially hinder collaborative efforts in clinical care that rely on the flexibility provided by LDTs; and,
- [n]egatively impact small and medium-sized laboratories, which will face economic challenges with complying with the rule as written."

Exempting blood center LDTs from diagnostic regulation reforms is a priority of America's Blood Centers' (ABC) 2025 Advocacy Agenda. ABC has sent a letter of support for the legislation explaining that blood centers have developed and use LDTs and that, "[t]he quality and validity of these tests are already ensured by a comprehensive regulatory framework including compliance with extensive FDA regulatory requirements, state specific requirements, and accreditation standards. Yet, despite these safeguards, in May 2024, the FDA issued a final rule subjecting *in vitro* diagnostic products (IVDs) to additional regulatory burden. The current regulatory framework already includes a multi-layered approach providing rigorous oversight

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House Bill Introduced to Prevent "Overregulation" of LDTs (continued from page 2)

and regular inspections. The additional FDA regulations are redundant burdens on blood centers without providing any increase in patient safety. Indeed, these regulatory burdens will likely hinder patient care by introducing unnecessary delays and reduced availability of needed tests." ABC previously submitted comments in April 2024 responding to a request for information (RFI) for reforms to diagnostics regulation from Sen. Bill Cassidy, MD (R-La.), ranking member of the Senate Committee on Health, Education, Labor, and Pensions (HELP).

The FDA's five stage phaseout policy will take place over a four-year period and is set begin on May 6th. We encourage members to also send a letter to your Representative asking them to support H.R. 1463. ABC has developed a one-pager to assist you in your advocacy efforts. Rep. Finstad previously introduced a resolution to repeal the FDA's LDTs rule. Please contact ABC Vice President of Government Affairs Diane Calmus, JD with any questions.

(Sources: H.R. 1463, 2/21/25; Rep. Brad Finstad News Release, 2/21/25; ABC Support Letter, 3/4/25) ♦

Researchers 'Confirm' the Safety of Blood from COVID-19 Vaccinated Individuals and Those with Prior COVID-19 Infection

A paper published in *Transfusion*, "assessed whether the transfusion of plasma or plasma-rich platelet products from blood donors with prior SARS-CoV-2 infection and/or vaccination was associated with increased risk of thrombotic events, respiratory requirements, or hospital mortality in transfusion recipients without COVID-19." The researchers from Kaiser Permanente Northern California (KPNC), Vitalant Research Institute, the University of California San Francisco, the American Red Cross, Vitalant, a member of America's Blood Centers, and the University of British Columbia performed a, "retrospective cohort study using electronic health record (EHR) data from KPNC[and] included all hospitalized adult, non-obstetric KPNC patients who were transfused plasma or platelet products in 21 hospitals from June 1st, 2020 to March 31st, 2022."

The authors noted that, "[i]nformation on blood donors, donations, and processing was obtained from databases of Vitalant and the American Red Cross, which supply blood components to all 21 KPNC hospital facilities. Both blood collection organizations participated in universal SARS-CoV-2 screening of all blood donations from June 2020 to June 2021 and subsequently as part of the CDC-funded Nationwide Blood Donor Serosurveillance (NBDS) study." The paper reported that, "no associations between the number of platelet transfusions from SARSCoV-2 vaccinated blood donors and outcomes of thrombosis (OR 1.00 [95 percent CI 0.96, 1.04]), increased respiratory requirement (OR 0.99 [95 percent CI 0.96, 1.02]), or hospital mortality (OR 1.01 [95 percent CI 0.99–1.04]) in recipients. In parallel, there were no associations between

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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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Researchers 'Confirm' Safety of Blood from COVID-19 Vaccinated Individuals (continued from page 3)

the number of plasma transfusions from SARS-CoV-2 vaccinated blood donors and thromboses (OR 0.96 [95 percent CI 0.90–1.02]), respiratory requirements (OR 1.00 [95 percent CI 0.98, 1.04]), or hospital mortality (OR 1.02 [95 percent CI 0.99–1.05]). There were also no significant associations between the receipt of plasma and platelet units from SARS-CoV-2 uninfected vaccinated donors and donors with hybrid immunity."

Additionally, the authors discovered, "no evidence of adverse outcomes in recipients of plasma or platelet units within 60 days of initial nucleocapsid antibody seroconversion, indicating recent infection. [They] found no association of adverse outcomes with the receipt of plasma or platelet units with the highest titers of SARS-CoV-2 spike or nucleocapsid antibodies." The researchers concluded that, "this study provides reassuring insights into the safety of blood transfusions from donors with varying SARS-CoV-2 exposure histories. These results provide some reassurance in the context of the national prevalence of blood donor SARS-CoV-2 prior infection and vaccination. Nationally, the combined infection- and vaccination-induced SARS-CoV-2 donor seroprevalence was estimated to be 96 percent by September 2022. The findings support the continued use of blood products from vaccinated and previously infected donors, addressing patient concerns about potential risks."

