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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #17 **May 10, 2024**

INSIDE:

Please Note: The *ABC Newsletter* will not be published on May 17th. We will resume regular publication on May. 24th. Thank you for your continued interest.

BPAC Discusses Strategies to Reduce Risk of Transfusion-transmitted Malaria

The U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) met on Thursday, May 9th to discuss, "proposed strategies to reduce the risk of transfusion-transmitted malaria (TTM) by testing blood donations from donors at risk of malaria exposure." The committee focused their discussions on commenting on:

- FDA's proposed strategies for selectively testing blood donations from donors at risk for malaria using an FDA-licensed nucleic acid test (NAT):
  - Strategy 1A: Selective testing for history of malaria, history of prior residence in malaria-endemic country, history of travel to a malaria-endemic area;
  - Strategy 1B: One-time testing of all donors and selective testing for history of malaria and history of travel to a malaria-endemic area; [and]
- FDA's proposal that blood establishments should implement time-limited NAT screening of all donations collected in area(s) of the U.S. when a single case of local mosquito-borne malaria is reported by public health authorities."

The meeting featured experts from the Centers for Disease Control and Prevention (CDC), FDA's Center for Biologics Evaluation and Research's (CBER) Office of Blood Research and Review (OBRR), the OBRR Division of Emerging and Transfusion Transmitted Diseases (DETTD), and Roche Diagnostics Solutions presenting on topics that included the surveillance and epidemiology of malaria; local malaria outbreaks in the U.S.; transfusion-transmitted malaria in the U.S.; the scientific rationale regarding FDA's proposed measures to mitigate TTM risk in the U.S; donor characteristics and clinical presentation of TTM; the potential impact of malaria risk deferrals on donor availability; NAT to screen blood donors for malaria risk; molecular testing for of asymptomatic *Plasmodium* infections; describing FDA's regulatory framework for blood safety against TTM; and discussing the pro and cons of the proposed selective testing strategies.

During the public hearing portion of the meeting, America's Blood Centers (ABC) Chief Medical Officer Jed Gorlin, MD, MBA addressed the committee explaining that, "ABC recommends delaying publication of a draft guidance on malaria testing, until real world modeling studies help determine the clinical sensitivity of available

(continued on page 2)

BPAC Discusses Strategies to Reduce Risk of Transfusion-transmitted Malaria (continued from page 1)

tests in specific donor populations. Virtually all U.S. cases of transfusion-transmitted malaria in the last two decades were from asymptomatic donors originally from endemic countries. Those individuals are known to have relatively low levels of parasitemia relative to symptomatic cases, so we have concerns whether the assay sensitivity is sufficient. While clinical studies may not be feasible, we recommend waiting for completion of modeling studies demonstrating adequate clinical sensitivity, as well as the approval of more than one test prior to issuing guidance."

Dr. Gorlin also stated that, "we [agree] with FDA that universal testing at this time would be quite cost-ineffective…ABC recommends that FDA maintain allowing the current deferral options given the fact that [only] been 13 cases in the last 21 years in over 200,000,000 donations. We recommend they allow current deferral options while also allowing for a selective testing strategy to qualify a donation after returning to the U.S. following a short incubation period for individuals who traveled to an endemic country but who were not prior residents of a malaria-endemic country." He concluded by noting that, "given the recent cases of autochthonous malaria in Florida and other states at our southern borders, ABC supports the potential for testing strategy for donations in regions with local, mosquito-borne malaria transmission, but recommends having a higher minimum threshold than a single case for triggering testing determined through the recommended modeling studies."

During the committee discussion, the FDA addressed concerns it received in public comments about the performance of the Roche cobas® Malaria NAT. The agency approved a biologics license application (BLA) from Roche for the malaria test in March but the test is not commercially available yet. CBER explained that from the data presented, the arguments being used in public comments calling into question its sensitivity, "are flawed. From the data that we have, we believe the test would be sensitive and has proven sensitive [in cases of TTM] where the donor was called back and performed less sensitive PCR tests that were still positive. For those reasons, although admittedly it is indirect, we believe there is more evidence to support that the test will work to detect asymptomatic parasitemia than it won't work."

Additionally, babesia was not seen as a good example or comparable to malaria. Another potential limitation of Strategy 1B was identified with the three-month interval following travel to an endemic area and asymptomatic donors, while residents of an endemic area are being tested at every donation. It was acknowledged that three-months might not be the correct interval for consideration for testing following re-exposure to a malaria-endemic area. However, it was stated by CBER that, Strategy 1B, "picks up more of what we know is causing the cases of TTM to make it through." It was also noted that, while additional modeling is beneficial, it could prove challenging with such low malaria numbers in the U.S.

