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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #28 **August 23, 2024**

INSIDE:

Trauma Survival Outcomes of High FFP to RBC Ratio Explored in *JAMA*

A study published in *JAMA* assessed, "the association between high fresh frozen plasma (FFP) to red blood cell (RBC) transfusion ratio and mortality in patients with severe blunt trauma." The authors sought to determine, "whether there was a nonlinear relationship between the transfusion ratio and survival to establish the optimal transfusion strategy." They performed a retrospective analysis of the Japan Trauma Data Bank, "a nationwide, multicenter, prospective, and observational trauma registry established in 2003 [that] collects data on trauma admissions from more than 200 participating hospitals in Japan and is compiled annually."

For this study, the researchers included individuals from the database who suffered severe blunt trauma and required blood transfusion (without a traumatic brain injury (TBI)). They specifically, "targeted patients with blunt trauma and an Injury Severity Score (ISS) of 16 or more [dividing them] into two groups according to their FFP to RBC ratios. [They] defined the exposure of interest as high FFP (FFP to RBC ratio >1) and the comparison as low FFP (FFP to RBC ratio ≤1)."

The authors explained that, "[the] primary outcome was all-cause in-hospital mortality. We evaluated the occurrence of transfusion-related adverse events, including pulmonary edema, acute respiratory distress syndrome, pulmonary thromboembolism, pneumonia, acute kidney injury, and sepsis." The study included, "[a] total of 1,954 patients (median [IQR] age, 61 [41-77] years; 711 female[s] [36.4 percent]; 1,243 male[s] [63.6 percent])." It found that, "transfusions with high-FFP ratios were associated with favorable outcomes. [The authors] observed a nonlinear relationship between the FFP to RBC ratio and in-hospital mortality, suggesting a dose-response relationship between a low ratio and poor outcomes and a ceiling effect in the association between a high ratio and favorable outcomes. This finding suggests the existence of an optimal transfusion ratio. [Additionally, the authors noted that the] primary finding of this study was that the transfusion of an FFP to RBC ratio greater than one was associated with a favorable outcome, which is partially different from the current transfusion consensus based on previous randomized controlled trials (RCTs)…Furthermore, this study reflects the latest hemostatic resuscitation trauma treatment strategies, including a massive transfusion protocol and damage control surgery, based on real-world data, with potential confounders carefully controlled and robustness reinforced by several sensitivity analyses."

The researchers also noted that, "the high ratio of FFP transfusions may be disadvantageous. Although no clear statistical association was demonstrated in this study,

(continued on page 2)

Trauma Survival Outcomes of High FFP to RBC Ratio (continued from page 1)

[certainly,] high FFP transfusions have been reported to pose risks, such as volume overload and dilution of blood components, which need to be considered carefully. Thus, the trend of complications seen in this study is similar to or emphasized in previous studies, and transfusion of large amounts of FFP without setting an upper limit at a ratio too high for RBC should be avoided. Therefore, it is crucial to determine the optimal transfusion ratio."

The study concluded that, "a high FFP to RBC ratio greater than one was associated with lower in-hospital mortality than a low-FFP ratio in adults with severe blunt trauma; however, there may be a ceiling effect at a ratio of more than 1.5. Future RCTs focusing on blunt trauma are warranted to demonstrate the efficacy of high FFP ratios in trauma settings." Limitations of the study included, "the number of patients with severe trauma requiring transfusion was limited due to the decline in the number of trauma cases, [the study] could not adjust for time-dependent confounding factors owing to the lack of data over time after the hospital visit, [and] there are concerns about external validity in other countries owing to differences in trauma care." An "Invited Commentary" has also been published in *JAMA*.

Citation: Fujiwara, G., Okada, Y., Ishii, W, *et al*. "High fresh frozen plasma to red blood cell ratio and survival outcomes in blunt Trauma." *JAMA*. 2024

BRIEFLY NOTED

The Association for Molecular Pathology (AMP) has filed a lawsuit against the U.S. Food and Drug Administration (FDA) regarding the regulation of, "laboratory developed test (LDT) procedures as medical devices under the Federal Food, Drug, and Cosmetic Act." According to an AMP news release, "[t]he lawsuit was filed in the U.S. District Court for the Southern District of Texas against the FDA; Robert M. Califf, MD, in his official capacity as Commissioner of Food and Drugs; the U.S. Department of Health and Human Services (HHS); and Xavier Becerra, JD, in his official capacity as Secretary of HHS." AMP President Maria Arcila, MD explained in the news release, "AMP remains very concerned about the wide-sweeping and long-lasting consequences the FDA rule will have for our members and patients across the country. We filed this lawsuit to ask the Court to vacate the FDA rule given the agency's lack of authority to regulate LDTs and to avert the significant and harmful disruption to laboratory medicine. AMP will continue working with key stakeholders to develop a more effective and efficient legislative framework that ensures high-quality patient care while continuing to foster rapid innovation and the promise of new diagnostic technologies."

