

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2025 #38

December 15, 2025

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Cryopreserved Platelets Inferior to Liquid-stored? Results of the CLIP-II Trial Reported in *JAMA*

Researchers in Australia have <u>published</u> a paper in *JAMA* that reported on the findings of the Cryopreserved versus Liquid Platelets II (CLIP-II) study,"[a] randomized, double-blind, parallel-group noninferiority trial." The authors explained that the study aimed to assess the, "effectiveness and safety of cryopreserved platelets, compared with liquid-stored platelets, as treatment for bleeding." They examined cardiac surgery patients specifically as it is the, "most common cause of bleeding in hospitalized patients, accounting for 44 percent of surgical platelet use."

The trial took place between August 2021 and April 2024 and enrolled patients who were 18 years of age or older and at, "high risk of requiring a platelet transfusion [using] the Australian Cardiac Surgery Platelet Transfusion (ACSePT) score." Excluded individuals were those, "previously enrolled in a trial of a bleeding medication or if they had a history of deep vein thrombosis or pulmonary embolism. As all study cryopreserved platelets were collected from rhesus D (RhD)—positive donors, females between 18 and 55 years of age who were RhD negative or had an unknown RhD status were excluded. Patients with abnormal coagulation, due either to bleeding conditions or medications, were also [excluded.]"

The authors explained that, "Cryopreserved group O apheresis platelets were reconstituted in ABO-group matched or AB plasma using the Netherlands Military Blood Bank method, with slight modifications. Liquid platelets in a mixture of plasma and platelet additive solution were either derived from whole blood (pooled from the buffy coats from four donors) or donated by apheresis, with ABO group matching according to hospital practice."

The study's primary outcome was, "postsurgical chest drain bleeding volume within the first 24 hours following ICU admission. Secondary and tertiary effectiveness and safety outcomes were prospectively defined."

The study included 202 randomized individuals who required platelet transfusion and 104 of them received cryopreserved platelets while 98 received liquid-stored platelets. The paper explained that the, "mean (SD) age of liquid-stored platelet units transfused was 5.5 (1.0) days. Few liquid-stored units (15.6 percent) were obtained by apheresis; most were derived from whole blood. All cryopreserved platelet units were frozen in dimethyl sulfoxide (DMSO) within 50 hours of apheresis donation, reconstituted within two years of freezing, and transfused within four hours of resuspension." The researchers found that, "blood loss in the chest drains

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<u>Cryopreserved Platelets Inferior to Liquid-stored? Results of the CLIP-II Trial Reported in JAMA</u> (continued from page 1)

over the first 24 hours in the ICU, was not different between the study groups (median [IQR], 610 [410 to 950] vs 523 [370 to 780]; difference, 87 [-50 to 280]; ratio of geometric means, 1.13 [95 percent CI, 0.96 to 1.34]; P = .07). [The 24-hour hemoglobin concentration] nadir was not lower in the cryopreserved group (median [IQR], cryopreserved platelets group, 83 [74 to 94] vs liquid-stored platelets group, 88.5 [78 to 100] mg/dL; difference, -5 [-11 to 1]). Fresh frozen plasma (FFP) and cryoprecipitate were transfused to a greater proportion of patients in the cryopreserved group. [Other prespecified study effectiveness outcomes were worse in the cryopreserved platelets group. Intraoperative blood loss (ratio of geometric means, 1.42 [95 percent CI, 1.12-1.80]), chest drain volume at ICU admission (ratio of geometric means, 2.48 [95 percent CI, 1.40-4.38]), and total postoperative blood loss (ratio of geometric means, 1.31 [95 percent CI, 1.07-1.60]) were all higher in the cryopreserved group. [More patients] who received cryopreserved platelets were transfused red [blood] cells (cryopreserved platelets group, 74.0 percent vs liquid-stored platelets group, 59.2 percent; difference, 14.9 percent [95 percent CI, 2.0 percent to 27.7 percent])." Additionally, the authors noted that, "[t]here were no differences in the prespecified or additional adverse effects."

The researchers concluded that, "[c]ryopreserved platelets did not demonstrate noninferiority in 24-hour postoperative ICU blood loss when compared with liquid-stored platelets, with confidence intervals that indicated a potential increase in blood loss of up to 34 percent. [The results suggest that cryopreserved platelets should not replace liquid-stored platelets as a treatment for bleeding in situations where liquid-stored platelets are readily available. However, noting absence of hypothesized prespecified adverse events, cryopreserved platelets might still have utility in mitigating exhaustion of liquid platelet supply, as a means of providing human platelet antigen— and human leukocyte antigen—matched platelets." Limitations of the study acknowledged by the authors included, "results in high-risk cardiac surgery patients might not translate to trauma, gastrointestinal bleeding, or obstetric hemorrhage; cryopreserved platelets were reconstituted in FFP while liquid-stored platelets were suspended in platelet additive solution with less plasma. This should favor a greater hemostatic effect in the cryopreserved platelets group; however, this study observed the opposite result; a higher proportion of patients in the cryopreserved platelets group received open-label platelets before all three study platelets had been transfused, suggesting that clinicians possibly anticipated delayed receipt of cryopreserved platelets, or observed lesser hemostatic effectiveness or inadequate platelet increment."