Citation: Roubinian, N.H., Greene, J., Spencer, B.R., *et al*. "Blood donor SARS-CoV-2 infection or vaccination and adverse outcomes in plasma and platelet transfusion recipients." *Transfusion*. 2025.

BRIEFLY NOTED

A report by *Bloomberg Law* noted that the U.S. District Court for the Northern District of Ohio ruled that the, "American Red Cross (ARC), is entitled to judgment before trial in a blood donor's suit alleging it provided her with negligent aftercare, because she didn't present expert medical testimony." According to the article, the plaintiff, Deanna Walton, donated blood at an ARC facility in April 2021. She alleges that an ARC employee "directed her to a refreshment table but left her sitting alone in the donation chair. [She] slid off the chair, passed out, and hit her head on the floor." Ms. Walton sued ARC, "for providing negligent aftercare, and ARC moved for summary judgment, saying she failed to raise a genuine issue of fact due to her lack of expert testimony on the standard of care." By filing motion for summary judgement, the ARC argued that, "there can be no real dispute about material facts [and that they are] entitled to win the case as a matter of law." Ms. Walton countered their argument by explaining that, "[e]xpert testimony wasn't necessary because the injury involved ordinary, not professional, negligence, [acknowledging that] courts have consistently held that blood collection procedures are subject to professional standards, but said her case was different because it involved aftercare, not processing a donation." However, the judge stated that ARC, "has only ever been held to a professional standard of care regardless of the injury or part of the blood donation process during which the injury occurred." Additionally, Ms. Walton attempted to explain that, "everyone knows that there's a standard waiting period following a blood donation to address 'ordinary symptoms.' [However,] she didn't say what the symptoms were, identify the duration of the waiting period, or describe what a collection agency is expected to do during that time period," the judge stated. The court determined, "[t]hat information wouldn't be within an average juror's common knowledge."

(Source: *Bloomberg Law*, "Red Cross Prevails Over Blood Donor's Negligent Aftercare Claim," 3/6/25)

REGULATORY NEWS

The U.S. Department of Health and Human Services' (HHS) Immediate Office of the Secretary has rescinded, "the policy on Public Participation in Rule Making (Richardson Waiver) and re-aligning the Department's rule-making procedures with the Administrative Procedure Act (APA)." The policy statement published in the *Federal Register* on March 3rd from HHS Secretary Robert F Kennedy Jr. explained that, "[e]ffective immediately, the Richardson Waiver is rescinded and is no longer the policy of the Department. In accordance with the APA, 'matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts,' are exempt from the notice and comment procedures of 5 U.S.C. 553, except as otherwise required by law. Agencies and offices of the Department have discretion to apply notice and comment procedures to these matters but are not required to do so, except as otherwise required by law. Additionally, the good cause exception should be used in appropriate circumstances in accordance with the requirements of the APA. The Department will continue to follow notice and comment rulemaking procedures in all instances in which it is required to do so by the statutory text of the APA."

(Source: *Federal Register* HHS Policy Statement, 3/3/25)

WORD IN WASHINGTON

The Senate Health, Education, Labor and Pensions (HELP) Committee voted to advance the nominations of Martin A. Makary, MD, MPH as commissioner of the U.S. Food and Drug Administration (FDA) and Jay Bhattacharya, MD, PhD as director of the National Institutes of Health (NIH) to the full Senate for votes. Mehmet Oz, MD, MBA, nominee to serve as administrator of the Centers for Medicare & Medicaid Services (CMS), also took part in a confirmation hearing with the Senate Finance Committee on March 14th.

The White House has withdrawn the nomination of Dave Weldon, MD for director of the U.S. Centers for Disease Control and Prevention (CDC). Dr. Weldon, a former congressman, had been scheduled to appear before the Senate HELP last week.

(Source: *Reuters*, "White House withdraws vaccine critic Weldon for CDC director, 3/13/25)

Both the U.S. Senate and House of Representatives have passed a short-term spending bill to fund the federal government and avoid a shutdown through the end of September. President Trump signed the bill on March 15th.

