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A N D URRENT EVENTS TRENDS IN BLOOD

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2025 #25

August 11, 2025

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#### Vinay Prasad, MD, MPH Returns to CBER Director Role



After resigning on July 29th, Vinay Prasad, MD, MPH has decided to resume his role as director of the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER). A spokesperson at the U.S. Department of Health and Human Services (HHS) told STAT News in a statement, "[a]t the FDA's request, Dr. Vinay Prasad is resuming leadership of the Center for Biologics Evaluation and Research." The publication added that it was, "not clear if Dr. Prasad will also serve as FDA's Chief Med-

ical and Scientific Officer," a role that he also held prior to his resignation.

As CBER Director, Dr. Prasad will, "supervise the FDA's work regulating biological products for human use under applicable federal laws." He previously served as a, "professor at The University of California at San Francisco in the Department of Epidemiology and Biostatistics [and] a professor of Medicine in the Division of Medical Oncology and the Department of Public Health and Preventive Medicine at Oregon Health & Science University. His specialty is hematology and oncology. Before entering academia, Dr. Prasad had a fellowship in Cancer Prevention at the National Cancer Institute and prior to that he was a fellow in Oncology at the National Institutes of Health. Dr. Prasad graduated from Michigan State University with a Bachelor of Science in Physiology and Philosophy. He received his medical degree from the University of Chicago Division of Biological Sciences Pritzker School of Medicine, with an internship and residency in Internal Medicine at Northwestern University, and a Master of Public Health from the Johns Hopkins University Bloomberg School of Public Health."

George Tidmarsh, MD, PhD, director of the Center for Drug Evaluation and Research (CDER) at FDA, had been serving as CBER's Acting Director.

(Source: STAT News, "Vinay Prasad returns to the FDA, weeks after his ouster," 8/9/25)



## In Vitro Quality of Blood Concentrates Stored in DEHT vs. DEHP Blood Bags Explored in Vox Sanguinis

A paper published in *Vox Sanguinis* examined, "the *in vitro* quality of red blood cell concentrates (RCCs) produced from whole blood (WB) collected in di(2-ethylhexyl) terephthalate (DEHT)/phosphate-adenine-glucose-guanosine-saline-mannitol (PAGGSM) bag sets" as an alternative to di(2-ethylhexyl) phthalate (DEHP)/saline-adenine-glucose-mannitol (SAGM) sets. The study included, "500-mL DEHP/SAGM (n = 37) and prototype 475-mL DEHT/PAGGSM (n = 29) blood bag sets [compared] in independent study arms." The authors explained that, [a]lthough the current DEHP/SAGM bags used at Canadian Blood Services have a 500-mL volume, the prototype DEHT/PAGGSM bags had a 475-mL volume, chosen to better align with our 480-mL nominal WB collection volume. *In vitro* quality of leu[k]oreduced RCCs (LR-RCCs) post-expiry was the main outcome assessed."

The study found that, "[a]t expiry, there was no statistically significant difference in supernatant  $K^+$  levels between DEHP/SAGM and DEHT/PAGGSM RCCs (47.8 ± 4.7 mmol/L and 48.8 ± 3.7 mmol/L, respectively; p = 0.346). DEHT/PAGGSM RCCs had slightly higher mean h[e]molysis levels at expiry; however, this difference was not statistically significant (0.29 percent ± 0.10 percent in DEHP/SAGM vs. 0.33 percent  $\pm$  0.12 percent in DEHT/PAGGSM; p = 0.083). There was statistically significantly higher free Fe<sup>2+</sup> in DEHT/PAGGSM units at Day 43 (5.7  $\pm$  1.1  $\mu$ mol/L in DEHP/SAGM and 8.4  $\pm$  1.9 in DEHT/PAGGSM; p < 0.001). Overall, the expected metabolic changes with RBC storage lesion were observed in both arms; however, there were some differences between arms. Adenosine triphosphate (ATP) was statistically significantly higher at Day 43 in DEHT/PAGGSM RCCs compared to DEHP/SAGM RCCs  $(3.23 \pm 0.58 \,\mu\text{mol/gHb})$  and  $2.83 \pm 0.5 \,\mu\text{mol/gHb}$ , respectively; p = 0.004;). Supernatant glucose levels were statistically significantly lower in DEHT/PAGGSM versus DEHP/SAGM RCCs at expiry  $(15.4 \pm 1.7 \text{ mmol/L})$  and  $18.1 \pm 2.3 \text{ mmol/L}$ , respectively; p < 0.001), despite PAGGSM having a higher level of starting glucose. There was no difference in supernatant lactate levels between DEHT/PAGGSM and DEHP/SAGM RCCs at expiry  $(23.6 \pm 2.4 \text{ mmol/L})$  and  $23.5 \pm 2.8 \text{ mmol/L}$ , respectively; p = 0.976;). Lorrca analysis indicated that DEHT/PAGGSM RBCs are less deformable than DEHP/SAGM RBCs (maximum elongation index [EI<sub>MAX</sub>];  $0.581 \pm 0.015$  and  $0.611 \pm 0.010$ , respectively; p < 0.001) and require larger amounts of force ( $K_{EI}$ ) to physically deform (2.300 ± 0.288 and 1.834 ± 0.177, respectively; p < 0.001). Osmoscan analysis revealed osmotic fragility differences between DEHP/SAGM and DEHT/PAGGSM RBCs. O<sub>min</sub>, O<sub>hyper</sub>, O<sub>max</sub> and ΔO are all lower in DEHT/PAGGSM, suggesting an overall shift in the osmolality curve to the left (all p < 0.001)."