Platelet Desert Editorial. An accompanying editorial published in *JAMA* titled, "An Oasis in the Platelet Desert?" describes the constraints of the global supply of platelets including the, "requirement to store platelets at room temperature, combined with their limited 5- to 7-day shelf life." The authors of the editorial

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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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<u>Cryopreserved Platelets Inferior to Liquid-stored? Results of the CLIP-II Trial Reported in JAMA</u> (continued from page 2)

explained that such, "gaps in access have resulted in so-called platelet deserts." The editorial highlights that a, "rapidly evolving area of investigation involves the search for an 'oasis in the platelet desert' — a product that works at least as well as room temperature-stored liquid platelets to stop bleeding but that does not have the same storage limitations and risk of wastage, allowing access in remote and austere environments." The authors of the editorial ask the question, "[e]ven if cryopreserved platelets are inferior to room temperature-stored liquid platelets, which we conclude from the present study, are they better than no platelets at all? In other words, in scenarios where room temperature-stored liquid platelets are not available, could cryopreserved platelets be an option?" The editorial's authors concluded their paper by explaining that, "[r]esearch around platelet products and substitutes is rapidly evolving, and we believe likely represents the single greatest area of opportunity in bleeding control in the coming years. [S]trategies to address the challenges of platelet deserts are also underway. Cold storage of platelets at 4°C has recently been shown to be feasible and safe in trauma, both in hemorrhagic shock and traumatic brain injury. Cold storage can extend shelf life from 5-7 days to 21 days and may enhance access to platelets at hospitals with lower utilization rates, which is likely to reduce waste. However, efforts to further increase the shelf life and remove cold chain storage requirements in remote or far forward locations (particularly relevant to military applications and large-scale combat operations) are needed. These currently include lyophilized plateletderived products and synthetic strategies. Both have the potential advantage of extended storage duration and portability without cold chain requirements. [Together,] these and other advances on the cutting edge of hemostasis and transfusion carry great promise that an oasis may be on the horizon and that a solution to the public health crisis of platelet access may soon come."

Cost-effectiveness of Cryopreserved Platelets vs. Liquid-stored Examined. The authors of a separate study <u>published</u> in *JAMA Network Open*, "assessed the cost-effectiveness of cryopreserved platelets compared with liquid-stored platelets alongside the CLIP-II trial for the management of cardiac surgical bleeding." The study found that, "treatment with cryopreserved platelets was more costly and less effective than standard therapy with liquid-stored platelets for managing active bleeding in patients undergoing cardiac surgery at metropolitan Australian hospitals. The higher mean per-patient costs of cryopreserved platelets were primarily driven by longer ICU stays and a 7-fold increase in the costs of cryopreserved platelets utilization, including manufacturing and transportation of frozen platelets. Additionally, cryopreserved platelets were associated with greater bleeding volumes and higher mortality rates." The researchers concluded that, "[i]n this economic evaluation, we provide novel evidence supporting the dominance of liquid-stored platelets over cryopreserved platelets in postoperative bleeding management following cardiac surgery. [However,] further evaluation of the potential costs and benefits of cryopreserved platelets implementation in regional and remote settings may be warranted to ensure equitable access to emergency bleeding management across the country."

Citations: Reade, M.C., Marks, D.C., Howe, B.D., et al. "Cryopreserved vs Liquid-Stored Platelets for the Treatment of Surgical Bleeding The CLIP-II Randomized Noninferiority Clinical Trial." JAMA. 2025.

Neal, M.D., Spinella, P.C., and Kornblith, L.Z. "An Oasis in the Platelet Desert?" JAMA. 2025.

Orman, Z., Reade, M.C., and Marks, D.C. "Cost-Effectiveness of Cryopreserved vs Liquid-Stored Platelets for Managing Surgical Bleeding." *JAMA Network Open.* 2025



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BRIEFLY NOTED

PharmaPhorum has published an article titled "Why Pharma's Future May Run Through Your Local Blood Center." The authors of the article are Lee Buckler, senior vice president of Advanced Therapies at Blood Centers of America (BCA), Jeff Wren, vice president of Biotherapies at the Association for the Advancement of Blood & Biotherapies (AABB), and Kate Fry, chief executive officer of America's Blood Centers (ABC). The piece highlights the value of blood centers as partners for pharmaceutical innovation in the form of advanced therapies. It also describes and raises awareness of the Blood and Cell Advocacy Roster (BCAR), an industry collaboration between blood and tissue collection networks, related technology providers, biotherapy communities, and other stakeholders that communicates the importance of blood and increasing patient access to life-saving blood and advanced therapies. ABC joined BCAR earlier this year.

(Source: PharmaPhorum, "Why Pharma's Future May Run Through Your Local Blood Center," 12/5/25)

WORD IN WASHINGTON

The National Defense Authorization Act (NDAA) for Fiscal Year 2026 continues the blood irradiator replacement program. The House and Senate have released a bicameral compromise NDAA bill that includes language for the "[a]cceleration of replacement of cesium blood irradiation sources" with the stated goal of, "eliminating the use of blood irradiation devices in the United States that rely on cesium chloride by December 31st, 2027." The NDAA bill also includes \$500,000 in research and development funding for freeze dried platelet hemostatics. The House passed the bill last week as it is awaiting a vote in the Senate.

(Source: <u>S. 1071</u>, 12/11/25)

The U.S. Food and Drug Administration (FDA) released a communication on December 3rd noting that Tracy Beth Høeg, MD, PhD, has been appointed acting director of the Center for Drug Evaluation and Research (CDER). According to the announcement, Dr. Høeg is a, "physician and epidemiologist [who was a Visiting Scholar at the Massachusetts Institute of Technology Sloan School of Management and practiced physical and interventional spine and sports medicine before joining the FDA as senior advisor for Clinical Sciences in the Office of the Commissioner and the Center for Biologics Evaluation and Research (CBER). [She] completed her Doctor of Medicine at the Medical College of Wisconsin, Doctor of Philosophy in Public Health and Epidemiology at the University of Copenhagen, and residency at the University of California, Davis." She succeeds Richard Pazdur, MD who was appointed as director of CDER last month but has announced his intent to retire at the end of calendar year." Dr. Høeg stated in the news release, "CDER plays a crucial role in ensuring the medicines we rely on are both safe and effective. This is an incredible opportunity to serve my fellow Americans. I am committed to transparency, honesty, and decisions based on rigorous science and ensuring important changes happen efficiently. I am humbled to support the FDA's work to modernize and strengthen how we evaluate evidence so the public benefits from the best science."