(Source: AMP News Release, 8/20/24)

(continued on page 3)

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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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BRIEFLY NOTED (continued from page 2)

A report from *Bloomberg News* stated that, "[a] federal judge ruled the U.S. Federal Trade Commission (FTC) can[not] enforce its near-total ban on noncompete agreements that was set to go into effect next month, blocking an effort by the agency to make labor markets more competitive. In a ruling Tuesday, U.S. District Judge Ada Brown in Dallas sided with the U.S. Chamber of Commerce and a Texas-based tax firm that sued to block the measure. The judge said the FTC lacked the authority to enact the ban, which she said was "'unreasonably overbroad without a reasonable explanation.'"

(Source: *Bloomberg News*, "FTC ban on worker noncompete deals blocked by federal judge (2)," 8/20/24)

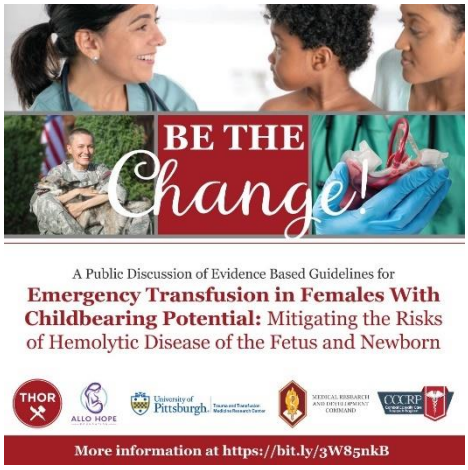
***Becker's Hospital Review* recently held its 13th Annual Meeting which included a workshop sponsored by Abbott and Blood Centers of America (BCA) on, "the future of the nation's blood supply and the potential of biotherapies to transform patient care."** A panel discussion featured:

- "Joana Araujo, senior global marketing director [at] Abbott;
- Debra BenAvram, FASAE, CAE, chief executive officer (CEO) [of] the Association for the Advancement of Blood & Biotherapies (AABB);
- Chris Miskel, MBA, president and CEO [of] Versiti Inc.; [and]
- Harpreet Sandhu, MBA, CEO [at] Stanford Blood Center (Palo Alto, Calif.), and chairperson [of] BCA."

Key takeaways from the workshop included:

- "to strengthen the nation's blood supply, engagement with younger donors is essential;
- [a]s biotherapies evolve, the existing blood ecosystem can be used in new ways; [and]
- [t]he healthcare sector can never take its eye off [blood] safety."

(Source: *Becker's Hospital Review*, "Strategies for maintaining the resilience of the nation's blood supply, 8/19/24)



The Department of Defense (DoD) Combat Casualty Care Research Program is sponsoring a meeting in Bethesda, Md. on "Emergency Transfusion in Females [w]ith Childbearing Potential: Mitigating the Risks of Hemolytic Disease of the Fetus and Newborn" organized by the Trauma Hemostasis and Oxygenation Research (THOR) Network that will welcome attendees from the U.S., Canada, and other countries. This event will present evidence-based guidelines for emergency transfusion in females with childbearing potential with a focus on methods to mitigate and manage the risks of hemolytic disease of the fetus and newborn (HDFN). Due to the increase in use of Rh(D) positive whole blood nationally in the U.S. for life-threatening bleeding, guidelines are required to inform best practices on the use of this product in Rh(D) negative females with childbearing potential due to the risk of HDFN. On the first day of the conference, draft guidelines will be presented with the opportunity for public comment. There will also be presentations from patient advocates, including women who have required transfusion for bleeding, and from the Allo Hope Foundation, which is a 501(c)3 organization founded to offer resources, education, and support to alloimmunized patients and their providers. Methods for implementation and dissemination of the recommendations developed from this conference will also be discussed. Join THOR Network meeting attendees on November 19th at the

(continued on page 4)

(continued from page 3)

Hyatt Regency Bethesda to hear from experts in the fields of trauma surgery, emergency medicine, anesthesiology, transfusion medicine, obstetrics, maternal fetal medicine, hematology, pathology, neonatology, and pediatrics. The November 20th program is open to the invited experts panel to vote on the recommendations and will be closed to general public attendees. More information and the full agenda are available at: https://bit.ly/3W85nkB.

(Source: THOR Network Meeting Announcement, 8/19/24)

STATE ADVOCACY BRIEFS

The Pennsylvania General Assembly has introduced Senate Bill #1301 titled "an act Amending Title 35 (Health and Safety) of the Pennsylvania Consolidated Statutes, providing for medical devices." The proposed legislation would ban di-2-ethylhexyl phthalate (DEHP). Specifically, the proposed bill states, "[b]eginning January 1st, 2026, a person may not manufacture, sell, or distribute intravenous solution containers made with an intentionally added DEHP. Beginning January 1st, 2026, a person may not manufacture, sell, or distribute intravenous tubing made with an intentionally added DEHP for use in neonatal intensive care units or for the purpose of nutrition infusions or oncology treatment infusions. Beginning January 1st, 2031, a person may not manufacture, sell, or distribute intravenous tubing made with an intentionally added DEHP. A person may not replace DEHP with another ortho-phthalate in a new or revised medical device. A health care practitioner shall notify a patient prior to use of an intravenous solution container or intravenous tubing that contains DEHP or other ortho-phthalate in the course of treatment." The proposed legislation would take effect, "90 days" after the bill's passage.