(continued on page 3)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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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BPAC Discusses Strategies to Reduce Risk of Transfusion-transmitted Malaria (continued from page 2)

The committee also discussed a single case of malaria being the trigger for implementation of time-limited NAT screening of all donations collected in areas where public health authorities report mosquito-borne malaria. Multiple committee members identified the challenges with the single-case trigger. A suggestion was made that rather than a specific trigger, FDA instead has the discretion to decide on local screening in consultation with CDC and local jurisdictions. Also, a question was raised regarding how long time-limited NAT would continue.

CBER officials thanked the committee for their discussion, the presenters and those individuals who made public comments for their participation. The agency will review the feedback received as they work on the next steps. A recording of the meeting is available.

ABC previously submitted written comments to the FDA ahead of the BPAC meeting that "strongly recommended" that the agency delay publishing draft guidance until modeling studies are finished and additional malaria testing assays are approved and available. "Prior to publication of a draft guidance on malaria testing, real world modeling studies should be performed to determine the sensitivity of available tests, including studies performed in malaria-endemic locations and including data on semi-immune donor populations." The comments specified that, "there is currently only one malaria test approved for screening of the blood supply. As FDA knows, this raises concerns about the blood supply's reliance on a single test. Without an alternative, supply chain challenges could cripple the blood supply." 🩸

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) have announced a final guidance, "to provide the medical device industry clarity on the definition of 'remanufacturing' for reusable devices needing maintenance or repair. According to an agency news release, "[t]he final guidance seeks to ensure that there is consistency regarding what constitutes remanufacturing activities and to promote a better understanding of applicable federal law and regulations implicated by remanufacturing activities. The final guidance was issued following the agency's extensive review of postmarket information and consideration of public comments, which highlighted the need for clarity, considering the different regulatory implications between 'servicing' and 'remanufacturing' of a medical device." The guidance would apply to changes with blood establishment computer systems (BECS), as well as other devices in blood establishments (e.g., apheresis devices). A final rule was published in May 2018 specific to BECS, which classified BECS and BECS accessories into class II devices, which are covered by the guidance. Section VII of the "Remanufacturing of Medical Devices" guidance specifies changes involving software, and lists "certain activities performed on software that are likely not remanufacturing." Devices that are intended to be reused and maintained (not reprocessed single-use devices) are also be covered by the guidance. Regulations related to medical devices and products used in establishments that manufacture blood and blood products are available here.

(Sources: FDA News Release, 5/9/24; FDA Guidance, 5/9/24;)

Contributed by Justine Coffey, JD, LLM, Director of Regulatory Affairs and Public Policy at ABC

An April 26th communication from the FDA titled, "Important Information for Human Cell, Tissue, and Cellular and Tissue-based Product (HCT/P) Establishments Regarding the Recall of Certain Saline and Sterile Water Medical Products by Nurse Assist," has been issued, "advising establishments that manufacture human cells, tissues and cellular and tissue-based products (HCT/Ps) about a recall of products that may have been used in manufacturing HCT/Ps." The recall covers 0.9 percent Sodium Chloride Irrigation USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1,000 mL bottles, 3.1oz

(continued on page 4)

REGULATORY NEWS (continued from page 3)

spray can, 7.1oz spray can, 3 mL syringes, 5 mL syringes, and 10mL syringes), and Sterile Water for Irrigation USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1,000 mL bottles, 120 mL cups, 10 mL syringes, and 30 mL syringes). These products may not be sterile and might be contaminated with bacteria.

(Source: FDA Communication, 4/26/24)

The FDA has published data regarding HCT/P inspections conducted in fiscal years 2019 through 2023. The number of FDA inspections increased to 445 in 2023, the highest amount since 563 in 2019. The inspections are categorized as:

- "NAI = no action indicated, meaning no objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further action);
- VAI = voluntary action indicated, meaning objectionable conditions were found and documented but the agency is not prepared to take or recommend regulatory action.; [or]
- OAI = official action indicated, meaning objectionable conditions were found and regulatory action should be recommended."

Of those inspections that took place in 2023, 350 were classified as NAI, 93 as VAI, and two as OAI.

(Source: FDA Communication, 5/7/24)

STATE ADVOCACY BRIEFS

Louisiana has introduced a bill regarding consent to donate. The legislation would repeal the provision of the Louisiana State code allowing minors to consent and donate blood. Current state law allows, "a minor to give consent to the donation of [blood] and to the penetration of tissue necessary to accomplish such donation if certain criteria are satisfied [including]:

- [t]he minor has reached the age of sixteen years and the written consent of the parents, legal guardian, or person who has legal authority to consent on behalf of the minor has been obtained; [or]
- [t]he minor has reached the age of seventeen years. The consent of the parents or guardian of a minor who has reached the age of seventeen years shall not be required."