(Source: FDA News Release, 12/3/25)

The Medical Technology Enterprise Consortium (MTEC) has announced a Request for Project Proposals (RPP) in support of the Defense Health Agency (DHA) in alignment with the Department of Defense (DoD) 2022 National Defense Strategy [that aims] to invest in manufacturing capabilities within the Continental United States (CONUS) as part of a greater effort to bolster the Defense Industrial Base and secure domestic supply chains." The notice explained that, "[i]n recent years, there has been a shortage of much needed blood storage bags, which is acute within the DoD system where there is a requirement for individually wrapped blood bags for use in far forward situations. The U.S. Government

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WORD IN WASHINGTON (continued from page 4)

(USG) is looking for solutions to stand up CONUS manufacturing capabilities to ensure rapid scalable blood bag production in the event of need. [The USG currently] has up to \$4 million available for the upcoming program. MTEC expects to make one or more awards for approximately \$1-3 million to a qualified Offeror(s) for an initial base period of performance (Phase I) not to exceed 12 months, but preferably six months. The Government anticipates a performance period after Phase I and continuation in subsequent stages of development not to exceed 42 months, including all proposed phases of work (Phases I, II, and III) based up[on] performance, military relevancy, and funds availability." The blood bag specifications described in the announcement are:

- "[i]ndividually wrapped single aseptic collection kit inclusive of 16-gauge donor phlebotomy needle with protection needle guard, tubing, labels, and a sample diversion pouch;
- [c]ompliant with FDA (21 CFR 864.9100), ISO 10993 and 3826, USP and MIL 810H standards and guidance1,2;
- [s]upports whole blood donor phlebotomy of 500 mL (+/-10 percent, 450-550 mL) or 450 mL (+/-10 percent, 405-495 mL);
- [c]ontains a solution of anticoagulant and preservatives meeting the USP standards that allows for storage of blood for a minimum of 21 days up to 35 days. Novel formulation will be considered based on budgetary and regulatory provisions;
- [f]oil wrapping that is easy to open requiring no tools and if practical, textured for better grip with brightly marked notches not only at the corners but also in the center of the packaging;
- [t]he manufactured bags should have a shelf life of 18-24 months at room temperature (15–30 °C);
- [a]ppropriate fatigue and distortion testing; [and]
- [a]chieve FDA clearance or exemption for the kit."

Manufacturing expected deliverables include:

- "[c]apability to manufacture no less than 10,000 standard blood donor/storage bags per year;
- [h]ave a validated surge capability plan to increase manufacture to 240,000 bags every 60 days during times of increased demand (i.e., near peer conflict or domestic disaster) for full single blood bag kits with compliant materials and processes;
- [d]emonstrate redundancy in sourcing of raw materials (e.g., anticoagulant solution, tubing, PVC, seals) from multiple vendors; and
- [d]evelop contingency plans for raw material disruptions."

Inquiries regarding the announcement can be directed here.

(Source: MTEC Announcement, 11/21/25)

The U.S. Department of Health and Human Services (HHS) is being <u>sued</u> by, "a group of organizations responsible for partnering with hospitals to facilitate the organ donation process," according to a report from *Bloomberg Law*. The publication explained in the article that, "[t]he organizations, nonprofits that obtain organs from deceased donors for transplants, alleged the agency will begin enforcing new rules starting next year that only guarantee survival of the top organizations based on competitive performance metrics. The new rules will be to the 'substantial detriment of donors, donor families, and patient candidates on the transplant waiting list,' [stated] the lawsuit filed by procurement organizations in Michigan, South Carolina, and New England."

(Source: *Bloomberg Law*, "HHS Sued by Organ Donor Nonprofits Over 'Cutthroat' Competition," 12/12/25) ♦

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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.

Registration Is Open for 2026 ABC Annual Meeting

Register and join us in Tucson, Ariz. for the 2026 America's Blood Centers (ABC) Annual Meeting! Don't miss out on being part of the conversation at this premier gathering March 9th-12th at the at the Loews Ventana Canyon Resort. Be sure to book your hotel reservation early to secure the group rate before Friday, February 13th. View the preliminary schedule as the ABC Annual Meeting unites leaders from blood centers, industry, and government, fostering connections and exploring the latest in advocacy, operations, science, medicine, quality, regulatory, and more. New in 2026, we are pleased to announce a Quality and Regulatory track! This series of sessions, developed for quality and regulatory professionals, will provide attendees with actionable insights and the opportunity to collaborate with peers facing similar challenges fostering idea and information sharing. Please contact us with any questions.

Executive Compensation Survey Results Are Available

The results of the Executive Compensation Survey are in! Authorized individuals from participating blood centers received an email on December 3rd from benchmarking@americasblood.org with instructions to access the survey data. If you participated and did not receive the results email, please contact-us. Non-participants can purchase the results by clicking here. The Executive Compensation Survey serves as a resource for blood center chief executive officers (CEOs) and their boards in setting executive salaries/benefits, as well as meeting the Internal Revenue Service (IRS) Form 990 requirements to demonstrate comparability of executive compensation.

Medical & Scientific Achievement Award Nominations Close December 15th

We are thrilled to announce the inaugural <u>ABC Medical & Scientific Achievement Award!</u> This honor will recognize and support early to mid-career medical and scientific professionals (those within 20 years of completing their training) who demonstrate outstanding leadership, innovation, and a commitment to advancing the field of blood banking and/or transfusion medicine. The ABC Medical & Scientific Achievement Award aims to foster engagement and encourage future contributions to the fields of blood banking and/or transfusion medicine. You may <u>submit a nomination or self-nominate</u> by the Monday, December 15th deadline. Eligibility criteria for nominees include:

- active in the field of blood banking and/or transfusion medicine and employed by an ABC member organization;
- demonstrated commitment to advancing the mission and values of ABC;
- demonstrated leadership in clinical, research, or operational roles; and
- must meet at least one of the following criteria:
 - o contributions to innovation, education, or advocacy in blood banking and/or transfusion medicine:
 - o engagement in mentorship or professional development activities; or
 - o evidence of impact through publications, presentations, or program development.