(Source: Pennsylvania General Assembly Senate Bill #1301, 8/20/24)

WORD IN WASHINGTON

The U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra, JD issued a statement on August 16th concerning the BD BACTEC™ blood culture media bottle shortage. The statement explained that, "[w]e are aware of disruptions in the availability of BD BACTEC™ blood culture media bottles, which could impact clinical practices for health care providers and laboratories. We recommend that health care providers, laboratory professionals, and health care facility administrators prioritize and conserve BD BACTEC blood culture media bottles per [the] U.S. Food and Drug Administration's (FDA) published recommendations during this shortage. Additionally, we encourage those affected by this shortage, along with state, tribal, local, and territorial health departments, to assess their situations and develop plans and options to mitigate the potential impact of the shortage on patient care." Additionally, he emphasized in the statement that, "HHS and FDA are working closely with the manufacturer and other partners to accelerate rapid resolution of the shortage, including expediting any necessary review (e.g., for shelf-life extension), meeting with alternative suppliers, and communicating best practices and conservation strategies. The Centers for Disease Control and Prevention (CDC) issued a Health Alert Network Health Advisory with additional resources to mitigate the potential impact on patient care. The Centers for Medicare & Medicaid Services (CMS) is coordinating with partner agencies and the hospital industry to monitor the disruption and is providing hospitals with an update."

(Source: HHS Statement, 8/16/24)

(continued on page 5)

WORD IN WASHINGTON (continued from page 4)

FDA announced this week that it has, "approved and granted emergency use authorization (EUA) for updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2." According to the agency, [t]he mRNA COVID-19 vaccines have been updated with this formula to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death. Today's actions relate to updated mRNA COVID-19 vaccines manufactured by ModernaTX Inc. and Pfizer Inc."

(Source: FDA Announcement, 8/22/24)

The Centers for Medicare & Medicaid Services (CMS) has announced, "the state Notice of Funding Opportunity (NOFO) for participants in the Cell and Gene Therapy (CGT) Access Model." According to an August 23rd notice published by the agency, "the CGT Access Model is a voluntary model that aims to improve the lives of people with Medicaid living with rare and severe diseases by increasing access to potentially transformative treatments. All states and U.S. territories that participate in the Medicaid Drug Rebate Program (MDRP) are eligible to apply to participate in the model."

(Source: CMS Announcement, 8/23/24)

PEOPLE

Macopharma USA recently named **Simone Fernandes, MBA** as country manager. She brings 18 years of experience in the medical devices and diagnostics industry Macopharma, according to a company announcement. Ms. Fernandes has previously worked at Edwards Lifesciences and Abbott Laboratories in several roles, "ranging from [o]perations, [s]ales and [m]arketing, [c]ommercial management, and [g]eneral [m]anager in both the U.S. and South America. [She] has a [b]achelor's degree in Business Administration, a MBA, and a [m]aster's [d]egree in Digital Marketing." The Macopharma USA announcement also noted that Ms. Fernandes, "will work with **Roxane Smith** during the next few weeks to ensure a smooth transition [following Ms. Smith's previously announced retirement after a 12-year career at Macopharma effective October 1st.]"

(Source: Macopharma USA Announcement, 8/20/24)

MEMBER NEWS

Bader Philanthropies has awarded a $40,000 grant to **Versiti Blood Center of Wisconsin** in support of Versiti on King (VOK), "the organization's new community resource and permanent blood donation center on Milwaukee's North Side within the ThriveOn King Development." According to a blood center news release, "VOK will serve as Versiti's community hub and will focus on providing resources to address healthcare disparities in Milwaukee neighborhoods and beyond through training, employment, education, and blood donation. [Additionally, it] will provide valuable community resources, including, "[e]mployment and job skill training, including for new Versiti phlebotomists; [d]isease education, including sickle cell disease, diabetes and other conditions commonly affecting communities of color; [b]lood donation services, including a permanent Versiti donor center; [c]ommunity health navigator; [and] [b]asic social services." Versiti President and Chief Executive Officer (CEO) Chris Miskel, MBA added in the news release, "[w]e are incredibly grateful to Bader Philanthropies for their support of VOK. This investment is more than monetary. It is a generational investment in the wellbeing of our Milwaukee community and the donors and patients we serve."