The researchers concluded that, "our study findings reiterate the need to focus research on DEHP alternatives on impacts to the red blood cell (RBC) membrane, with interrogation of h[e]molysis, microvesicle release, membrane composition, morphology, deformability and osmotic fragility likely to shed the most light on how RBC products will look in a DEHP-free future." Limitations of the study included, "it was not a pool and split study design and did not address changes in the additive solution and plasticizer separately; [t]here was a higher proportion of male donors in the study, not reflective of Canadian Blood Services usually balanced male/female donor ratio; while the study was conducted using nominal processing conditions, such as temperatures and processing times, the approach taken was to conduct the study closer to the 'worst case for quality' of these nominal conditions (e.g., processing closer to the end of the allowable time ranges, if feasible). Therefore, the results of this study may skew towards a worst-case scenario for product quality, something that may be viewed as a study limitation, but also a potential strength."

Citation: Stephenson, T., Howell, A., Olafson, C. et al. "In vitro quality of whole blood-derived red cell concentrates collected, processed and stored in a blood bag set plasticized with di (2-ethylhexyl) terephthalate." Vox Sanguinis. 2025. ◆

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#### WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) issued a statement from FDA Commissioner Marty Makary, MD, MPH indicating that shortages of intravenous (IV) saline solutions have been resolved. "I am pleased to announce that the nationwide shortage of sodium chloride 0.9 percent injection products, a form of intravenous (IV) saline, has officially ended." The statement noted that, "[t]his success is the result of close collaboration between the FDA, the Administration for Strategic Preparedness and Response (ASPR), and our industry partners, who worked swiftly and strategically to expand manufacturing capacity and restore stability to the supply chain. Their responsiveness and innovation have been vital to this achievement. In addition, the FDA used its available regulatory tools to help increase supplies available to hospitals to help meet patient needs. For example, the FDA conducted scientific and regulatory assessments to help facilitate the temporary importation of intravenous solutions and expedited reviews to increase manufacturing capacities and extend product expiry. The shortage of sodium chloride 0.9 percent injection products has resolved, and therefore these products will be removed from the FDA list of Current Shortages in the Drug Shortage Database on the FDA website. We generally recommend hospitals, health systems, and clinics use the FDA-approved drug when available...The availability of reliable medical products is essential to patient care and the overall resilience of our healthcare system. Addressing this shortage has been a top priority for the FDA and aligns with the Trump Administration's broader commitment to strengthening the U.S. drug and medical supply chain. The FDA remains focused on doing all we can to help mitigate shortages and prevent them from occurring."

(Source: FDA Statement, 8/8/25)

The U.S. Department of Health and Human Services (HHS) has announced that the agency has started, "a coordinated wind-down of its mRNA vaccine development activities under the Biomedical Advanced Research and Development Authority (BARDA), including the cancellation and de-scoping of various contracts and solicitations. The decision follows a comprehensive review of mRNA-related investments initiated during the COVID-19 public health emergency." In the HHS statement, HHS Secretary Robert F. Kennedy, Jr. explained specifically that, "BARDA is terminating 22 mRNA vaccine development investments because the data show these vaccines fail to protect effectively against upper respiratory infections like COVID and flu. We're shifting that funding toward safer, broader vaccine platforms that remain effective even as viruses mutate." The agency also noted that, "[t]he move signals a broader shift in federal vaccine development priorities. Going forward, BARDA will focus on platforms with stronger safety records and transparent clinical and manufacturing data practices. Technologies that were funded during the emergency phase but failed to meet current scientific standards will be phased out in favor of evidence-based, ethically grounded solutions — like whole-virus vaccines and novel platforms." Secretary Kennedy added in the announcement, "[let me be absolutely clear: HHS supports safe, effective vaccines for every American who wants them. That's why we're moving beyond the limitations of mRNA and investing in better solutions."

(Source: HHS Statement, 8/5/25) •

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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.

#### **America's Blood Centers**

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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.

### Register for the ABC WELC Webinar: "Recommitting to Transformative Leadership: A WELC Community Experience"

Join us for the America's Blood Centers (ABC) Women's Executive Leadership Community (WELC) Webinar: "Recommitting to Transformative Leadership: A WELC Community Experience" taking place on Tuesday, August 26<sup>th</sup> at 2 p.m. EDT. This virtual event will reignite your leadership journey with a powerful reconnection to the core principles that have shaped your growth. The engaging and interactive session will help you revisit key themes from past WELC webinars — Authentic Leadership, Lessons from Leadership, Taming the Tyranny of the Urgent, and The Art of Listening and Facilitation. Attendees will be able to choose a breakout room focused on the topic that resonates most. Dive deep into meaningful conversations with fellow members of WELC, share how you're working to integrate these concepts into your daily life, and brainstorm ways to overcome roadblocks. Additional information a link to registration are available to ABC members here.

#### **ABC Workforce Trends Survey Opens**

ABC has launched its Workforce Trends Survey. 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. We encourage all members to participate. The survey analyzes overall trends in compensation, benefits, and human resources (HR) policies and provides specific data for 74 different blood center employee roles. It 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. The survey combines the previous Compensation & Benefits and Employee Turnover & Retention surveys. Please contact us with any questions or to add/change authorized individuals. This survey closes on August 31st.

#### **ABC Offers Stop the Bleed Virtual Trainings for Members**

ABC is pleased to announce an opportunity to help certify ABC members as Stop the Bleed Trainers. As part of a national <u>partnership</u> between ABC and Stop the Bleed, ABC will host three virtual training sessions taking place on:

- August 12<sup>th</sup> at 4 p.m. EDT; and
- August 21st at 2 p.m. EDT.