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INSIDE ABC (continued from 6)

The award winner will present a 1-hour lecture during the Medical & Scientific Emerging Leader Lecture-ship Session at the 2026 ABC Annual Meeting in Tucson, Ariz. on March 11th. The lecture is meant to inform, inspire, and stimulate thought-provoking conversations as well as give the awardee an opportunity to gain lecture experience and make connections with experts and peers. The recipient of this award will receive registration and travel expenses to support the opportunity to speak at the meeting. Please contact us with questions.

FINAL CALL: ABC Awards of Excellence Nominations Closing

ABC is accepting nominations for the 29th Annual Awards of Excellence. This program provides ABC members with the opportunity to offer national recognition and showcase the best and brightest in the blood donation community. This year we will recognize award winners at a lunch during the 2026 ABC Annual Meeting in Tucson, Ariz. March 9th-12th, where we can celebrate their achievements with fellow meeting attendees. Descriptions of each award are available <u>here</u>.

The following awards will be presented and are currently open for nominations:

- ABC Outstanding Blood Drive of the Year; (drive must fall between Oct. 1, 2024 Sept. 30, 2025)
- Outstanding Public Relations Campaign;
- Corporation of the Year Award; and
- Larry Frederick Award.

ABC will also present the following discretionary awards:

- William Coenen President's Award;
- Blood Community Advocate of the Year Award; and
- Thomas F. Zuck Lifetime Achievement Award (click here for a list of past winners).

The Foundation for America's Blood Centers will present:

• ITxM Award for Excellence in Technical Operations.

ABC encourages all members to take advantage of this opportunity to recognize your supporters by submitting your nominations before December 15th. We are accepting up to three nominations per category from each member blood center. Nominations will be reviewed by an independent committee. Award recipients will be announced in January 2026. Travel and hotel expenses of recipients of the ABC *Awards of Excellence* are the responsibility of the nominating blood center.

The recipient of the ITxM Award for Excellence in Technical Operations will have their expenses covered by the Foundation for America's Blood Centers. Please <u>contact us</u> with questions.

Celso Bianco Lectureship Nominations Close December 15th

The Dr. Celso Bianco Lecture Series is an endowment that funds the search, travel, lodging, and speaker fees to allow a blood banking industry expert to speak on a topic related to blood banking or transfusion medicine every year at the ABC Annual Meeting. This lecture series is an outstanding opportunity to honor the more than 40 years of Dr. Bianco's contributions and accomplishments as well as to recognize other leading blood banking and transfusion medicine experts and continue the cycle of knowledge transfer. You may submit a nomination or self-nominate by the December 15th deadline. A listing of previous lecturers is available. Please contact us with any questions.

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INSIDE ABC (continued from 7)

Submit an Abstract for the 2026 ADRP Annual Conference

The call for 2026 ADRP Annual Conference presenters <u>is open</u>! You are encouraged to please share your knowledge, insights, and expertise with ADRP's global community in Minneapolis, Minn. May 14th-16th. The submission form can be started and revisited at your convenience prior to the January 5th submission deadline. Sessions include abstract presentations and discussions (60 minutes), quick hits (25 minutes), and digital posters! Abstracts should include data and research findings, case studies, practical pilots, and innovative policy and practices. Desired topics include:

- donor recruitment, engagement, and retention;
- collaboration between blood center departments for best outcomes;
- collections: technical and operational topics;
- social media applications in blood centers/TikTok use/social interaction;
- marketing initiatives, earned media and public relations strategies;
- first-time donors;
- donor journey/donor management;
- social sciences and donor behaviors;
- artificial intelligence (AI) practices, policies, and implementations;
- industry innovations; and
- cellular therapies/biotherapies.

Please contact us with any questions.

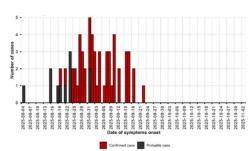
Workforce Trends Survey Report Available

ABC has published the 2025 Workforce Trends Survey Report. This resource offers deep insights into compensation, benefits, human resources policies, turnover and retention rates, and workforce trends specific to blood centers. Those ABC member blood centers who participated in the Workforce Trends Survey can purchase the report at a discounted price (code required and has been emailed to authorized individuals) of \$450 while non-participating blood centers can purchase the report at the full price of \$900. This survey combines the previous Compensation & Benefits and Employee Turnover & Retention surveys. Please contact us with questions.

INFECTIOUS DISEASES UPDATE

EBOLA

The World Health Organization (WHO) <u>announced</u> on December 1st that, "the Ministry of Health (MoH) of the Democratic Republic of the Congo (DRC) has declared the end of the Ebola virus disease (EVD) outbreak which began on September 4th." According to the communication, "[t]he end was declared after two consecutive incubation periods (a total of 42 days) since the last person confirmed with EVD tested negative for the virus and was discharged on October 19th. A total of 64 cases (53 con-



firmed, 11 probable), including 45 deaths (CFR 70.3 percent), were reported from six health areas in Bulape Health Zone, Kasai Province. WHO and partners provided technical, operational, and financial support to the government to contain the outbreak. This is the country's 16th outbreak of Ebola. Although the outbreak has been declared over, health authorities are maintaining surveillance to rapidly identify and respond to