(Source: Louisiana House Bill 975, 4/25/24)

A bill has been introduced in Ohio that would, "remove the criminal offense related to donating blood when the donor is a carrier of the virus that causes AIDS." The law was passed before the implementation of nucleic acid testing.

(Source: Ohio House Bill 498, 4//22/24)

Pennsylvania has passed a law relating to plasma. The legislation, Act No. 6 of 2024, removes state requirements that exceed federal laws related to source plasma donation centers, eliminating obstacles and encouraging source plasma centers to operate effectively.

(Source: Pennsylvania Act No. 6 of 2024, 5/1/24)

WORD IN WASHINGTON

The U.S. Government Accountability Office (GAO) published a May 2nd report titled "Public Health Preparedness: U.S. Department of Health and Human Services (HHS) Should Address Strategic National Stockpile Coordination Challenges." The report examined, "the Strategic National Stockpile (SNS) resources provided to jurisdictions; challenges jurisdictions faced in accessing SNS assets during two recent emergencies; and jurisdictional and tribal SNS coordination issues that might affect future responses." Based on the findings, the GAO made recommendations that the Assistant Secretary for Preparedness and Response should:

- "work with CDC to clearly define ASPR's and CDC's roles and responsibilities related to the SNS in a formal document and share that document with jurisdictions;
- develop standard operating procedures, outlining how and when guidance documents, such as those for requesting and receiving SNS assets, are updated. Consistent with GAO's Standards for Internal Control, these standard operating procedures should include internal review processes, opportunities for stakeholder feedback, and timeframes for updating; [and]
- formally designate an entity—such as the Office of SLTT Preparedness—to regularly engage with Tribes and relevant stakeholders to (1) assess the unique challenges, such as infrastructure and geography, that could affect the delivery of SNS assets to Tribes during future emergencies and (2) develop options for how to address those challenges."

(Source: GAO Report, 5/2/24)

The Biomedical Advanced Research and Development Authority (BARDA) has announced the launch of the, "first two hubs of the next generation of the BARDA Accelerator Network (BAN): the Diagnostics and Medical Devices Hub and the Therapeutics and Vaccines Hub." According to the agency news release, "the International Consortium for Research, Engineering, Acceleration of Technology Excellence (I-CREATE) will serve as the BAN Diagnostics/Medical Devices Hub. [It] will support the development and acceleration of game-changing diagnostics and medical devices to detect, prevent, or respond to medical consequences that result from health security threats. The Vaccine Innovation and Therapeutic Acceleration Launchpad (VITAL) Hub will serve as the BAN Therapeutics/Vaccines Hub. [It will] support the development and acceleration of next-generation therapeutic and vaccine platforms and technologies. This next-generation BAN is built based on the experience with the first iteration of the Network and the lessons learned from the COVID-19 pandemic regarding the importance of agile and scalable mechanisms to support innovation. Together these five hubs will enable BARDA to foster the growth of the innovation ecosystem and partner with entrepreneurs, innovators, and companies to develop adaptable, scalable, sustainable, accessible, and equitable health security solutions."

(Source: BARDA News Release, 5/6/24)

MEMBER NEWS

South Texas Blood & Tissue is celebrating its 50th anniversary this year. According to a report in the *Victoria Advocate*, "[t]he organization started 1974 as the South Texas Regional Blood Bank with only 12 employees in San Antonio, Texas, but also opened its first branch outside of San Antonio here in Victoria that same year…In May 1974, the organization held its first blood drive in San Antonio and was able to collect over 28,000 units of blood that year." Roger Ruiz of South Texas Blood & Tissue added in the article, "[w]e've come so far in those 50 years from not only collecting blood, but what we've grown into. So, the possibilities of what we can do for the next few years are endless, and we look forward to serving our communities and as they grow."