Registration is open to ABC members. Additional information and links to register for the training are available <a href="https://example.com/hem2">here</a>. During these training sessions, Stop the Bleed Senior Manager Jimm Dodd, MPAS, MA, U.S. Army (Ret.), will spend the first 30 minutes covering new marketing resources available to blood centers. He will also discuss the rollout of a new Stop the Bleed portal, including instructions for logging into the portal, navigating the system, and guidance through the instructor registration process, before leading a training session. Participants are asked to complete the <a href="https://energiance.com/online-pre-training-activity">online-pre-training-activity</a> prior to attending a virtual session. Please <a href="https://energiance.com/online-pre-training-activity">contact us</a> with questions.

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**INSIDE ABC** (continued from 4)

#### Register for the SMT Journal Club Webinar on August 29th

Registration is open for the next ABC Scientific, Medical, and Technical (SMT) Journal Club webinar on August 29<sup>th</sup> at 12 p.m. EDT. The webinar is complimentary for all ABC members as this virtual event will review two scientific/medical articles followed by open discussion by participants, presenters, and article authors. The articles to be reviewed are listed below:

- Fatal hemolytic disease of the newborn due to anti-B isohemagglutinin: An unfamiliar presentation of a familiar disease (*Transfusion*); and
- Food and inhaled allergens may play a more prominent role in allergic transfusion reactions than previously recognized (*Transfusion*).

A Continuing Medical Education (CME) credit (1.0) is now offered for all ABC SMT Journal Club webinars upon completion of the activity and evaluation. Additional information and a link to registration are available to ABC members <u>here</u>. Please <u>contact us</u> with any questions.

## Registration Is Open for the August ADRP Webinar: "Building Lifesavers: Internal Preparedness and External Engagement for High School Donors"

Register for the Wednesday, August 27th at 1 p.m. EDT titled: "Building Lifesavers: Internal Preparedness and External Engagement for High School Donors." Don't miss the chance to explore insights and tips for, "educating and empowering both internal team members as well as external partners in the high school blood donation journey. Learn how to enhance staff readiness, support coordinators, and guide young donors through the process with confidence." The webinar also will feature a review of ABC's & ADRP's Vein to Vein program, a powerful tool to enrich donor education and engagement. Please contact us with questions.

### Full Schedule Available for 2025 ADRP Master Class September 24th-25th

Register for the 2025 ADRP Master Class taking place September 24th-25th. The complete two-day schedule has now been released. This year's theme is "Building Brighter Experiences: Empowering Customers, Engaging Employees." See why you should attend. In today's competitive market, organizations that prioritize both employee and customer experience gain a significant edge. A motivated and engaged workforce leads to improved customer interactions, higher satisfaction, and long-term brand loyalty. The customer experience starts with the employee experience. Don't miss keynote speakers Janice Honeycutt Hering and Dave Murray help attendees identify the components of a culture that promotes satisfaction and engagement, while discussing and sharing insights for taking small steps to make your donor experience the most significant competitive advantage for your organization. Please contact us with questions.

#### SAVE THE DATE: ABC WELC Rise & Lead Workshop November 13th-14th



ABC is excited to announce that the 2025 ABC Women's Executive Leadership Community (WELC) <u>Rise & Lead Workshop</u> will take place November 13th-14th in San Antonio, Texas at the Westin Riverwalk. <u>Book now</u> to secure

the discounted rate. Registration will open this month. This workshop is designed for women in leadership positions, emerging leaders, and professionals seeking personal and professional growth. It also welcomes individuals who want to cultivate diverse perspectives. Attendees will engage in an intimate, engaging, and interactive environment focused on networking, mentorship, and meaningful discussions on leadership and growth. Please contact us with questions.

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#### **INFECTIOUS DISEASE UPDATES**

#### **DENGUE**

The European Centre for Disease Prevention and Control (ECDC) published a <u>report</u> on August 5<sup>th</sup> describing "deferral criteria and testing strategies for dengue virus in blood donors returning from affected areas." The report is based on survey results to, "support discussions with the ECDC network on substances of human origin (SoHO-Net) [from a ECDC survey of members] of the SoHO-Net blood group on the donor assessment and deferral strategies for blood donors in the European Union/European Economic Area (EU/EEA) countries with regard to dengue virus." Key findings include:

- "[w]hile 91 percent of the responding EU/EEA countries have deferral criteria for blood donors returning from dengue-endemic areas, only 55 percent have specific criteria for those returning from affected non-endemic areas within the EU/EEA;
- [f]or countries that defer donors returning from endemic countries or affected areas in non-endemic countries, the deferral period is consistently 28 days. For donors with a confirmed dengue diagnosis, the deferral period is reported as 120 days;
- [d]ifferent trigger criteria are used to implement safety measures for prospective donors returning from affected areas with local dengue outbreaks in EU countries. Five countries implement safety measures when there is at least one locally-acquired case in an area with an active cluster of dengue, while six countries implement measures on a case-by-case basis;
- [d]eferral of prospective donors who have travelled to a dengue affected area is the most commonly used blood safety measure for prevention of transfusion-transmitted dengue. Nucleic Acid Testing (NAT) for dengue is rarely reported as a screening tool; [and]
- [t]here is no standardi[z]ed definition for the geographical scope of an 'affected area' for local dengue outbreaks in EU countries, with risk levels being applied at the country, regional, or municipal level by different Member States.

The report concluded that, "[t]he increasing frequency and size of autochthonous dengue outbreaks in EU/EEA countries presents an emerging challenge for blood safety. Safety measures reported by EU/EEA countries generally address trave[l]ers returning from endemic countries outside the EU and only a few countries report measures for trave[l]ers returning from affected areas in non-endemic countries."