(Source: Versiti News Release, 8/7/24)

RESEARCH IN BRIEF

Automated Red Blood Cell Exchange in Sickle Cell Patients with Higher End Hematocrit. A study published in the *British Journal of Haematology* "employed a post-red blood cell exchange (RCE) h[e]matocrit (Ht) target higher than typically used." The authors explained that this was a, "retrospective audit of all adults with sickle cell disease (SCD) and enrolled in chronic RCE for at least six consecutive months [from 2019-2021]…The cohort was divided into three Ht balance subgroups: same Ht (SH), and increased Ht (IH) or lowered Ht (LH)." The study included, "[a] total of 41 females and 60 males. [Genotype distribution] was 71 percent HbSS/Sβ0, 27 percent HbSC, and 2 percent HbSβ+disease. The most common indication for chronic RCE was a history of neurological complication (n = 53)." The researchers noted that, "[o]verall, 50 percent were managed with an increased Ht (IH) strategy, 43 percent with an SH strategy, and 8 percent with a lowered Ht (LH) strategy. Patients with HbSS/Sβ0 represented 98 percent of the IH cohort, with a mean post-transfusion Ht increment of 6 percent [range: 3 to 11], while the SH cohort included both HbSC patients (49 percent) and HbSS (47 percent) with an essentially neutral Ht balance of 0 percent. The Ht decrease observed in the LH group ranged from −7 to −2 percent." The study found that, "[c]ompared to the SH group, more patients in the IH group exceeded ferritin values >1,000 ng/ mL while on RCE (64 vs. 5 percent, $p < 0.001$) and were prescribed iron chelation therapy at least once (52 vs. 0 percent, $p < 0.001$)…Patients receiving chelation had a higher mean Ht increment with RCE compared to the total cohort (7.0 vs. 1.3 percent, $p < 0.001$)…Among the 29 adults who had a liver MRI performed for suspected iron overload, 16 were found with moderate or severe iron overload at least once." The authors also noted that, "[m]ore patients in the SH and LH group (56 and 88 percent, respectively) were prescribed iron supplements compared to the IH group (6 percent, $p < 0.001$)." They concluded that the study, "provide[d] an RCE model with a higher Ht goal of 34 percent and highlight[s] the importance of iron imbalances when a fixed post-procedure Ht is used. This finding reinforces the value of monitoring iron studies even in patients on automated RCE and suggests that personalized Ht targets may be more appropriate in certain settings."

Citation: Ross, J.M., Forté, S., Mercure-Corriveau, N., *et al*. "Automated red blood cell exchange with a post-procedure haematocrit targeted at 34 percent in the chronic management of sickle cell disease." *British Journal of Haematology*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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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.

ABC Announces Cybersecurity Webinar on September 17th

The next America's Blood Centers (ABC) Education Committee Webinar titled "Cybersecurity: Threats & Preventative Actions" will occur September 17th at 3 p.m. EDT. The webinar will cover the topics of threat landscape and best practices for the prevention of cyberattacks. Featured speakers include George Chacko, CISSP, HCISSP, PMP, executive director of Information Security and Compliance at the New York Blood Center Enterprises and Saiyed Iqbal, CRISC, CGEIT, CNE, director of Information Services at LifeStream. More information and a link to registration are available here.

ABC Workforce Trends Survey Deadline Extension

The new America's Blood Centers (ABC) Workforce Trends Survey deadline is now extended until August 30th. Instructions regarding how to access the survey have been distributed to authorized individuals. This valuable benchmarking survey is the most comprehensive source of information available on workforce trends at blood centers. The survey analyzes overall trends in compensation, benefits, and human resources (HR) policies and provides specific data for 74 different blood center employee roles. The survey also provides insights into employee turnover and retention for the preceding calendar year, analyzing trends overall as well as by department and length of service. This survey combines the previous Compensation & Benefits and Employee Turnover & Retention surveys. Please contact us with any questions or to add/change authorized individuals.

Attend ADRP's "Innovations in Blood Donor Recruitment and Retention" Webinar

The ADRP "Empowering Lifesavers: Innovations in Blood Donor Recruitment and Retention" webinar will take place on August 29th at 12:30 a.m. EDT to accommodate the schedule of presenters in Asia (a recording of this webinar will also be available to all registrants.) The event will be co-hosted and sponsored by Terumo Blood and Cell Technologies (Terumo BCT) and will feature:

- Dr. Anand Deshpande – Head of the Department of Transfusion Medicine at P.D. Hinduja Hospital in Mumbai, India;
- Luxi Zhang – Frequent Blood Donor and Active Blood Donor Advocate in Shenzhen, China;
- Theresa Pina – Vice President of Operations for Gulf Coast Regional Blood Center in Houston, Texas and ADRP Immediate Past President; and
- Prakash Menon – Group Director of the Blood Donor Progra[m] at the Singapore Red Cross.

This event includes leading blood centers from the Asia-Pacific (APAC) region sharing their innovative approaches and best practices. Aimed at blood center management, collection managers, and recruiters, this collaborative effort seeks to inspire and educate on enhancing donor recruitment and retention. Terumo BCT and ADRP unite to leverage their expertise and provide actionable insights for blood centers world-wide. Registration for this webinar is complimentary. Be part of the conversation that shapes the future of blood donation.