(Source: *NPR*, "Trump signs spending bill to avoid a government shutdown," 3/15/25)

Francis Collins MD, PhD retired from the National Institutes of Health (NIH) on February 28th. He served as the agency's director for more than 12 years before stepping down from the role in 2021. In a statement published by *Science*, Dr. Collins said, "NIH is the largest supporter of biomedical research in the world. It is the main piston of a biomedical discovery engine that is the envy of the globe. Yet it is not a household name. It should be. NIH supports everything from basic science to clinical trials, providing the foundation of many breakthroughs. [I have] loved being employed by this extraordinary, life-giving institution for 32 Years [and as] I depart NIH, I want to express my gratitude and love for the men and women with whom I have worked side by-side for so many years. They are individuals of extraordinary intellect and integrity, selfless and hard-working, generous, and compassionate. They personify excellence in every way, and they deserve the utmost respect and support of all Americans."

(Source: *Science* Statement, 3/1/25)

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INSIDE ABC

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

Participate in the *ADRP Trends in Donor Relations Study*

The *ADRP Trends in Donor Relations Study* has launched. This survey is a strategic tool for blood centers to evaluate and benchmark the performance of collection and recruitment operations and marketing strategies with your domestic and international peers. It streamlines and combines the previous ADRP Recruitment and Collections Survey and the ADRP Marketing Survey. ADRP is partnering with a third-party company, Dynamic Benchmarking, to improve the data collection and reporting experience. The confidentiality of your data and the information shared in this report is a top priority of ADRP and will only be disseminated in the aggregate and in accordance with anti-trust regulations. A key feature of the reporting platform is the ability to view how your operations compare to others using several dynamic filters, including blood center location, collection levels, and employee count. Only blood centers that participate in the survey will have access to this information. Participation in the study is open to all blood centers. Survey responses must be completed by March 24th. Please only submit one response per blood center. Contact us with questions.

March ADRP Webinar Announced — "Positive Impacts of a Global Pandemic: What Changed?"

Registration is open for the March 26th webinar at 1 p.m. EDT titled "Positive Impacts of a Global Pandemic: What Changed?" Hear Vitalant's Stephanie Radenz and LifeServe Blood Center's Danielle West discuss the significant changes and innovation implemented at their centers in the wake of the global pandemic, including adjustments to supply chains, the importance of a diversified vendor plan, pilot concepts with pseudo fixed sites for donor collections, and the benefits of virtual blood drives.

Register for the March 28th SMT Journal Club Webinar

Registration is open for the next America's Blood Centers (ABC) Scientific, Medical, and Technical (SMT) Journal Club Webinar taking place on March 28th at 1 p.m. EDT. The webinar is free to all ABC members. An email announcement with a registration link and the articles to be reviewed can be found here. A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars.

Register for the 2025 ADRP Annual Conference

Register now for the 2025 ADRP Annual Conference in Oklahoma City, Oklahoma, from May 6th to 8th at the Omni Oklahoma City Hotel. Remember to book your hotel room by April 11th for the discounted rate. This conference offers a chance to learn about industry trends, share ideas, and connect with other donor recruitment, donor services, collections, marketing, and communications professionals. Join more than 400 of your peers by participating in pre-conference workshops, attending compelling educational sessions, engaging in roundtable discussions, and exploring an expansive exhibit hall filled with innovative solutions. Seize this extraordinary opportunity to learn, share, and grow within the blood community.

INFECTIOUS DISEASE UPDATES

EBOLA

The World Health Organization (WHO) published March 8th communication providing an update of the Sudan virus disease (SVD) outbreak in Uganda. SVD is an Ebola disease. The agency has identified, "12 confirmed and two probable cases, among these four deaths (two confirmed, two probable) have been reported with a case fatality ratio (CFR) of 29 percent. The latest confirmed cases are reported to be epidemiologically linked to the two probable cases. The age range of confirmed cases is 1.5 years to 55 years, with a mean age of 27 years and males accounted for 55 percent of the total cases. The cases were reported from six districts in the country which include Jinja, Kampala, Kyegegwe, Mbale, Ntoroko and Wakiso." Last month, the U.S. Centers for Disease Control and Prevention (CDC) published a Health Alert Network (HAN) Health Advisory regarding the outbreak of Ebola disease in Uganda reporting that, "[c]urrently no suspected, probable, or confirmed Ebola cases related to this outbreak have been reported in the U.S. [However,] as a precaution and because there are other viral hemorrhagic fever (VHF) outbreaks in East Africa, CDC is sharing best practices for public health departments, public health and clinical laboratories, and healthcare workers in the United States to raise awareness about this outbreak. [The agency] recommends that travelers monitor themselves for symptoms of Sudan virus disease (SVD) while in the outbreak area and for 21 days after leaving. Travelers should also self-isolate and contact local health authorities or a clinician if they develop symptoms (early "dry" symptoms may include fever, aches, pains, and fatigue and later "wet" symptoms may include diarrhea, vomiting, and unexplained bleeding)."

The CDC has not classified the affected region as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that, "in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2)."