(Source: ECDC Report, 8/5/25)

#### **BABESIOSIS**

A brief report to be published in *Open Forum Infectious Diseases* highlights the "Increasing Length of the Babesia Season in New England in the Climate Change Era." The authors noted that they, "performed a retrospective chart review of adults (age ≥18 years) presenting with babesiosis as a primary diagnosis to three teaching hospitals in Boston, Massachusetts (Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, and Massachusetts General Hospital) between May 1<sup>st</sup>, 1993 and May 1<sup>st</sup>, 2024...Of the 1,130 cases, 986 were probably acquired in Massachusetts, 43 in New Hampshire, 25 in Rhode Island, eight in Maine, six in Connecticut, and one in Vermont. Sixty-one patients reported recent travel to or residence in two or more New England states. In a generalized linear model, Babesia diagnoses showed a strong correlation with each unit increase in time (year), corresponding to an annual growth in cases of 14.2 percent (95 percent confidence interval [CI], 13.1-15.2 percent). The model had similar results with the addition of state of Babesia acquisition as a fixed effect, with an annual rise in cases of 14.2 percent (95 percent CI, 13.2 percent to 15.3 percent). Cases continued to follow a marked seasonal pattern, with most patients reporting symptom onset in June and July, but the probability of cases in other months increased significantly over time. In a generalized linear model, the number of months in which symptom onset occurs increased by one month every three years (0.33 months per year, CI 0.27 to 0.39). The mean number of

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#### <u>INFECTIOUS DISEASE UPDATES</u> (continued from 6)

months of the active season for *Babesia microti* rose from 2.2 before 2000 to 9.2 after 2015. In 2023, it was 11 months long." The brief report concluded that, "we observed a significant expansion of the babesiosis season in the past 31 years, with the mean number of months per year with cases rising from 2.2 before 2000 to 9.2 after 2015. Possible explanations include diminished die-offs of blacklegged ticks during warmer winters, more rapid tick maturation in warm conditions, greater activity of adult ticks during winter warm spells, expansion of the active season for nymph forms into early spring and late fall, expanding populations and improving winter survival of tick hosts, and increased use of immunosuppressive agents such as anti-CD20 monoclonal antibodies in patients with latent Babesia infection. In endemic areas, babesiosis should be suspected in all patients presenting with fever and anemia, even during winter months."

Citation: Ross, J. Carlile, N., Ard, K.L. "Brief Report: Increasing Length of the Babesia Season in New England in the Climate Change Era." Open Forum Infectious Diseases. 2025. ▶

#### **RESEARCH IN BRIEF**

Influence of Donor's Sex on Neonates' Outcomes. A study in Vox Sanguinis, "aimed to assess the association between red blood cell (RBC) donor sex and certain clinical outcomes in very low birth weight (VLBW) (<1,500 g) infants." The authors wrote that, "[a] retrospective observational cohort of infants admitted to Mater Mothers' Hospital Neonatal Critical Care Unit between January 2016 and December 2022 who received at least one RBC transfusion was studied." They explained that, "[t]ransfusion component numbers were used to link to donor self-reported gender and donation collection date from the Australian Red Cross Lifeblood's donor records. [Outcomes of interest] included diagnosis of bronchopulmonary dysplasia (BPD), necrotizing enterocolitis (NEC), retinopathy of prematurity (ROP), late-onset infection, or death. Additionally, weight for gestational age centile and Clinical Risk Index for Babies (CRIB) II score (a mortality prediction score calculated at birth) were calculated." The paper reported that, "[f]ollowing exclusions, 394 neonates who received a total of 820 group O-negative transfusions, from 605 donors, were included for analysis. All transfusions were administered within the first 16 weeks of life (median = 3.5, interquartile range [IQR] = 3.5) and by 44 weeks corrected gestation (median = 30 weeks, 0 days, IQR = 4 weeks, 4 days). A median of two RBC components were transfused per neonate (range 1-6). A majority (68.2 percent) of transfused components had been collected from male blood donors, and the median time from donation to transfusion was 3.7 days (IQR = 1.8). When categorized, 184 neonates received a total of 310 transfusions that had been collected from only male donors, whereas 66 neonates received a total of 80 transfusions that had been collected from only female donors." The researchers discovered that, "[n]o statistically significant association was found between blood donor sex and the risk of any of the outcomes in each model. Furthermore, additional analyses were conducted for severe ROP (\geqreg Stage 3) and a composite outcome comprising diagnoses of BPD, NEC, ROP, or death. In both cases, there was no statistically significant association with RBCs donated from a specific gender." The authors concluded that their, "findings support the continued practice of restrictive use of RBC transfusions in Australian VLBW neonates, without consideration of the sex of the donor from whom the component was collected."

Citation: Jacko, G., Sivakaanthan, A., Cunningham, P., et al. "Exploring the influence of blood donor sex on outcomes in Australian very low birth weight infants." Vox Sanguinis. 2025.

Contributed by Richard Gammon, MD

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#### **MEMBER NEWS**

**Gulf Coast Blood** has <u>announced</u> that its newest donor center is open, as of August 11<sup>th</sup>, across the street from its headquarters. According to a blog post on the blood center's website, the new facility, known as Gulf Coast Blood – The Medical Center, is 15,000 square feet and features:

- "up to 13 beds for whole blood and apheresis donations;
- a zero-gravity massage chair to help you relax after donating;
- a donor massage bed to keep you comfortable during your visit;
- a Bevi Smart water dispenser to keep you hydrated;
- covered parking with direct access to the Donor Room; [and]
- a new artificial intelligence (AI) assistant kiosk, Teagan, ready to answer your questions and guide your experience."