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<u>INFECTIOUS DISEASES UPDATE</u> (continued from page 8)

any re-emergence. Risk communication and community engagement activities will continue to provide accurate information, monitor, and address community feedback and rum[o]rs, and support efforts to reduce stigma toward individuals affected by the outbreak." In September 2025, the U.S. Centers for Disease Control and Prevention (CDC) published a communication noting that the, "DRC is experiencing an outbreak of Ebola virus disease (Ebola) caused by Ebola virus (species Orthoebolavirus zairense) in Kasai Province." The CDC did not classify 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 Announcement, 12/1/25)

MEASLES

The WHO has <u>published</u> a report that, "[g]lobal immunization efforts have led to an 88 percent drop in measles deaths between 2000 and 2024. The announcement describing the report noted that, "an estimated 95,000 people, mostly children younger than 5 years of age, died due to measles in 2024. [Despite fewer deaths,] measles cases are surging worldwide, with an estimated 11 million infections in 2024, nearly 800,000 more than pre-pandemic levels in 2019." The WHO highlighted in the communication announcing the report that, "[m]easles cases in 2024 increased by 86 percent in the WHO Eastern Mediterranean Region, 47 percent in the European Region, and 42 percent in South-East Asian Region compared with 2019. Notably, the African Region experienced a 40 percent decline in cases and 50 percent decline in deaths over this period, partly due to increasing immunization coverage. While recent measles surges are occurring in countries and regions where children are less likely to die due to better nutrition and access to health care, those infected remain at risk of serious, lifelong complications such as blindness, pneumonia, and encephalitis (an infection causing brain swelling and potentially brain damage)." WHO Director General Dr Tedros Adhanom Ghebreyesus stated in the announcement, "[m]easles is the world's most contagious virus, and these data show once again how it will exploit any gap in our collective defenses against it. Measles does not respect borders, but when every child in every community is vaccinated against it, costly outbreaks can be avoided, lives can be saved, and this disease can be eliminated from entire nations." Transfusion-transmission of measles has never been demonstrated, and any risk to the blood supply is believed to be theoretical.

(Source: WHO Announcement, 11/28/25

PEOPLE



Versiti Blood Research Institute's (VBRI) **Nicole Leon** has been recognized as the 2025 Histotechnologist of the Year by the National Society of Histotechnology (NSH). According to announcement from the institute, "the award is presented to an individual who demonstrates outstanding dedication, service, and impact in the histotechnology field." Ms. Leon is VBRI's senior coordinator of the Histology Core and, joined the organization after a, "long clinical career and more than 25 years of experience in

adult and pediatric pathology." She stated in the announcement, "[i]t means a lot to see the work I've put

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PEOPLE (continued from 9)

into advancing this amazing profession be recognized. I've been very involved in the histology field and with NSH for many years, so being recognized like this is incredibly humbling." She added in the announcement, "[s]ince making the switch from clinical histology to research, I've learned so much and really enjoy diving into a whole new side of the field. On top of that, the people here at VBRI are great. The collaborative environment has been such a refreshing change of pace." The announcement also noted that, "[s]he is active in the NSH, serving as chair of the Lab Operations Committee and a member of the Program Team. Ms. Leon also serves on advisory boards for the Marshfield Clinic Histology Program and Mopec Group and is a member of the Wisconsin Histology Society." It described, "[h]istology [as] a branch of biology that studies the microscopic anatomy of biological tissues. In health care, histology is vital for detecting things like infection or cancerous cells within patient cell samples. Histotechnologists prepare tissues for microscopic examination."

(Source: VBRI Annoucement, 10/15/25)

MEMBER NEWS

At the 2025 Association for the Advancement of Blood & Biotherapies Annual Meeting, LifeSouth Community Blood Centers was recognized for shipping the most rare blood products of any blood center through ARDP (American Rare Donor Program) in 2024. LifeSouth also won this award in 2023. ARDP is an international program run through the American Red Cross that allows blood centers to request rare antigen negative blood products for patients when they are unable to be found anywhere else. LifeSouth has shipped products for patients across the U.S. as well as to New Zealand, France, and Canada. LifeSouth's investments in molecular and serologic technologies have allowed them to characterize their donor base and ensure that they are able to provide the right products for patients. LifeSouth continues to be on the forefront of testing technologies and are integrating next generation sequencing into their workflow giving them even more information about donors, allowing continued service to their communities and patients across the world.

Contributed by Brite Whitaker, Director of Communications and Outreach at LifeSouth Community Blood Centers

The Blood Connection recently announced the opening of its new Danville, Va. location "after assuming operations of the Sovah Health Blood Donor Center." According to the announcement, [t]his [fixed-site], situated in the heart of Southside Virginia, will expand donation opportunities for local donors and strengthen lifesaving support for patients at Sovah Health – Danville. A ribbon cutting ceremony took place on December 9th at the center, located at 159 Executive Drive, Suite K, Danville, Va. 24541. The Blood Connection has also announced the grand opening of a new location in Roanoke, Va. According to the organization, the donor center aims to be a, "permanent home for local blood donors serving patients throughout the Carilion Clinic network. A ribbon cutting ceremony was held on Wednesday, December 10th at the center, located at 4873 Valley View Blvd. NW, Roanoke, Va. 24012."

(Source: The Blood Connection Announcements, 12/4/25; 12/5/25)

Rock River Valley Blood Center has received a grant from the Community Foundation of Northern Illinois. The blood center is one of 90+ organizations to receive grants as part of the foundation's 2025 Community Grants Program which is awarding more than \$1.6 million cumulatively to the local community organizations. Rock River Valley Blood Center's grant will total \$13,800.