(Source: WHO Communication, 3/8/25)

MIDDLE EAST RESPIRATORY SYNDROME (MERS)

The WHO has shared findings from its biannual update of Middle East respiratory syndrome coronavirus (MERS-CoV) in Saudia Arabia. From September 2024 to February 2025, the agency reported that there have been, "four laboratory-confirmed cases of MERS-CoV infection, including two deaths, were reported to WHO by the Ministry of Health" in Saudi Arabia. The agency explained that, "[c]lose contacts of the four cases were followed up by the Ministry of Health. No additional secondary cases have been detected. The notification of these four cases does not alter the overall risk assessment, which remains moderate at both the global and regional levels. The reporting of these cases shows that the virus continues to pose a threat in countries where it is circulating in dromedary camels, particularly those in the Middle East [and] that cases will continue to be exported to other countries by individuals who were exposed to the virus through contact with dromedaries or their products (consumption of raw camel milk), or in a healthcare setting." There are no reported cases of MERS-CoV transmission via blood transfusion nor any other coronavirus.

(Source: WHO Update, 3/13/25)

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INFECTIOUS DISEASE UPDATES (continued from page 7)

Measles

The U.S. Centers for Disease Control and Prevention (CDC) has published an update regarding measles outbreaks. As of the March 13th, there have been three measles outbreaks (defined as three or more related cases) in the U.S. this year resulting in 301 confirmed cases, 50 hospitalizations (17 percent) and one confirmed death, the first in the U.S. since 2015, and another under investigation. According to the agency the cases have been reported by 15 jurisdictions: Alaska, California, Florida, Georgia, Kentucky, Maryland, New Jersey, New Mexico, New York City, New York State, Pennsylvania, Rhode Island, Texas, Vermont, and Washington with 93 percent of cases (280 of 301) being outbreak-associated. In 2024, the U.S. reported 285 total cases. Transfusion-transmission of measles has never been demonstrated, and any risk to the blood supply is believed to be theoretical.

Additionally, a WHO and United Nations Children's Fund (UNICEF) analysis released on March 13th indicated that, "127,350 measles cases were reported in the European Region for 2024, double the number of cases reported for 2023 and the highest number since 1997. Children under five years of age accounted for more than 40 percent of reported cases in the Region — comprising 53 countries in Europe and central Asia. More than half of the reported cases required hospitalization. A total of 38 deaths have been reported, based on preliminary data received as of March 6th. Measles cases in the Region have generally been declining since 1997, when some 216,000 were reported, reaching a low of 4,440 cases in 2016."

(Sources: CDC Announcement, 3/14/25; WHO & UNICEF Analysis, 3/13/25)

MEMBER NEWS

San Diego County Supervisor Terra Lawson-Remer's office recently honored **San Diego Blood Bank** with a proclamation recognizing, "their extraordinary collaboration with SeaWorld San Diego." A blood bank news release explained that in September 2024, "San Diego Blood Bank donors were gifted with a ticket to SeaWorld San Diego's Howl-O-Scream, San Diego's largest nighttime Halloween event. SeaWorld's generous in-kind donation of 12,000 Howl-O-Scream tickets was valued at over $1 million, making it the largest in-kind donation San Diego Blood Bank has ever received. Through this collaboration over 11,000 blood donors, including more than 2,000 first time donors, donated over 17,000 pints of blood products, equating to more than 34,000 lives saved."

(Source: San Diego Blood Bank News Release, 3/3/25)

Inova Blood Donor Services recently celebrated Richard Martin making his 700th platelet donation reported *WTOP News*. The milestone makes Mr. Martin Inova's highest active platelet donor. Mr. Martin told the news outlet that he began donating, "whole blood with the Red Cross and then switched to Inova when he was asked to consider a different type of donation in 1982. His father donated 17 gallons of whole blood, and Martin tried to reach that same achievement, but only made it to seven when he was asked about donating platelets. [Mr. Martin] considered it the major leagues of blood donations and was eager to start. At that time, the process involved donating from both arms. He's continued to donate platelets ever since, visiting Inova's Blood Donor Service Center in Sterling, Virginia, every two weeks." Nicholas Lilly, senior director of Inova Blood Donor Services told *WTOP News*, "[i]t's lifesaving. When we think about the need for blood products every day, there's always hundreds of patients in our hospitals, truthfully, thousands in

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MEMBER NEWS (continued from page 8)

our hospitals that are in need. And so, by having somebody, or donors like Rick who donate frequently, it really helps us to maintain the need."