(Source: Gulf Coast Blood Announcement, 8/6/25)

Blood Assurance and the Commonwealth Transfusion Foundation (CTF) recently announced that the their specialist in blood banking program (SBB) has received, "national accreditation from the Commission on Accreditation of Allied Health Education Programs (CAAHEP)." According to a CTF news release, the Commonwealth Transfusion Foundation SBB Program at Blood Assurance, "is one of just 13 accredited Specialist in Blood Banking programs in the nation, recognized for meeting rigorous standards in education and training for professionals in transfusion medicine." Liz Culler, MD, president and chief executive officer (CEO) of Blood Assurance added in the news release, "[r]eceiving this accreditation is a tremendous honor and a testament to the strength of our program. It reflects the dedication of our team, the quality of our curriculum, and the commitment to excellence that defines our students. This recognition enhances the value of their education and helps prepare them to become leaders in the field." The news release also noted that, "[t]he SBB program was created through a strong partnership between CTF and Blood Assurance to address the growing need for highly trained blood bank professionals. With a generous \$450,000 grant over three years from CTF, the program was launched and will be sustained. This transformative funding not only made the program possible but also provides full scholarships for five students — three from Virginia and two from the Blood Assurance service area — to attend at no cost. The grant underscores CTF's deep commitment to strengthening the transfusion medicine workforce and expanding access to advanced education."

(Source: CTF News Release, 8/7/25)



LifeSouth Community Blood Centers and HCA Florida North Florida Hospital recently <u>celebrated</u> the unveiling of a commemorative plaque honoring umbilical cord blood donation and the mothers who made the decision to donate their baby's cord blood to LifeSouth Cord Blood Bank. The plaque represents 138 patients across the U.S. and the world who received a cord blood transplant collected at HCA Florida North Florida Hospital. LifeSouth is grateful to the doctors, nurses, and practitioners for their dedication to cord blood donation as many more patients will continue to benefit from this lifesaving gift. "Our

partnership with HCA Florida North Florida Hospital began over 50 years ago, providing life-saving blood to their patients, and continues with cord blood donation and the impact it can have to patients suffering from many diseases," said Kim Kinsell, JD, MBA, president and CEO of LifeSouth Community Blood Centers and president of America's Blood Centers. "Each cord blood donation matters and is an opportunity

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#### MEMBER NEWS (continued from 8)

for a mother to give the gift of life, which is not possible without dedication of doctors who collect cord blood and understand the life-saving significance of the donation."

(Source: LifeSouth Community Blood Centers Announcement, 8/6/25

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

#### **GLOBAL NEWS**

The United Kingdom (UK) has <u>published</u> data from its annual Serious Hazards of Transfusion (SHOT) Report. This is the annual United Kingdom (UK) hemovigilance report that describes transfusion-related adverse events across the UK. Key takeaways from the available data include:

- "[e]rrors continue to account for the majority of reports. In 2024, 3,322/3,998 (83.1 percent) of all reports (including near miss (NM) and right blood right patient (RBRP)), and 70.8 percent of incidents excluding NM and RBRP were due to errors;
- [t]here were no confirmed or probable transfusion-transmitted infections reported in 2024;
- [t]he risk of death related to transfusion in the UK is one in approximately 37,000 components issued, and the risk of serious harm is approximately one in 11,500 components issued (includes solvent detergent-treated fresh frozen plasma (SD-FFP) data) based on the reports submitted to SHOT;
- [t]ransfusion-related deaths reported to SHOT have almost doubled in 2024;
- [t]here were no deaths which were definitely related (imputability 3) to transfusion in 2024;
- [p]ulmonary complications and transfusion delays were the main causes of reported transfusion-related deaths in 2024;
- [t]here has been a steep rise in deaths due to transfusion-associated circulatory overload (TACO);
- [n]ear miss events continue to account for a large proportion, 1,408/3,998 (35.2 percent) of the incidents reported to SHOT;
- [i]nadequate staffing, lack of appropriate training, suboptimal supervision and poor safety culture continue to be identified as contributory factors to numerous incidents reported to SHOT;
- [t]rends in pathological transfusion reactions, like the febrile, allergic, hypotensive, and h[e]molytic reactions are similar to previous years; [and]
- [i]t is encouraging to see a reduction in the ABO-incompatible (ABOi) red cell transfusions reported. However, ABOi plasma component transfusions continue to be reported: these were mainly due to component selection errors in the laboratory."

Previous SHOT Reports can be accessed <a href="here">here</a>. "Since 1996 SHOT has been collecting and analy[z]ing anonymi[z]ed information on adverse events and reactions in blood transfusion from all healthcare organi[z]ations that are involved in the transfusion of blood and blood components in the UK. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. The recommendations are put into its annual report, which is then circulated widely and to all of the reporting hospitals. As h[e]movigilance is an ongoing exercise, SHOT can also monitor the effect of the implementation of its recommendations."

(Source: UK 2024 SHOT Report, 8/1/25)

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#### GLOBAL NEWS (continued from 9)