(Source: Rockford Register Star, "Organizations share \$1.63M in CFNIL community grants," 12/5/25)



GLOBAL NEWS

The World Health Organization has published a new strategic plan for, "the management of coronavirus disease threats, including COVID-19, Middle East respiratory syndrome (MERS), and potential new coronavirus diseases." The organization explained in the announcement that, "[t]his is the first such unified plan for coronavirus disease threats, marking a turning point in the transition from the COVID-19 emergency response to sustained, long-term, and integrated management." The plan aims to, "guid[e] national health authorities and partners in taking a coherent, action-oriented approach to managing coronavirus disease threats in the broader context of infectious disease management. [The strategic plan builds] on previous Strategic Preparedness and Response Plans for COVID-19 and reflects a consultative and inclusive process, drawing on input from WHO Member States, regional and country offices, technical partners, and the general public to ensure that the strategic plan is grounded in the diverse needs, priorities, and realities of health systems and communities worldwide. The plan encompasses both routine management as well as emergency scenarios, reflecting the flexibility national systems need to deal with known circulating coronaviruses and the emergence of a new coronavirus with pandemic potential. To strengthen global coronavirus monitoring, WHO has also expanded its Coronavirus Network (CoViNet), a network of disease surveillance program[s] and reference laboratories for SARS-CoV-2, MERS-CoV, and emerging coronaviruses of public health significance. CoViNet now includes 45 national reference laboratories across the human, animal, and environmental health sectors, with 11 laboratories added in 2025. CoViNet complements WHO's Global Influenza Surveillance and Response System (GISRS), which conducts global sentinel surveillance, including for SARS-CoV-2."

(Source: WHO News Release, 12/3/25)

The BBC is reporting that, "[a] landmark law to increase the number of organ donors has had little impact 10 years after it was introduced. [Wales was the first] United Kingdom (UK) nation to adopt the 'soft' opt-out legislation [in] December 2015, which presumes a person's consent to donate their organs when they die, unless they or their family have indicated otherwise. [The organ donor consent rate increased] by about 15 percent during the first three years of the opt-out law but dropped to its lowest level in a decade last year. The Covid pandemic, fewer big media campaigns, limited resources, and a possible distrust in the health service were some of the reasons provided for the reduction in recent years. [Under the legislation,] everybody is deemed to agree to organ donation after death unless they register a decision to opt-out. If a decision isn't registered, then a relative has the right to object to the 'deemed consent' rule. [According to official data,] the number of organ donations in recent months in Wales has reached its highest level since before the pandemic. [Studies of the effectiveness] of the opt-out laws in England and Wales have found the ambition of the policies have 'not had the desired impact in practice.' [Research also found that] support for organ donation in England was 20 percent lower among minority ethnic communities."

(Source: BBC, "Landmark law to increase organ donors 'has had little impact," 12/1/25)

The Chair of Parliament's Health Committee in Ghana recently stated that the country's partnership with Zipline, a medical drone delivery company that transports blood products via drones in Ghana was, "unnecessary and a mistake," reported *MyJoyOnline*. "Addressing journalists on Thursday, December 4th, Dr. Nawaane argued that the fundamental challenge facing health facilities is the lack of voluntary blood donors, not transportation constraints as previously suggested by former Vice President Dr. Mahamudu Bawumia, under whose leadership Zipline was introduced. [Dr. Nawaane explained] that the main barrier to blood availability remains the shortage of voluntary donors, which compels families, churches, and communities to be called upon when patients urgently need blood. He maintained that if health facilities were adequately equipped with cold rooms and blood storage capacity, they would be able to supply blood when needed without relying on drone delivery."

(Source: *MyJoyOnline*, "Health Committee Chair says Zipline's operations in Ghana were "unnecessary and an error," 12/4/25) ♦



COMPANY NEWS

Cerus Corp. and Blood Centers of America (BCA) are partnering to, "expan[d] access to pathogen reduction technology for platelets, plasma and pathogen reduced cryoprecipitated fibrinogen complex, commonly referred to as Intercept Fibrinogen Complex (IFC) across their blood center membership." The news release explained that, "[u]nder the terms of the agreement, ongoing production of IFC at BCA member blood centers will move under a resource-sharing model. This structure is designed to facilitate easier access to, and distribution of IFC across all BCA member blood centers and to their hospital customers. Through collaborative training and education initiatives, Cerus and BCA believe these efforts will expand awareness and adoption of pathogen reduction technologies."

(Source: Cerus Corp. News Release, 12/10/25)

Abbott and the Big Ten Conference have announced the University of Wisconsin as the winner of this year's "We Give Blood" competition. According to a company news release, the school recorded 15,476 blood donations that, "could save up to 46,428 lives. Overall donations in the competition surged 319 percent compared to 2024, marking a dramatic expansion of efforts to confront national blood shortages. In just the first 22 days of the initiative, donations surpassed last year's total as the entire Big Ten community united to strengthen the blood supply. [The initiative] ran throughout the college football season, from Aug. 27th through Dec. 5th. Donation totals were tracked live and the final results are



available at www.BigTen.Org/Abbott. Participants donated blood on campuses and at U.S. blood centers across the country and uploaded proof of donation to the campaign website or via text message to have their donation count for a Big Ten school." The University of Nebraska, the 2024 "We Give Blood" champion finished in second place, "as [the University of Wisconsin] [received] \$1 million from Abbott to advance student or community health. Overall, the conference recorded 83,043 blood donations, which could help save up to 250,000 lives in Big Ten communities and across the country," according to a news release. Abbott Chairman and Chief Executive Officer Robert B. Ford added in the announcement, "[t]his year's competition not only helped to save a record-breaking number of lives, but it also showed the power of using sports for good with all schools increasing their participation from year one. We are proud of the students, alumni, and fans who united to make a lasting impact on the blood supply, and we hope this spirit continues well beyond the season." Big Ten Conference Commissioner Tony Petitti stated in the news release, "[t]his life-saving partnership demonstrates the tremendous passion of the Big Ten community. We're proud to help activate our fans from coast-to-coast in support of such a valuable mission and excited for the opportunity to honor the University of Wisconsin during the 2025 Discover Big Ten Football Championship Game."