(Source: *WTOP News*, "This Virginia man has donated platelets 700 times and he isn't planning to stop," 3/5/25)

RESEARCH IN BRIEF

Adverse Reactions in Solvent Detergent vs. Standard Plasma in Pediatric Apheresis. A study in the *Journal of Clinical Apheresis* was conducted "to better understand the possible risks/benefits associated with using solvent/detergent treated plasma (SD) in therapeutic plasma exchange (TPE) in pediatric patients." The authors noted that, "[p]atient records of pediatric and adolescent/young adult patients who received at least one TPE procedure at [this] institution over a three-year period (January 1st, 2021 to December 31st, 2023) were retrospectively reviewed." They explained that, "[t]he decision to use SD plasma versus untreated plasma was largely based on inventory management, with both inventory availability and product expiry taken into consideration [though] there were no specific or strict criteria for when to use SD plasma or not." For this study, "SD plasma was used in 51 TPE procedures performed on 17 patients [whose] diagnoses varied. Out of these 51 procedures, five procedures utilized 100 percent SD plasma as replacement fluid, and 46 procedures used a combination of SD plasma and 5 percent albumin (average 44 percent SD plasma, median 49.4 percent)." The researchers noted that, "[u]ntreated plasma was used in 254 procedures in 68 patients. Out of these 254 procedures, 72 procedures utilized 100 percent plasma as replacement fluid, and 182 procedures used a combination of untreated plasma and 5 percent albumin (average 32.9 percent FFP, median 28.6 percent)." They explained that, "[n]o patient received both SD and untreated plasma during the same TPE procedure With SD plasma use, 1 of 51 procedures (2 percent incidence) had a non-severe allergic transfusion reaction reported. With untreated plasma use, 9 of 254 procedures (3.5 percent incidence) had a reported transfusion reaction, all of which were non-severe allergic reactions. Reaction symptoms consisted of urticaria and hives. The transfusion reaction rates between the two groups were not statistically different (p=0.7036, two-tailed Fisher's exact test). Circuit clotting issues were reported in one patient during two discrete TPE procedures utilizing untreated plasma. No other transfusion reactions or adverse events were reported with SD plasma or untreated plasma use. Of the six patients who received untreated plasma and SD plasma during different TPE procedures, three had transfusion reactions, all occurring with untreated plasma use but not with SD plasma." The study concluded that, "[o]verall, SD plasma used for TPE at [this] institution was well tolerated in [these] pediatric to adolescent patients. Transfusion reaction rates with SD plasma were similar to those seen with untreated plasma use in TPE at [this] institution over a 3-year period."

Citation: Phou, S., Berryhill, C., Nizzi, F., and Pasko, B. "Comparison of Adverse Reactions With Solvent/Detergent Treated Plasma Versus Untreated Plasma Use in Therapeutic Plasma Exchange in Pediatric Patients." *Journal of Clinical Apheresis*. 2025.

Contributed by Richard Gammon, MD

GLOBAL NEWS

The United Kingdom (UK) Department of Health and Social Care, NHS England, leader of the country's National Health Service, and NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the UK, have announced that the "first NHS patients in a generation" have received source plasma from UK donors. This milestone comes in the wake of, "a longstanding ban on UK [source] plasma [being] lifted in 2021, [since that time] the UK has been building its own supply of plasma medicines amid a global shortage. This will reduce reliance on imports, saving the NHS between £5 million and £10 million per year," according to a joint announcement. The organizations further explained the UK plans to continue expanding its, "capacity in the global plasma medicines industry, which was valued at over $30 billion in 2023 and is projected to reach $45 billion by 2027. [NHSBT] has collected 250,000 lit[ers] of plasma from donors in England since 2021. From this, two vital medicines are being produced: immunoglobulins, which treat autoimmune conditions, and albumin, which is essential for surgery and treating liver conditions. The NHS plans to reach 25 percent self-sufficiency in immunoglobulin by the end of 2025, rising to 30 to 35 percent in 2031, and 80 percent self-sufficiency in albumin by next year. [Previously,] the NHS relied solely on imported plasma medicines due to a longstanding ban on using UK plasma. The ban was introduced in 1998 as a precautionary measure against Variant Creutzfeldt–Jakob Disease (vCJD), linked to mad cow disease. In 2021 following rigorous scientific reviews, the Medicines and Healthcare products Regulatory Agency (MHRA) confirmed that plasma from UK donors is safe, supported by robust safety measures. Decades of rigorous research showed no confirmed cases of vCJD transmission through plasma-derived medicines."

(Source: UK Department of Health and Social Care, NHS England, and NHSBT Announcement, 3/6/25)

The South Korean Health Ministry has revised the donor deferral policy for individuals who previously lived in Europe. The *Korea JoongAng Daily* reported that the old policy, "prohibited blood donations [from those] who had stayed five years or more in Europe, since 1980, [due] to concerns regarding Creutzfeldt-Jakob disease (CJD) in the continent. It also stopped those who had spent over a month in Britain between 1980 and 1996 and those who had been in Britain for three months or more from 1997 until now from participating in blood donation. The new deferral policy applies, "restrictions only to [individuals] who had stayed in France and Ireland for five years between 1980 and 2001, as well as those [who] stayed in Britain for over three months between 1980 and 1996." The Health Ministry believes the policy shift will result in an estimated 16,000 previously ineligible individuals being able to become blood donors.