A research letter published in JAMA Network Open described the results of a study performed from July 1st to September 15th, 2024 by the French public transfusion service following the implementation of West Nile virus (WNV) nucleic acid testing (NAT), "for blood donations collected in areas where the virus circulated in the previous years. Four departments in the South of France were included: Bouches-du-Rhône, Gard, Hérault, and Var. Notably, Bouches-du-Rhône and Gard include the Camargue region, a vast wetland with an important staging point for migratory birds." The implementation took place during the period of the Olympic Games in France. The researchers reported that, "[f]rom all departments combined, there were approximately 56,000 blood donations. In the Var department, the first human WNV case was detected on week 29 through blood donation testing, two weeks before the first detection of WNV in equine and mosquito excreta and three weeks before the first human symptomatic case. In this department, a total of 24 human cases were reported, including 23 in a 100-km<sup>2</sup> area (10 people with [neurological disease], nine with WNV fever, five with asymptomatic infection). In Camargue, the first signal indicating WNV circulation was also observed among blood donors on week 34 in the Gard department, two weeks before the detection of the first symptomatic human case. A total of 10 symptomatic human cases (nine people with WNV fever, one person with [neurological disease]) and 73 equine cases were reported. The virus was also detected in mosquito traps." Additionally, the research letter noted that, "[t]he preventive blood donation nucleic acid testing strategy used during the Olympic Games allowed active surveillance for early WNV detection in humans. In areas with the highest number of human cases, the first WNV detection was through blood donation screening, occurring before the detection of symptomatic cases. Notably, in the Var department, detection in the blood donor with infection was two weeks before the appearance of equine, bird, and mosquito cases." The researchers acknowledged a limitation of the study being that, "most blood donors live in urban areas, which may not represent the most exposed population. To improve our national WNV human surveillance system and enable early preventive measures to avoid transmissions by substances of human origin, a strategy that combines systematic WNV screening in symptomatic cases with nucleic acid testing in blood donors in high-risk areas may be relevant. The place, cost, and benefits of implementing WNV nucleic acid screening of blood donations integrated in One Health surveillance should be assessed."

Citation: Grard, G., Franke, F, Laperche, S., et al. "Blood Donation Screening and West Nile Virus Surveillance Strategy in France." JAMA Network Open. 2025

NHS Blood and Transplant, the national blood provider for England and transplant services for the UK, recently partnered with Marvel Television's Ironheart to raise awareness of the need for blood donations from "Black heritage communities." An organization announcement stated that, "Dominique Thorne, who plays Riri Williams — a genius young inventor focused on creating something 'iconic' — is joined by Anthony Ramos, who portrays Parker Robbins aka 'The Hood,' an enigmatic figure



who appreciates Riri's talent. Together, they urge viewers to do something extraordinary and give blood...The message goes on to highlight the urgent need for more Black heritage donors, whose ethnically matched blood holds the key to improving and saving the lives of Black heritage patients needing transfusions." Owen Dommel, director of Marketing Partnerships for UK & Europe, the Middle East and Africa (EMEA) Studios at The Walt Disney Company, added in the announcement, "Ironheart is a story about courage, innovation, and building a legacy — values that align perfectly with NHSBT's mission. At Disney, we believe in the power of storytelling, and building on our prior collaborations for Marvel titles with

#### GLOBAL NEWS (continued from 10)

NHSBT, we hope this latest campaign encourages a new generation of fans to become heroes in their own right by giving blood and saving lives." Previous NHSBT partnerships with Marvel have included *Free Guy* in 2021, *Doctor Strange in the Multiverse of Madness*, *Black Panther: Wakanda Forever* in 2022, and *Deadpool & Wolverine* in 2024.

(Source: NHSBT <u>Announcement</u>, 7/4/25) ♦

#### **COMPANY NEWS**

The U.S. Food and Drug Administration (FDA) has <u>removed</u> the safety hold on **Valneva**'s Chikungunya vaccine (Ixchiq). An August 7<sup>th</sup> update published by the agency explained that, "[a]t the time of the May 9<sup>th</sup>, recommended pause, FDA conveyed its intention to conduct an updated benefit-risk assessment for the use of Ixchiq in individuals 60 years of age and older. FDA has completed an updated benefit-risk assessment of Ixchiq, including for use in individuals 18 years of age and older. Based on the available data, and its benefit-risk assessment, FDA has removed the recommended pause in the use of Ixchiq in individuals 60 years of age and older and has approved updates to the <u>Prescribing Information</u> and Patient Information that it required of the company, Valneva Austria GmbH." The FDA also added that, "Ixchiq contains a live, weakened version of the chikungunya virus and may cause symptoms similar to those of chikungunya disease. Some of the postmarketing reports include adverse events that are consistent with severe complications of chikungunya disease, resulting in hospitalization; one person died from encephalitis. Continuous monitoring and assessment of the safety of all vaccines remains an FDA priority."

(Source: FDA Safety Communication Update, 8/7/25)



Photo courtesy of DroneLife.

A report in *DroneLife* stated that **ParaZero** recently, "successfully concluded tests in which it completed 50 consecutive deliveries of blood and supplies, proving the system's reliability for use in real-life operations." According to the publication, "[t]he system, which ParaZero developed in conjunction with the Israeli Ministry of Defense, is currently being used by Israeli Defense Forces (IDF). [The system is designed for the drone to hover] "as high as 600 feet above the target [before it releases] the package, [which] free fall[s] for a specified [period] before the parachute system is deployed, to keep it from being carried away

from the target by the wind. Then a small parachute will get deployed, which pulls out a larger chute that slows the package's descent and lessens the force of impact on the ground." Amir Lavi, head of Marketing at ParaZero told *DroneLife*, "we minimize the drift in any sort of weather condition [through the design of the system.] We don't miss the target, but we also minimize the impact energy to such a level that the blood can endure."

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#### **CALENDAR**

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

#### 2025

August 12. America's Blood Centers (ABC) Stop the Bleed Training Session (Virtual). A link to registration and more information are available to ABC members <a href="here">here</a>.

August 21. **ABC Stop the Bleed Training Session (Virtual).** A link to registration and more information are available to ABC members here.

August 26. ABC Women's Executive Leadership Community (WELC) Webinar: Recommitting to Transformative Leadership: A WELC Community Experience (Virtual). A link to registration and more information are available to ABC members here.

August 29. **ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar.** A link to registration and more information are available to ABC members <a href="here">here</a>.

Sept. 10-12. 6th European Conference on Donor Health and Management (ECDHM). Wijk aan Zee, the Netherlands. Registration is open. More information available here.