(Sources: Abbott News Release, 12/6/25; University of Wisconsin News Release, 12/6/25)

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COMPANY NEWS (continued from 12)

CSL has <u>shared</u> that five-year results from the phase III HOPE-B trial for its advanced therapy (Hemgenix) to treat adults with hemophilia B has been published in *The New England Journal of Medicine*. The company news release stated that, "54 adult male participants with severe or moderately severe hemophilia B, with or without preexisting AAV5 neutralizing antibodies, were infused with a single dose of Hemgenix. Of the 54 participants, 50 completed five years of follow-up. The five-year follow-up analysis demonstrated:

- [m]ean factor IX activity levels were sustained at greater than 36 percent during years one through five post-infusion: mean factor IX levels of 41.5 IU/dL (n=50) at year one, 36.7 IU/dL (n=50) at year two, 38.6 IU/dL (n=48) at year three, 37.4 IU/dL (n=47) at year four, and 36.1 IU/dL (n=48) at year five;
- [t]he mean adjusted annualized bleeding rate (ABR) for all bleeds was reduced by approximately 90 percent from the lead-in (4.16, n=54) compared to year five (0.40, n=51) post-infusion. Additionally, joint bleeds were reduced by 93 percent from lead-in (mean ABR of 2.34 at lead-in to 0.16 at year five) and spontaneous bleeds were reduced by 94 percent (mean ABR of 1.52 during lead-in versus 0.09 during year five);
- 94 percent of patients remained free of continuous prophylaxis treatment following their one-time gene therapy infusion. This rate has remained consistent over time, with only one participant resuming continuous factor IX prophylaxis at month 30 post-infusion;
- [n]o serious adverse events were related to treatment with Hemgenix. [The advanced therapy] was generally well-tolerated, with a total of 100 treatment-related adverse events (TRAEs), most of which occurred in the first four months post-infusion. Only five TRAEs were reported between years four and five. The most common adverse events were an increase in alanine transaminase (ALT), for which nine (16.7 percent) participants received supportive care with reactive corticosteroids for a mean duration of 81.4 days (standard deviation: 28.6; range: 51-130 days).

[Hemgenix] has received regulatory approval in the United States, Canada, the UK, Switzerland, Australia, Saudi Arabia, Taiwan, South Korea, Singapore, and Hong Kong, and conditional marketing authorization from the European Commission (EC) for the European Union and European Economic Area."

(Source: CSL News Release, 12/7/25)

Beam Therapeutics has reported new safety and efficacy data from an ongoing clinical trial of its investigational advanced therapy ristoglogene autogetemcel (risto-cel), formerly known as BEAM-101, to treat patients with sickle cell disease (SCD) with severe vaso-occlusive crises (VOCs). The company noted that, "[a]s of an August 6th data cut-off, a total of 31 patients with severe SCD were treated with risto-cel in the BEACON Phase I/II trial and are included in the safety and efficacy analysis. Follow-up ranged from 0.3 to 20.4 months. [Risto-cel's efficient cell collection] and manufacturing processes combined with high, predictable yields from base editing resulted in patients requiring few stem cell collection cycles and total collection days to manufacture riots-cel. Patients required a median of 1 (range: 1-5) stem cell collection cycle, comprising a median of 3 (range: 1–13) total collection days for the risto-cel manufacturing process and back-up cell collection. Patients achieved rapid and robust bone marrow reconstitution post-risto-cel treatment. The median time to neutrophil engraftment was 17.5 days (range: 12-30), with a median duration of severe neutropenia of seven days (range: 1-17). The median time to platelet engraftment was 19 days (range: 11-53). In addition, 29 percent of patients did not require any platelet transfusions following ristocel treatment. No patients experienced any investigator-reported severe VOCs post-engraftment. Durable, high editing efficiency was observed in peripheral blood and bone marrow following treatment with ristocel. Mean peripheral blood editing was 67.4 percent at month six and 72.8 percent by month 12. Consistent with data presented at EHA2025, patients achieved mean HbF levels above 60 percent and a mean durable



COMPANY NEWS (continued from 13)

reduction in corresponding HbS below 40 percent. A pancellular distribution of HbF, reflecting expression across most of the circulating red blood cells, was observed, with mean per-cell HbF levels maintained above the sickling threshold throughout follow-up. Total Hb levels increased rapidly with all patients experiencing resolution of anemia after elimination of the transfused blood. Key markers of hemolysis, including indirect bilirubin, haptoglobin, lactate dehydrogenase, and reticulocytes, normalized or improved in all patients following risto-cel treatment. Erythropoietin levels also trended toward normal, indicating significant improvement in oxygen delivery to tissues. Sickling parameters all decreased in the blood following risto-cel treatment to levels comparable to that seen in individuals with sickle cell trait. The safety profile of risto-cel was consistent with busulfan conditioning, autologous HSCT and underlying SCD. The most common treatment-emergent adverse events were consistent with busulfan conditioning, including stomatitis, febrile neutropenia, and decreased appetite. As previously reported, one patient died four months after risto-cel infusion due to respiratory failure that was determined by the investigator to be likely related to busulfan conditioning and deemed unrelated to risto-cel."

(Source: Beam Therapeutics News Release, 12/6/25)

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.)

2026

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

Feb. 17-19. Administration for Strategic Preparedness and Response's Biomedical Advanced Research and Development Authority (BARDA), Radiological and Nuclear Medical Countermeasures Program, in collaboration with the Defense Health Agency (DHA), Research and Engineering, Combat Casualty Care Portfolio and the Medical Technology Enterprise Consortium (MTEC) Platelet and Platelet-like Products State of the Technology Meeting. Washington, DC. Registration is open. More information is available here.

Mar. 9-12. 2026 ABC Annual Meeting. Tucson, Ariz. Registration is open. More information is available here.

May 12-14. **2026 ADRP Annual Conference. Minneapolis, Minn.** Registration is open. More information is available here.

June 8-9. 2026 ABC Advocacy Workshop. Washington, D.C. More information is coming soon.