(Source: *Korea JoongAng Daily*, "Health Ministry revises blood donation restrictions for Koreans returning from Europe," 3/4/25)

The Flemish Red Cross is set to soon begin human trials of a nasal spray developed from COVID-19 convalescent plasma (CCP) to reduce COVID-19 transmission. According to *Belga News Agency*, "[t]he spray is based on [CCP] from people who have recovered, which contains virus-specific antibodies. [While] vaccines and antiviral drugs remain the key to controlling viral outbreaks, professor Hendrik Feys, [d]irector of Scientific Research at Red Cross Flanders, says a nasal spray derived from CCP could enable a faster response to future pandemics. It would offer protection to at-risk populations and frontline health workers, particularly in developing countries. Previous trials have confirmed the spray's effectiveness against coronaviruses. The next phase will test its effect on other viruses, including influenza and respiratory syncytial virus (RSV), a common respiratory virus that infects the nose, throat, and lungs. If results continue to be positive, human trials could begin by the end of the year, with a full evaluation expected within three years."

(Source: *Belga News Agency*, "Flanders Red Cross advances research on nasal spray to prevent virus transmission," 3/14/25)

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GLOBAL NEWS (continued from page 10)

James Harrison, an Australian blood and plasma donor whose donations are reported to have save 2.4 million Australian babies, has passed away. Known as the 'Man with the Golden Arm', he donated plasma more than 1,100 times during his life according to Australia's national blood provider (Australian Red Cross Lifeblood). "Mr. Harrison's plasma contained the rare and precious antibody, Anti-D, which is used to make the life-saving medication given to mothers whose blood is at risk of attacking their unborn babies. After receiving many life-saving blood transfusions following lung surgery as a 14-year-old, James awoke in the ICU determined to give back. Encouraged by his blood donor father, James started donating in 1954 at the age of 18 and never missed a single appointment, donating fortnightly until his retirement in 2018, aged 81." Lifeblood Chief Executive Officer Stephen Cornelissen AM stated that, "James was a remarkable, stoically kind, and generous person who was committed to a lifetime of giving and he captured the hearts of many people around the world. It was James' belief that his donations were no more important than any other donors' and that everyone can be special in the same way that he was. James extended his arm to help others and babies he would never know a remarkable 1173 times and expected nothing in return. He continued to donate even in his darkest days, after the passing of his wife Barbara, who was also a blood donor, and helped inspire his career as a lifesaver. He leaves behind an incredible legacy, and it was his hope that one day, someone in Australia would beat his donation record. On behalf of Lifeblood, and the entire Australian community, we thank James for the incredible life-saving contribution he made and the millions of lives he saved."

(Source: Lifeblood Announcement, 3/1/25)

COMPANY NEWS

Cerus Corporation has received CE mark approval from the European Union (EU) for the "next-generation LED-based illumination device (INT200) for the Intercept Blood System for platelets and plasma." According to a March 5th news release, the CE mark approval permits Cerus to, "market the INT200 throughout the EU and in other regions that recognize the CE mark. Some countries may require additional in-country regulatory approval prior to commercialization." The company also noted that, "[the] approval completes the authorization of the Intercept Blood System for both platelets and plasma within the EU medical device regulation (MDR) framework [and] is the first regulatory approval received for Cerus' next-generation illuminator." Cerus anticipates additional regulatory submissions to follow.

(Source: Cerus Corporation News Release, 3/5/25)

The Advanced Medical Technology Association (AdvaMed) has published its advocacy priorities. Included among the organization's legislative and regulatory priorities are:

- "support the modernization of CMS to strengthen the U.S. position as the global leader in medical technology (Medtech) Innovation;
- ensure tax law keeps pace with Medtech innovation;
- harness the power of artificial intelligence (AI) to improve outcomes and increase patient access to innovative Medtech;
- strengthen the U.S. Medtech industry's global leadership position;
- secure American Medtech supply chain resilience;
- strengthen the regulatory process to ensure the latest medical technologies reach every patient;

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COMPANY NEWS (continued from page 11)

- ensure the U.S. Food and Drug Administration (FDA) keeps pace with the speed of MedTech innovation; and
- ensure patient access to accurate diagnostic tests."

(Source: AdvaMed Announcement, 3/3/25)

CALENDAR

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

2025

Mar. 26. **ADRP Webinar: "Positive Impacts of a Global Pandemic: What Changed?"** Registration is open. More information is available here.