Sept. 17-19. 58<sup>th</sup> Annual Conference of the German Society for Transfusion Medicine and Immunohematology (DGTI). Manheim, Germany. Registration is open. More information is available here.

Sept. 24-25. 2025 ADRP Master Class: "Building Brighter Experiences: Empowering Customers, Engaging Employees" (Virtual). Registration is open. More information is available here.

Sept. 28. U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Public Listening Meeting: "Leveraging Knowledge for Facilitating the Development and Review of Cell and Gene Therapies" (Virtual). Registration is open. More information is available here.

Sept. 30-Oct. 1. 3<sup>rd</sup> Annual European Blood Alliance (EBA) and the International Society of Blood Transfusion (ISBT) Rare Blood Provision Workshop. Bilbao, Spain. Registration is open. More information is available here.

Oct. 12-15. American Association of Tissue Banks (AATB) Annual Meeting. Atlanta, Ga. Registration is open. More information available <a href="here">here</a>.

Oct. 14-15. International Protein Forum. Old Town Alexandria, Va. Registration is open. More information is available here.

Oct. 25-28. AABB Annual Meeting. San Diego, Calif. Registration is open. More information is available here.

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

Nov. 12. 2025 ADRP International Showcase. More information is coming soon.

Nov. 13-14. 2025 ABC Women's Executive Leadership Community (WELC) Rise & Lead Workshop. More information available here.

Nov. 13-14. EBA Benchmarking Workshop. Amsterdam, Netherlands. More information is coming soon.

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

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#### <u>CALENDAR</u> (continued from page 12)

2026

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

Mar. 9-12. 2026 ABC Annual Meeting. Tucson, Ariz. More information is coming soon.

May 12-14. 2026 ADRP Annual Conference. Minneapolis, Minn. 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: <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a>

#### **POSITIONS**

Director of Recruitment. For over 75 years, SunCoast Blood Centers has been the region's nonprofit community blood bank and the exclusive supplier of blood products to local hospitals. Located on Florida's beautiful Treasure Coast, we are committed to saving lives, advancing research, and supporting the health of our community. Take the lead in shaping the future of donor recruitment at SunCoast Blood Centers. Oversee our Contact Center, Mobile Recruitment, and Concierge Program teams, developing bold, innovative strategies that not only meet but surpass our blood collection goals. This high-impact role requires a Bachelor's degree (Master's preferred), 5+ years in recruitment or related fields with at least 3 years in leadership, and exceptional skills in leadership, public speaking, and project management. Click here to apply.

Clinical Services Apheresis LPN. For over 75 years, SunCoast Blood Centers has been the region's nonprofit community blood bank and the exclusive supplier of blood products to local hospitals. Located on Florida's beautiful Treasure Coast, we are committed to saving lives, advancing research, and supporting the health of our community. Join our Clinical Services and Research team in Sarasota and play a vital role in patient care and medical advancement. In this specialized position, you'll perform therapeutic apheresis procedures for hospital patients and contribute to groundbreaking research collections. Candidates must hold a current Florida LPN with IV certification, have 1–2 years of hospital patient care experience, and demonstrate proven expertise in apheresis. Click <a href="https://example.com/heresis/h

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.

Director of Technical Services (LIFELINE Blood Services). The Director of Technical Services manages and supervises technical staff including laboratory, distribution, and components. The Director of Technical Services must meet the regulatory responsibilities and demonstrate active involvement in the laboratory's operation and be available to the laboratory staff onsite, phone, or electronic consultation. The Director of Technical Services is responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel. Even though there is the option to delegate some responsibilities, the Director is ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met. It is the responsibility of the Director of Technical Services to ensure that your laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable test results. Refer to Code of Federal Regulations Title 42 Part 493, Laboratory Requirements. Education: Medical Technologist with Bachelor's Degree in Medical Technology or chemical, physical, or biological science. Individual must hold a Current State of Tennessee Supervisor License. A Specialist in Blood Bank (SBB) certification is preferred.

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#### **POSITIONS** (continued from page 13)

Experience: Five years of experience as a working Medical Technologist. Three years of Management or Supervisory experience. as a Specialist in Blood Bank preferred. Has a working knowledge of cGMP, AABB, CLIA and CFR blood banking requirements. Click <a href="https://example.com/here-to-view-th-example.com/h

Lead Quality Control Specialist. Gulf Coast Blood is seeking a Lead Quality Control Specialist! This key role supports quality assurance by preparing and testing blood component samples to ensure safety and effectiveness for patients and hospitals throughout the Texas Gulf Coast region. It's ideal for detail-driven individuals who uphold high standards and contribute meaningfully to patient outcomes. Showcase your expertise by performing advanced quality control testing, managing lab operations in the absence of supervisors, and responding to critical situations such as positive bacterial cultures. You'll initiate recall procedures, track and trend QC results, train new hires, coordinate workflow, and recommend process improvements, all while ensuring compliance with lab standards and supporting patient safety. Why join us? We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. Qualifications: MT/MLS certification (ASCP or equivalent) with at least two years of hematology experience. Flow cytometry experience is a plus. This role operates Monday through Friday, 7:00 AM to 3:00 PM. If you embody integrity, commitment, and respect, apply now and help make a difference!