(continued on page 8)

INSIDE ABC (continued from page 7)

Speakers Announced for 2024 ADRP Master Class

The schedule of speakers is now available for the 2024 ADRP Master Class: "Bring in the Coach — The Path to Effective Leadership!" Register now and do not miss your shot to grow and learn. This virtual event is taking place September 18th-19th and will include:

- Health Psychologist Nicole Eull;
- Leadership Coach Jonathan R. Parker;
- Leadership Expert William B. Henry; and
- Business Strategy and Development Leader Dr. Meghan Kinter.

The 2024 Master Class promises an interactive journey filled with powerful insights, practical tools, and actionable strategies. Gain the skills you need to enhance communication, build effective teamwork, and boost emotional intelligence. This is your opportunity to leave the bench and master effective leadership. Secure your spot today and equip yourself with the knowledge and expertise needed to lead your team to victory. When we thrive, patients thrive. Grab your clipboard, register today, and get ready to elevate your team to new heights!

ABC Economic Outlook Survey Report Available

The ABC Economic Outlook Survey results are in! ABC member blood centers that participated in the survey can access the results, download final trend reports, and create customized reports based on selected filters. This survey is a new resource that consolidated the previous ABC Financial Ratio and Median Service Fee surveys while offering 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. ABC member blood centers that were non-participants may purchase the report here. Please contact us with questions.

Register for ABC WELC Rise & Lead Workshop

Registration is open for the ABC Women's Executive Leadership Community's (WELC) Rise & Lead Workshop. This event will take place November 6th -7th in San Antonio, Texas at the Hyatt Regency Hill Country Resort. The workshop will ignite meaningful conversations and cultivate diverse perspectives. This event goes beyond traditional conferences by encouraging dynamic conversations that spark connections and drive personal and professional growth. At the Rise & Lead Workshop, you will delve into topics that matter, participate in interactive networking sessions, and walk away with tangible, real-life strategies to become a more resilient leader in today's ever-evolving world. Elevate your leadership journey with us! A preliminary agenda is available. Book your room by October 9th to secure the group rate.

GLOBAL NEWS

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK), recently announced that, "[b]lood packs have been successfully flown by drone in a series of 'beyond visual line of sight' flights, for the first time in the UK." A joint research study by NHSBT and Apian evaluated the, "viability of flying blood via drone [by transporting] 10 units of packed blood cells on a 68km journey across Northumbria's skies, while an identical ten packs were transported via road," according to a NHSBT news release. The companies noted that the results, "showed both sets remained viable, with no significant difference in the biochemical or h[e]matological

(continued on page 9)

GLOBAL NEWS (continued from page 8)

Photo courtesy of NHSBT

profiles of the blood, which determine if it has maintained quality and can be used for clinical purposes. The study was the first in a series of NHS trials to ascertain the feasibility and safety of delivering medical supplies via drone, which can be faster and more environmentally friendly than road travel." Additionally, the news release explained that, "[e]ach pack [was] analy[z]ed to assess factors including concentration of potassium and the percentage of h[e]molysis (destruction of the blood cells). Results showed that drone delivery did not influence the blood's quality or longevity and therefore could be used as a safe mode of transport…The drones travelled at a speed of 68mph, flying out to the coastline, over the sea and back in-land for each leg. The complete journey covered 68km and took a total of 61 minutes. The ground vehicle path was 74.6km long and took 68 minutes. For the purposes of the study, the drone's travel path was not the most direct possible - distances would be shorter and travel times significantly quicker in a real-world setting. A similar trial for platelets is being planned."

(Source: NHSBT News Release, 8/21/24)

Photo courtesy of The Japan Times

***The Japan Times* is reporting that, "Nara Medical University will begin a clinical trial in spring 2025 to test reusing artificial red blood cells made from donated blood that is past its shelf life and usually discarded.** A research team from a university in Nara Prefecture aims to make use of the artificial cells practical by around 2030." According to the article the, "[a]rtificial red blood cells are produced by extracting hemoglobin, which carries oxygen, from donated blood and wrapping it with an artificial lipid membrane, according to the team. The artificial cells have a purplish color, unlike the common red color of blood, as they are made in a way that they do not oxidize until they are used. The artificial cells produced using this method can be stored for up to about two years at room temperature and up to five years under refrigerated conditions." Additionally, the media outlet explained that, "[t]he original membrane that determines blood types has been removed, making blood typing unnecessary, a big advantage in emergency situations…In the clinical trial, 16 healthy adults will each receive up to 400 milliliters of artificial red blood cells. The team will confirm safety by administering the cells in various patterns with different infusion speeds and volumes."