June 20-24. International Society of Blood Transfusion (ISBT) 39th International Congress. Kuala Lumpur, Malaysia. Registration is open. More information available here.

Oct. 4-7. American Association of Tissue Banks (AATB) Annual Meeting. San Francisco, Calf. More information available here.

Oct. 17-19. Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Atlanta, Ga. More information is coming soon.

Nov. 17-20. American Society for Clinical Pathology (ASCP) and Canadian Association of Pathologists- Association Canadienne des Pathologistes (CAP-ACP) Joint Annual Meeting. Montreal, QC. Registration is open. More information available here.

ABC Newsletter -15- December 15, 2025

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

Director of Hospital Services (Fresno, CA). This position is a senior leadership role responsible for overseeing the manufacturing, distribution, testing, and coordination of quality blood products and services to hospital partners. This role is responsible for ensuring hospital partners have access to quality products and services in a 24/7 capacity. This leadership position is responsible for guaranteeing products and services are following all regulatory requirements designed to create and maintain a safe blood supply through the management and oversight of three separate and distinct business units. For more information, go to: https://talent.paylocity.com/Talent/Jobs/Details/3539641. The deadline to apply is Friday, January 16, 2026.

Medical Laboratory Technologist (MEDIC Regional Blood Center - Knoxville, TN). We are seeking a highly skilled and detail-oriented Medical Laboratory Technologist to join our reference laboratory team. The ideal candidate will possess extensive experience in clinical laboratory procedures, laboratory management, and advanced diagnostic techniques. This role offers an exciting opportunity to contribute to cutting-edge research, clinical trials, and patient diagnostics by performing precise laboratory tests and ensuring the integrity of specimen processing. The successful applicant will demonstrate strong data management skills, proficiency in various laboratory techniques, and a thorough understanding of medical terminology and physiology. Essential Duties & Responsibilities: Operate and maintain laboratory equipment in a safe, clean, and orderly manner. Perform routine and special laboratory procedures for testing blood products, including but not limited to donor testing, quality control testing, component preparation, suitability of returned components, screening for antigen-negative blood, and labeling of blood components. Perform as a batch review and release technologist to verify the acceptability of blood products for transfusion and manufacturing use. Required: Medical Technologist license valid in TN. Bachelor's degree in a related field. Preferred: Minimum of two years of blood banking experience. Next Steps: If you would like to apply, please click here.

Reference Lab Supervisor. OneBlood is currently recruiting for a Lab Supervisor in our AABB-Accredited Immunohematology Reference Laboratory in Orlando, FL. This position provides leadership and technical expertise, coordinates workflow and staff scheduling, and performs training and quality activities for the staff responsible for performing basic through advanced testing procedures on patient and/or donor samples. Applicants

must have a bachelor's degree in medical technology, biological science or related scientific field from an accredited college or university. Three or more years in a clinical laboratory, preferably blood banking environment, or an equivalent combination of education, certification, training, and/or experience. Applicants must have a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Florida Supervisor license and SBB certification preferred. To apply and view a complete Job Description of this position, go to www.oneblood.org and click on the Careers tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Chief Scientific Officer. A national search is underway to recruit a recognized executive with exceptional vision and leadership abilities to become the next Chief Scientific Officer (CSO) of Gulf Coast Blood, headquartered in Houston, Texas. Reporting to the CEO, the CSO serves as the senior medical and scientific leader of Gulf Coast Blood. They are responsible for ensuring the highest standards in quality, clinical and operational excellence, and innovation across all laboratory and blood services, in addition to ensuring compliance with regulatory and accreditation standards. As a physician and strategic thought leader, the CSO drives the organization's quality and continuous improvement agenda while also serving as the medical expert to advise on future investments in the blood research investment fund which will advance translational initiatives. The CSO also oversees the scientific coordination of research partnerships, leads the medical advisory committee, serves as a part of the diligence team, and champions laboratory strategy and performance. This role is instrumental in aligning operational excellence with a forward-looking research and innovation agenda that supports the mission to save and sustain lives. To be considered for the role, inquiries, nominations, and applications (detailed CV for now) should be submitted electronically in confidence, to: charlotte.fredericks@kornferry.com.

Laboratory Testing Manager (Fresno, CA). The Laboratory Testing Manager will assist in managing and maintaining the day-to-day activities of all Laboratory Testing, including staff assets. The Laboratory Testing Manager will need to use their experience and judgment to ensure all quality control mechanisms in the laboratory comply with blood bank cGMP, FDA, CLIA, California Department of Health, and AABB regulations and standards. Must be comfortable in a fast-paced, dynamic team

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POSITIONS (continued from page 15)

environment. The testing manager will report directly to the Director of Hospital Services and will collaborate with teams across the organization to ensure Laboratory Testing excellence in supplying and distributing safe blood products with the utmost quality and fiscal integrity. Persons filling this position are responsible for the oversight of outsourced testing, product quality control testing, and patient testing. Please click here to view the full job description and apply. The deadline to apply is Friday, December 12, 2025.

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

Regional Director - Donor Operations. OneBlood seeks an experienced leader to direct all donor blood collection operations in Jacksonville, FL, ensuring compliance with regulatory and accreditation standards. This position oversees managers and supervisors, drives recruitment and collection goals, and works across departments to maintain a safe, sufficient blood supply. Responsibilities include improving operational processes, managing budgets and resources, and contributing to strategic planning to meet regional blood demands. Qualifications: Bachelor's degree required and 10+ years of management experience in a related field (or equivalent combination of education and experience). Strong leadership, analytical, and communication skills. Ability to travel up to 50 percent. We offer competitive salary, medical, dental, vision, life, and short/long-term disability programs to qualified employees. Paid time off (PTO) and a 403b program are also available. Join our life-saving Mission and apply here.

Associate Medical Director/Medical Director. 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.