(Source: *Victoria Advocate*, "South Texas Blood and Tissue Celebrates 50 years," 5/5/24"

RECENT REVIEWS

The Oxygen Extraction Ratio Guides Transfusions. A narrative review published in *Transfusion Medicine Reviews*, "uses four studies to explore the oxygen extraction ratio (O_2ER) — the ratio of consumed oxygen to delivered oxygen in a tissue bed — as a more physiologically relevant indicator for guiding red blood cell (RBC) transfusions in patients with moderate anemia." The reviewers explained that the authors of the first study, "recruited 62 intensive care unit (ICU) patients with moderate-to-severe anemia." The study results suggested that, "abnormally low mixed venous oxygen saturation (SvO_2) may identify increased O_2ER and therefore identify patients with moderate anemia who will benefit from an RBC transfusion." The review noted that, "[o]ptimizing SvO_2 is an endpoint in Early Goal-Directed Therapy (EGDT), a protocol-based approach to sepsis treatment." The second study included in the review was a, "retrospective, cohort study of 572 patients treated with a uniform EGDT protocol across 21 hospitals." The findings of that study suggested that, "[e]levated O_2ER in moderate anemia may not only indicate transfusion responsiveness but selectively identify patients whose chances of living are improved with RBCs." The reviewers noted that, "[though the] results [of the second study] are fragile: there were only 13 in-hospital deaths among the 71 patients [transfused], so the statistical significance of the results may rest on a single outcome…Nonetheless, [this study] provid[es] evidence that using O_2ER to guide RBC transfusion in moderate anemia may reduce in-hospital mortality." The third study included in the review was, "a prospective, observational cohort study in 177 hemodynamically-stable ICU patients with hemoglobin concentration 7 – 10 g/dL." The reviewers explained that, "the patients were classified as 'appropriately' transfused if O_2ER was >0.29, or if O_2ER was ≤0.29 and they did not receive RBCs. The authors of that study found that, 'appropriately' managed patients had lower 90-day mortality than 'inappropriately' managed patients (OR 0.44, p = 0.02)." The reviewers also noted that this, "study suggests that using O_2ER identifies patients with compromised oxygen delivery and does so with enough accuracy to improve outcomes and optimize blood utilization." The final study featured in the review, "recruited eight healthy, adult, male[s], and used a commercially available digit cuff with a pulse oximetry (PPG) sensor placed distally. Venous blood gases were drawn [for comparison.]" The reviewers explained that, "the estimated noninvasive venous saturation ($SpvO_2$) correlated strongly with the invasively measured peripheral SvO_2 ($r^2 = 0.95$)." They added that, "the results provide proof of concept for noninvasive O_2ER measurement." The review concluded that, "using the oxygen extraction ratio appears to improve the accuracy of transfusion decision-making, particularly in patients with moderate anemia, or a hemoglobin between 7-10 g/dL. Although currently limited to patients with invasive venous access, technology exists that could make O_2ER measurable noninvasively and cheaply at the bedside."

Citation: Hess, A.S. "Oxygen Extraction Ratios to Guide Red Blood Cell Transfusion." *Transfusion Medicine Reviews*, 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

NEW on Coll*ABO*rate

COLLABORATE

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Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Trima Kit Issue (MEMBER RESOURCES)
- ACP 215 Washed RBC QC (MEMBER RESOURCES)
- Product Testing (MEDICAL ISSUES)
- Phlebotomy Start Times (COLLECTIONS & DONOR SERVICES)
- Reconstituted RBCs (TECHNICAL DIRECTORS)
- 2 Door Blood Storage Fridge and Temperature Monitoring (TECHNICAL DIRECTORS)
- BacT Alert Temp Range (TECHNICAL DIRECTORS)

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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.

ADRP Marketing Survey Launches

ADRP, The Association for Blood Donor Professionals has launched the first-ever ADRP Marketing Survey to serve as a tool to enhance your blood center's marketing strategy. The anonymized data from this resource can be used to benchmark your blood center's marketing spend and marketing activities to your peers. This survey will also provide participants with key information and insights to drive future decision-making including:

- appointment acquisitions and donor retention;
- spend allocation through various marketing channels; and
- paid advertising, donor incentives, and social media activity.

The deadline to complete the survey is June 14th. Only blood centers who participate in the survey will receive a report of the survey findings. Data is always anonymized, and no raw data will be provided. ADRP recommends that your marketing team complete this brief survey. A webinar will be hosted by ADRP in July to review the findings and key insights. Please contact us with any questions.

Still Time to Register for 2024 ADRP Annual Conference

Time is running out to register for the 2024 ADRP Annul Conference. The schedule is available! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that do not exist, and Candy Whirley, a recognized motivational speaker, leadership, and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Please contact us with questions.

Upcoming ABC Webinars & Virtual Events – Don't Miss Out!

- **ABC Body Interact Training Webinar** – May 22nd. A link to registration and more information available to ABC members in MCN 24-033.
- **ABC Blood Advocacy Week Partners Briefing** – May 29th. A link to registration and more information available to ABC members in MCN 24-034.
- **ADRP Master Class** – Sept.18th-19th. Registration is open. More information available here.