(Source: *The Japan Times*, "Clinical trial to reutilize expired blood to start in Japan," 8/18/24)

COMPANY NEWS

Preservation Bio recently reported on a study published in *Blood* regarding an *ex vivo* platelet additive, "could revolutionize blood banking by enabling long-term cold storage of platelets [by extending the shelf life for up to 14 days well beyond the current 5-7 days, thereby reducing seasonal and regional fluctuations in platelet supply and minimizing waste.]" According to the news release, "[b]y significantly enhancing storage quality and safety with refrigeration, Preservation Bio's *ex vivo* platelet additive reduces the risk of bacterial contamination associated with traditional room temperature storage methods. The additive is versatile enough to support the production of long-term stored platelets across various platforms, ensuring they are suitable for transfusion in all patient groups. This flexibility allows blood centers and hospitals to maintain a unified inventory that can serve both trauma patients and those with hematologic conditions, simplifying logistics and improving resource allocation. These advancements could play a crucial role in

(continued on page 10)

COMPANY NEWS (continued from page 9)

stabilizing the platelet supply and easing the burden of declining donation rates." Key findings from the study included:

- "RHOA GTPase Activation Identified: [t]he study identified RHOA GTPase activation as a key molecular switch controlling cold platelet storage lesions;
- Development of RHoA Inhibitors: RHOA chiral enantiomer inhibitors (R-G04 and S-G04) were developed to effectively prevent cold storage-induced damage;
- Prolonged Survival and Function: [c]old-stored platelets treated with these inhibitors for up to 14 days maintained survival and hemostatic function comparable to 5-7 days for room temperature stored platelets;
- Prevention of Cold Damage: [t]he inhibitors act by blocking the key regulator of cold-induced damage, preventing multiple biochemical, structural, and functional problems of cold-stored platelets resulting in platelet clearance and hemostatic dysfunction;
- Prevention of Bacterial Growth: [t]he inhibitors will prevent bacterial growth and allow cold storage of platelets amenable to be transfused to essentially all patients in need including immunodeficient cancer patients; [and]
- Potential for Clinical Application: [t]he inhibitors preserved clotting activity of human platelets transfused and corrected the excess bleeding in animals with reduced platelet count and/or deficient activity, supporting an application for clinical transfusion."

Preservation Bio intends to submit an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) and begin a phase I clinical trial at Hoxworth Blood Center and the American Red Cross. "The key endpoints will be platelet survival and recovery. Following successful Phase I results, Preservation Bio plans to conduct a pivotal trial at major cancer centers in the U.S."

(Source: Preservation Bio News Release, 8/21/24)

Immucor, Inc. (acquired by Werfen) has received 510(k) clearance from the FDA for "ImmuLINK (v3.2)." According to the letter, "ImmuLINK is software intended for use in a blood banking environment to aid in interfacing and managing data between blood bank instruments, Blood Establishment Computer Software (BECS), and Laboratory Information Systems (LIS)."

(Source: FDA Letter, 8/6/24)

Cresilon Inc. announced that the FDA has cleared Traumagel®. According to a company news release, Traumagel is a, "revolutionary plant-based hemostatic gel technology is designed to stop and control life-threatening bleeding in a matter of seconds when applied to a wound at the point of care. [It uses] Cresilon's proprietary hydrogel technology [and] is a first-of-its-kind hemostatic medical device with FDA clearance for temporary external use in moderate to severe bleeding." The company plans to, "develop and manufacture Traumagel to address the needs of the U.S. military, government health agencies, emergency medical services (EMS) systems, and medical professionals who routinely encounter traumatic wounds and need a solution to quickly and effectively stop and control severe bleeding." Cresilon anticipates "launching" the product in U.S. later this year. The news release also noted that, "[t]he company recently reported promising results from its cooperative research and development agreement with the U.S. Defense Department's Walter Reed Army Institute of Research (WRAIR) from a study of Cresilon's gel technology as a potential field and prehospital treatment to mitigate life-threatening brain hemorrhage and provide neuroprotection following a penetrating traumatic brain injury ("TBI").

(Source: Cresilon Inc. News Release, 8/15/24)

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.)*

2024

Aug. 29. **ADRP Webinar Sponsored by Terumo Blood and Cell Technologies — Empowering Lifesavers: Innovations in Blood Donor Recruitment and Retention.** Registration is open. More information available here.

Sept. 3-6. **American Society for Clinical Pathology (ASCP) Annual Meeting. Chicago, Ill.** Registration is open. More information is available here.

Sept. 5. **U.S Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Town Hall: Cell Therapy Chemistry, Manufacturing, and Controls (CMC) Readiness for Late-Stage Investigational New Drug Applications (INDs) (Virtual).** Registration is open. More information is available here.

Sept. 12. **FDA Grand Rounds – Advancing Blood Safety and Patient Health in HIV/AIDS through FDA's Research on Viral Genome Surveillance, Diagnostic Technologies, and Biomarker Discovery (Webcast).** Registration is open. More information available here.

Sept. 12-14. **Society for the Advancement of Patient Blood Management (SABM) 2024 Annual Meeting. Phoenix, Ariz.** Registration is open. More information available here.

Sept. 16-18. **2024 FDA CBER Science Symposium (Hybrid), Silver Spring, Md.** Registration is open. More information available here.

Sept. 17. **America's Blood Centers (ABC) Webinar: Cybersecurity: Threats & Preventative Actions.** More information and a link to registration are available here.

Sept. 18-19. **2024 ADRP Master Class: Bring in the Coach — The Path to Effective Leadership (Virtual).** More information available here.