Mar. 28. **ABC Scientific, Medical, and Technical (SMT) Journal Club Spring Webinar.** More information and a link to registration are available to ABC members here.

May 6-8. **2025 ADRP Annual Conference. Oklahoma City, Okla.** Registration is open. More information available here.

May 14-15. **International Plasma and Fractionation Association (IPFA)/Paul-Ehrlich Institut[e] (PEI) 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Heidelberg, Germany.** Registration is open. More information available here.

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

June 1-4. **International Society of Blood Transfusion (ISBT) 35th Regional Congress. Milan, Italy.** Registration is open. More information available here.

June 10-11. **ABC Advocacy Workshop. Washington, D.C.** More information is coming soon.

June 25-26. **HHS OIDP TBDAIC Community Engagement Meeting (Hybrid). Portland, Maine.** More information is coming soon.

June 30-July 1. **HHS Administration for Strategic Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2025 (Hybrid). Washington, D.C.** More information available here.

Sept. 10. **FDA CBER Office of Blood Research and Review (OBRR) Public Webinar: FDA Review of Biologics License Applications for Blood and Source Plasma (Virtual).** More information is coming soon.

Oct. 12-15. **American Association of Tissue Banks (AATB) Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** More information is coming soon.

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

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

Vice President, CFO. LifeStream Blood Bank, headquartered in San Bernardino, California, an independent blood center serving 80 hospitals in six counties in Southern California is seeking a VP, CFO. Reporting to the President/CEO, the preferred candidate is one who has demonstrated successful leadership in other blood centers or healthcare related organizations. The successful candidate must possess strong strategic planning skills to navigate a competitive environment and strong interpersonal and communication skills to develop strong business partner relationships as well as within the organization. The CFO is directly responsible for all financial systems and functions of the organization and ensures legal and regulatory compliance for all accounting and financial reporting functions. The CFO participates as a member of the organization's Leadership and Executive Teams. Minimum seven years' progressive management experience is required. Bachelor's degree in accounting or other business-related field required with CPA and/or MBA or other relevant specialty preferred. Experience in not-for-profit healthcare setting; strong experience managing contracts, and good working knowledge and relationship with industry trade associations is preferred. Competitive salary, relocation package and excellent benefits. Please submit cover letter, resume and salary requirements to Judy Taylor, VP Human Resources at taylorju@LStream.org. The deadline for applications is **March 28, 2025**.

Vice President of Technical Operations (Oklahoma City, OK). Our Blood Institute (OBI) is looking for a **Vice President of Technical Operations** who will provide strategic planning, operational management, budgeting, and leadership to the OBI and provide technical and leadership support to the Testing Lab, Quality Control Lab, Manufacturing Operations, Logistics/Inventory Management, and Technical Operations Systems departments. Overseeing the day-to-day operations, implementing business plans, managing the department's P&L, and fostering high performance, customer-oriented culture. Successful applicants must have a Bachelor of Science degree in Medical Technology and a Master's degree is strongly preferred. Position requires ASCP certification as a Medical Technologist. Position requires a minimum of ten years progressive management in a related medical industry. **Salary Range:** Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. **How to apply:** https://obi.org/about/careers/

Medical Technologist. Join Suncoast Blood Centers – Where Every Drop Saves Lives! Sarasota, FL. We're looking for a passionate and skilled Medical Technician (Blood Banking) to be part of our mission-driven team! You'll play a vital role in blood collection, processing, compatibility testing, and transfusion services—all while ensuring top safety and compliance standards. For 75+ years, Suncoast Blood Centers has been a lifeline for our community, delivering lifesaving blood products with dedication and care. We offer amazing benefits, generous PTO, and a sign-on bonus! Make a difference—apply today! To apply: Careers - SunCoast Blood Centers

Vice President of Operations. LifeSouth Community Blood Centers is currently looking for a highly driven individual with outstanding leadership, communication, and interpersonal skills to join our Executive Team as Vice President of Operations. This is a senior leadership role who reports directly to the Chief Operating Officer and is responsible for overseeing and driving the operational effectiveness of LifeSouth Community Blood Centers across a multi-state footprint set by executive leadership. In this position you will develop, implement, and lead strategic initiatives to enhance blood donations, blood processing, and blood distribution while ensuring operational efficiency and compliance with regulatory standards. This position is also responsible for maintaining optimal staffing ratios, overseeing training programs, and ensuring continuous operational growth and innovation. Join our team and help us continue our dedication to making sure blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Chief Medical Officer (CMO). Carter BloodCare seeks a dynamic **Chief Medical Officer (CMO)** to lead medical and technical operations and ensure excellence in transfusion medicine, cellular therapy, and donor care. As a key executive team member, the CMO will drive innovation, compliance, and strategic growth. **Why Carter BloodCare?** Mission-Driven Work: Your leadership directly impacts patients in need. Executive Leadership: Collaborate with the CEO and executive team to shape policies and strategy. Industry Influence: Represent Carter BloodCare as a thought leader in transfusion medicine. Growth & Innovation: Lead research initiatives and partnerships with medical institutions. **Key Responsibilities:** Oversee medical services, ensuring safety, compliance, and quality. Act as CLIA Lab Director for high and moderate-complexity testing labs. Serve as one