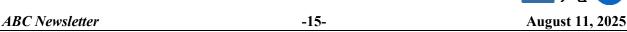
Consultation & Reference Lab Tech III - Weekend Shift. Gulf Coast Blood is seeking a Consultation & Reference Lab Tech III - Weekend Shift! This key role supports advanced testing and preparation of special blood components for patients and donors, serving over 170 hospitals across the Texas Gulf Coast region. Ideal for detail-oriented professionals who value precision, quality, and meaningful community impact. Showcase your expertise by performing advanced antibody identification, compatibility testing, and donor serological testing to support life-saving transfusions. You'll prepare consultation reports, process sample requests, maintain specialized blood component inventory, perform quality control, and ensure compliance with all lab standards, directly impacting patient care. Why join us? We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign-on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. Qualifications: MT/MLS certification (ASCP or equivalent) and at least two years of recent blood banking experience. New graduates are also encouraged to

apply. This full-time role operates Friday through Sunday, from 7:00 a.m. to 7:00 p.m. If you embody integrity, commitment, and respect, we encourage you to <a href="mailto:apply-now">apply now</a> and help make a difference!

Consultation & Reference Lab Tech III - Night Shift. Gulf Coast Blood is seeking a Consultation & Reference Lab Tech III - Night Shift! This key role supports advanced testing and preparation of special blood components for patients and donors, serving over 170 hospitals across the Texas Gulf Coast region. Ideal for detail-oriented professionals who value precision, quality, and meaningful community impact. Showcase your expertise by performing advanced antibody identification, compatibility testing, and donor serological testing to support life-saving transfusions. You'll prepare consultation reports, process sample requests, maintain specialized blood component inventory, perform quality control, and ensure compliance with all lab standards, directly impacting patient care. Why join us? We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign-on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. Qualifications: MT/MLS certification (ASCP or equivalent) and at least two years of recent blood banking experience. New graduates are also encouraged to apply. This position operates Wednesday through Saturday, 10:00 p.m. to 8:00 a.m. If you embody integrity, commitment, and respect, we encourage you to apply now and help make a difference!

Consultation & Reference Lab Tech III – Evening Shift. Gulf Coast Blood is seeking a Consultation & Reference Lab Tech III - Evening Shift! This key role supports advanced testing and preparation of special blood components for patients and donors, serving over 170 hospitals across the Texas Gulf Coast region. Ideal for detail-oriented professionals who value precision, quality, and meaningful community impact. Showcase your expertise by performing advanced antibody identification, compatibility testing, and donor serological testing to support life-saving transfusions. You'll prepare consultation reports, process sample requests, maintain specialized blood component inventory, perform quality control, and ensure compliance with all lab standards, directly impacting patient care. Why join us? We offer a competitive salary, full benefits, free parking at the Texas Medical Center, and opportunities for a sign-on bonus and relocation assistance to support a smooth transition. Enjoy professional development and career advancement opportunities while making a meaningful difference every day. Qualifications: MT/MLS certification (ASCP

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#### POSITIONS (continued from page 14)

or equivalent) and at least two years of recent blood banking experience. New graduates are also encouraged to apply. This full-time role operates from Sunday through Wednesday, 11:00 AM to 9:00 PM. If you embody integrity, commitment, and respect, we encourage you to apply now and help make a difference!

Manager, Regional Development. Be part of something bigger; change the world with us by joining ImpactLife's team. We are seeking a Manager, Regional Development, to lead donor engagement and blood drive development efforts across Central Illinois. In this key leadership role, you'll guide a dynamic regional team in growing our mission to connect donors and patients through life-saving blood collections. This role requires direct supervision of a regional team. This position can be located at our Peoria, Springfield, or Urbana, Illinois locations. For more information including job details, benefits, and compensation click here: Change the World With Us.

Cell Therapy Technologist (Carter BloodCare). The Cell Therapy Technologist 1 (CTT1) participates in activities in the Cellular Therapy Laboratory. These activities include, but may not be limited to, cellular therapy (CT) processing, performing and troubleshooting quality control of reagents and equipment, participating in educational instruction of students and new employees, familiarity and full compliance with all CT and general laboratory regulations, and participating in design and implementation of new methodology for processing CT products. A CTT1 ensures daily operations within the department meet and follow all established guidelines and provide excellence in service and patient care. Ability to work a flexible schedule, long and/or odd hours with little notice. Regular full-time attendance is required during normal working hours. This position requires a valid driver's license. Education: MT (ASCP), MLS(ASCP) or equivalent, or eligible with certification obtained within 90 days of hire. Bachelor of Science Degree in Clinical Laboratory Science, Medical Laboratory Science, Medical Technology, or a related field in laboratory science. Experience: Minimum of one year of experience as an MT/MLS. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job Cell Therapy Tech or Cell Therapy Technologist.

Instructor - Phlebotomy (Carter BloodCare). Under the direction of the Education Coordinator, the Instructor is responsible for the training and continuing education of the Collection Services staff in all procedures involved in the blood collection process (i.e., medical history, donor lookup, phlebotomy, quality control, apheresis, CPR). This position ensures trainees receive applicable clinical experience, safely perform all required skills, and successfully complete competency testing. The Instructor plans for and guides the learning process to help students achieve the objectives required within the allotted time. This position maintains open communication with supervisory staff and informs them of employee progress. This position creates schedules, inputs data, and runs reports. Adequate transportation is necessary to travel to and from all donor centers/mobile drives to perform competency evaluations and retraining in a timely and efficient manner. This position adheres to all regulations and requirements set forth by the Food and Drug Administration (FDA), American Association of Blood Banks (AABB), CBC, and departmental policies and procedures. This position must be available to work any shift, including nights and weekends. Regular full-time attendance is required during normal working hours. Education: High School Diploma or equivalent. Experience: Six (6) months of supervisory experience required. Minimum of one year of blood banking, preferred. Six (6) months of apheresis experience, preferred. Teaching experience (professional and informal), preferred. Equal Oppor-Employer: Disability/Veteran. www.carterbloodcare.org, click Careers & search for job **#49098. ♦**