Sept. 19. **National Institutes of Health (NIH) Department of Transfusion Medicine NIH Clinical Center and the American Red Cross 43rd Annual Immunohematology and Blood Transfusion Symposium (Virtual).** Registration is open.

Sept. 24. **FDA Webinar: Labeling Requirements for *In Vitro* Diagnostic Products (IVD), Including Laboratory Developed Tests (LDTs), Under 21 CFR 809.10(b).** More information available here.

Sept 26. **ABC Women's Executive Leadership Community (WELC) Webinar.** More information coming soon.

Sept. 30-Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** Registration is open. More information available here.

Oct. 16-17. **Biomedical Excellence for Safer Transfusion (BEST) Fall Meeting. Galveston, Texas.** More information available here.

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information available here.

Nov. 6-7. **ABC Women's Executive Leadership Community (WELC) Workshop. San Antonio, Texas.** Registration is open. More information is available here.

(continued on page 12)

CALENDAR (continued from page 11)

Nov. 13. **2024 ADRP International Showcase.** More information coming soon.

Nov. 19-20. **Trauma Hemostasis & Oxygenation Research (THOR) Network Emergency Transfusion in Females with Childbearing Potential: Mitigating the Risks of Hemolytic Disease of the Fetus and Newborn Meeting. Bethesda, Md.** Registration is open. More information available here.

Nov. 19-20. **Plasma Protein Forum. Washington, D.C.** More information available here.

2025

Mar. 10-12. **ABC Annual Meeting. Arlington, Va.** More information is coming soon.

May 6-8. **2025 ADRP Annual Conference. Oklahoma City, O.K.** More information is coming soon.

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

Oct. 12-15. **AATB Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** 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

Associate Medical Director (Oklahoma City, OK). Our Blood Institute (OBI) seeks an Associate Medical Director for its Oklahoma City headquarters location. The Associate Medical Director is a licensed physician with shared responsibility for the medical, technical, and clinical leadership and direction of OBI's operations. This position will help direct and supervise key staff and processes to ensure the safety and well-being of all blood donors, the quality of all blood products manufactured, and the provision of premier laboratory and patient services. Ample complex medical care and professional growth opportunities arise from our Therapeutic Apheresis, AABB accredited IRL, and FACT accredited cell therapy operations. Numerous clinical research, public health, and product development initiatives can inspire projects ranging from community health surveillance to entrepreneurial start-ups. Empowering resources including clean rooms, a high-volume donor testing laboratory, and sizable software engineering skunkworks are additional resources. OBI has a variety of outstanding opportunities to propel your career in a nimble, supportive, and friendly environment. Management experience and business skill acquisition is guaranteed in a complex, 1100-employee non-profit organization. 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/

Technical Director. The Northern California Community Blood Bank seeks a skilled leader and laboratory professional to join our team as Technical Director. Located in the magnificent Northern California coastal redwoods, Eureka is the market and cultural center of a beautiful region filled with iconic redwoods and stunningly beautiful, rugged remote ocean landscapes. Our blood bank offers a low-stress environment, excellent work-life balance, and the opportunity to join a supportive, inclusive team and an organization with a vibrant community relationship. The Technical Director has overall responsibility for the Laboratory and all activities related to the production of blood products. This position supervises Laboratory Staff performing component production, inventory control, distribution, and reference immunohematology, ensuring that all details of blood product manufacture are compliant with regulatory and standard-setting agencies. A qualified candidate must meet CLIA General supervisor qualifications and hold a California Clinical Laboratory Scientist License (CLS). Experience as a technologist performing high complexity testing in a clinical laboratory and familiarity with standard laboratory methods and techniques is required. For details and to apply, visit www.nccbb.net/employment.html.

(continued on page 13)

POSITIONS (continued from page 12)

Medical Laboratory Scientist (MLS)/Technologist (MLT). This role at LIFELINE Blood Services performs lab procedures such as compatibility testing, reference lab work, specimen processing, test performance, and reporting test results. Also, may perform computer aided labeling, component production, and distribution. Responsible for maintenance and storage of blood components including temperature monitoring, labeling of blood, biohazard disposal, Quality Control and Preventative Maintenance, bexWISE Process and bexWISE Affirm Operation, component preparation, packing recovered plasma, daily orders, blood shipments and returns, shipping recovered plasma, inventory control, resource management, importing and exporting, irradiation of Blood Products. Laboratory Duties include qualifications of Apheresis Platelets and Plasma, lot release, sending tubes to testing lab, RRC program, and management of Soot. RRC Duties include pulling retention samples to send to Ortho Diagnostics for antigen typing and recruit new donors for the RRC program based on the needs of the manufacturers. EDUCATION: MLS, Bachelor's degree in Medical Technology, Clinical Laboratory Science or chemical, physical, or biological science and Current State of Tennessee licensure. Apply for Medical Laboratory Scientist/Technologist by clicking here.