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POSITIONS (continued from page 13)

of the medical and scientific faces of Carter BloodCare. Lead and mentor Medical Directors, fostering a culture of excellence. Guide organizational strategy and budgeting. Advance clinical research, academic collaborations, and medical education initiatives. **What We're Looking For:** M.D. or D.O. (or equivalent) with board certification in transfusion medicine or a related field. Eligibility for a Texas medical license and willingness to obtain additional state licenses as needed. 7+ years of experience in blood banking/transfusion medicine or related field. 3+ years of leadership experience. **Apply today:** www.carterbloodcare.org/careers

Medical Laboratory Scientist - Blood Bank (Overnight). LifeSouth Community Blood Centers is looking for an experienced Medical Laboratory Scientist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Atlanta, GA. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The Medical Laboratory Scientist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. Join our team and help us continue our dedication to making sure blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Associate Medical Director/Medical Director (Versiti Blood Center of Ohio). Serve as the physician face of Versiti and Versiti Ohio, translating complex medical issues to educate other physicians, support staff and the public. Opportunities in educational initiatives and clinical/applied research are available within Versiti and with our affiliated health systems. As part of the Versiti physician team you will have the opportunity to participate in clinical research projects with investigators at our world-renowned diagnostic laboratory and blood research institute. Joining our Medical Science Institute transfusion medicine physician team will provide you with a uniquely diverse and collaborative experience. Requirements: MD or DO Degree. Board certified/eligible in Blood Banking/Transfusion Medicine. At least three years of experience in blood center/transfusion medicine practice preferred. Licensed or eligible for an Ohio and Indiana; other state licenses may be required. Driver's License in good standing. Please click here to read the full job description and apply.

Medical Director/Associate Medical Director. Carter BloodCare seeks a passionate and dedicated **Medical Director/Associate Medical Director** to join our mission driven team in North Texas. This role offers the opportunity to collaborate with a dynamic group of medical professionals and lead innovative initiatives that save lives every day. As Medical Director/Associate Medical Director, you'll play a pivotal role in the medical and technical oversight of blood centers, transfusion services, and advanced biotherapies. Working closely with the Chief Medical Officer and fellow directors, you will ensure our operations remain at the forefront of transfusion medicine. From providing consultative expertise to fostering relationships with healthcare providers, your work will directly influence patient care across the region. Carter BloodCare seeks candidates with an MD, DO, or equivalent degree, board certification/eligibility in Blood Banking/Transfusion Medicine, and qualified for an unrestricted medical license in Texas. The successful candidate will bring expertise, compassion, and a collaborative spirit to this vital role with strong knowledge and experience in blood banking and/or advanced biotherapies. This is a chance to join an organization dedicated to excellence and innovation in transfusion medicine. Apply at //www.carterbloodcare.org/careers. Carter BloodCare is an EEO/Affirmative Action employer.

Assistant/Associate/Full Professor, Clinical Track (Hoxworth Blood Center). Hoxworth Blood Center (HBC) was founded in 1938 and serves more than 30 hospitals in 18 counties in Ohio, Kentucky, and Indiana. Annually, HBC collects more than 100,000 units of blood from local donors to help save the lives of patients in area hospitals. HBC is located within the University of Cincinnati (UC), College of Medicine, and is seeking an academic physician to advance clinical services and research in Blood Banking and Transfusion Medicine. The rank of the clinical track appointment is open and will be commensurate with the experience and professional accomplishments of the selected applicant. Essential Functions: Provide clinical blood banking/transfusion medicine coverage in an active academic transfusion service supporting a robust academic teaching hospital specializing in hematology/oncology, high risk obstetrics, organ transplantation and surgery; including a Level I Trauma Center. Provide medical coverage for a large regional independent blood collection center with an active apheresis program supporting cell therapy collections. Engage in the training of Transfusion Medicine fellows, pathology residents, and rotating fellows, residents, and medical students. Minimum Requirements: MD or MD/PhD; Board eligibility or Board certification in Blood Banking/Transfusion Medicine; and active or eligible for a State of Ohio Medical License. Click here to view the full job description and apply. EOE