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, 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 IRL Medical Technologist will resolve 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 the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Jacksonville, FL. 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. This individual 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 the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Laboratory Education Coordinator. LifeSouth Community Blood Centers is looking for a team-oriented, goal-driven individual with a passion for education to join the team as a Laboratory Education Coordinator in Gainesville, FL. This position is responsible for the overall execution and development of LifeSouth's Blood Banking and Transfusion Medical education programs. Additional responsibilities include assisting with the training of laboratory employees, assessing competencies, and maintaining training materials. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Marketing Executive. LifeSouth Community Blood Centers is looking for a highly skilled leader with a solid understanding of marketing principles and techniques, a data-driven approach, and a passion for innovation, to join the team as Marketing Executive in Gainesville, FL. This position is responsible for the overall marketing strategy across the organization. This position requires active communication with executive leadership and department directors within the organization to ensure adequate planning and execution of strategic marketing plans. This position is dedicated to advancing the organization's objectives in blood donation, cord blood services, cellular therapy, new business development, and meeting patient needs. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

IRL Supervisor. Bloodworks Northwest, a recognized leader in transfusion medicine, currently has an opening for an IRL Supervisor in the Immunohematology Reference Laboratory. Key responsibilities include supervising departmental staff, ensuring the management of departmental projects, and participating in interdepartmental projects according to established priorities and timelines. Coordinating quality review and management of errors. Providing technical expertise in IRL testing and the development and implementation of new methods and as needed and perform clinical laboratory testing. Requirements include: Must qualify as General Supervisor, High Complexity Testing, under CLIA personnel requirements found in Subpart M of the Code of Federal Regulations. Certification as a Specialist in Blood Banking (SBB) is required. Certification as a Medical Laboratory Scientist (MLS) is preferred. Five years of laboratory technical experience with at two years of experience in

(continued on page 14)

POSITIONS (continued from page 13)

immunohematology reference testing is required or an equivalent combination of education and experience. Three years of laboratory supervisor or Lead experience is preferred. Demonstrated expertise in immunohematology reference testing. Basic knowledge of molecular techniques is preferred. We offer competitive benefits: Medical, dental, vision, life insurance, retirement plan, subsidized back-up childcare program, subsidized transit program, educational reimbursement and more! Interested candidates should apply directly on our website at www.bloodworksnw.org/careers

Supervisor, Immunohematology Reference Lab (San Diego Blood Bank). The San Diego Blood Bank is currently seeking a motivated, knowledgeable professional to lead the Immunohematology Reference Lab. This person will oversee the daily operation of the department as well as support the greater Lab Management Team following safety, cGMP, and Quality Plan. Additionally, the ideal candidate will supervise the flow of samples, blood, and blood components through the department from satellite centers, mobile collection vehicles, hospitals, blood banks, and laboratories. **Qualifications** include a minimum of 2 years in blood bank related fields to include leadership experience and IRL experience. **Certification/Licensure** required include MLS(ASCP)CM/MT(ASCP) or equivalent experience and a California Clinical Laboratory Scientist License (CLS). Certification as a Specialist in Blood Bank (SBB) or equivalent is preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com)

Immunohematology Reference Laboratory CLS (San Diego Blood Bank). Under the direction of the department leadership, the Medical Laboratory Scientist I will assist the Immunohematology Reference Laboratory in daily operations according to cGMP compliant policies and Standard Operating Procedures implemented by the San Diego Blood Bank (SDBB). The ideal candidate will successfully complete/pass an initial training program resulting in the ability to provide guidance and expertise for the laboratory to meet the needs of SDBB customers, in accordance with accepted standards and regulations. Requirements: Bachelor's degree, MLS/MT (ASCP)CM or equivalent experience, Clinical Laboratory Scientist (CLS). Certification as a Specialist in Blood Banking (SBB) preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com)

Massachusetts General Hospital
Founding Member, Mass General Brigham

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital; Boston, Massachusetts). The Department of Pathology at the Massachusetts General Hospital (MGH), a founding hospital of Mass General Brigham, and a major teaching affiliate of the Harvard Medical School, seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology, or hemostasis. The Blood Transfusion Service at MGH encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. We collaborate closely with colleagues in bone marrow and solid organ transplantation, CAR-T cell therapy, cardiac surgery, trauma and critical care, neurology, and pediatrics. Our faculty also work closely with transfusion medicine faculty within the MGB network. Service and teaching responsibilities will be shared with two full- and several part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatric). Academic rank as Associate Professor, Assistant Professor or Instructor and salary will be commensurate with experience and accomplishments. Interested candidates should send a personal statement with research interest, three potential referees and Curriculum Vitae to: Dr. Robert Makar; Director, Blood Transfusion Service; Department of Pathology; Massachusetts General Hospital; 55 Fruit Street, GRJ 148; Boston, MA 02114. Email: rmakar@mgh.harvard.edu C/O Diane Savickas dsavickas@mgb.org. We are an equal opportunity employer, and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, gender identity, sexual orientation, pregnancy, and pregnancy-related conditions, or any other characteristic protected by law.

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