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ADRP The Association for Blood Donor Professionals

GLOBAL NEWS

The European Commission (EC) recently announced that the European Parliament has adopted, "new rules to increase the safety and quality of substances of human origin (SoHO)." The regulation explains that, "[t]he use of financial incentives for SoHO donations can have an impact on the quality and safety of SoHO, posing risks to the health of both SoHO donors and recipients and therefore to the protection of human health. Without affecting the responsibilities of the Member States for the definition of their health policy, and for the organization and delivery of health services and medical care, SoHO donation should be voluntary and unpaid, and be founded on the principles of altruism of the SoHO donor and solidarity between donor and recipient." However the regulation does allow for compensation that fits the definition of financial neutrality, "compensation to remove any such risk is deemed appropriate as long as it endeavors to guarantee financial neutrality and does not result in a financial gain for the SoHO donor or constitute an incentive that would cause a SoHO donor to not disclose relevant aspects of their medical or behavioral history or to donate in any way that could pose risks to their own health and to that of prospective recipients, in particular by donating more frequently than is allowed. It should be possible for compensation to consist of the reimbursement of expenses incurred in connection with SoHO donation or of making good of any losses, preferably based on quantifiable criteria, associated with the donation of SoHO. Whatever the form of compensation, including through financial and nonfinancial means, compensation schemes should not result in competition between SoHO entities for SoHO donors, including cross-border competition and in particular between SoHO entities collecting SoHO for different purposes, such as the manufacture of medicinal products versus human application as a SoHO preparation. The setting of an upper limit for compensation at national level and the application of compensation that is financially neutral for the SoHO donor have the effect of removing any incentive for SoHO donors to donate to one SoHO entity rather than another, significantly mitigating the risk that compensation differences might result in competition between SoHO entities, in particular between public and private sectors." The European Blood Alliance published a statement supporting the new regulation as it:

- "strengthens the health protection of donors and patients;
- reaffirms the principle of voluntary non-remunerated donation and forbids financial gains;
- contributes to increase the resilience and continuity in supply of SoHO; [and]
- sets an agile and robust quality and safety standards system."

The Plasma Protein Therapeutics Association (PPTA) also explained in a statement that, "[the] SoHO regulation [is] an important step toward enhancing plasma collection and increasing donor safety in the EU. The compromise text from the co-legislators (EC, European Parliament, and European Council) recognizes that all forms of compensation, including a fixed-rate allowance with conditions set by Member States, are compatible with the principle of voluntary unpaid donation. This model has been successfully implemented for plasma donation in Austria, Czech Republic, Germany, and Hungary. In these countries, plasma collection is four times higher than the EU average and is based on safe, efficient, state-of-the-art plasmapheresis program[s] that contribute to the collection of more plasma for European patients."

(Source: EC News Release, 4/24/24; SoHo Regulation, 4/15/24)

Bermuda has shifted to individual donor assessments for blood donations. According to a report from *The Royal Gazette*, "the Bermuda Hospitals Board said the change brought Bermuda in line with blood donation criteria in Britain, Canada, and the U.S." and is designed to, "ensure that the criteria maximi[z]ed the safety of blood supply…Previously, the Bermuda Blood Donor Cent[er] criteria [had] time-based deferrals specific to [sexually active gay and bisexual men], as well as women who had sex with [sexually active gay and bisexual men], during the previous three months."

(Source: *The Royal Gazette*, "Blood donation rules in line with international standards," 5/9/24) .

COMPANY NEWS

Bavarian Nordic A/S has announced the initiation of the rolling submission process with the U.S. Food and Drug Administration (FDA) for a biologics license application (BLA) for its investigational chikungunya virus (CHIKV) vaccine candidate. According to a company news release, the investigational vaccine is for, "immunization against chikungunya virus infection in individuals 12 years of age and older." The company intends to provide additional data to the FDA in the coming months and hopes to finish the BLA submission in the first half of 2024. The investigational vaccine candidate previously, "received Breakthrough Therapy designation and Fast Track designation from the FDA in October 2020 and April 2018, respectively, and PRIME designation from the EMA in September 2019. These designations are designed to facilitate the development or expedite review of medicines that either target an unmet medical need or may demonstrate substantial improvement over available therapy."

(Source: Bavarian Nordic News Release, 4/29/24)

QuidelOrtho Corp. has named Brian J. Blaser, MBA as president and chief executive officer as of May 6th. Mr. Blaser previously served as, "executive vice president of Diagnostic Products for Abbott Laboratories where he oversaw the global diagnostics organization, including core laboratory, point of care, rapid diagnostics, and molecular diagnostics businesses. Prior to that role, Mr. Blaser held various strategic, operational, and diagnostic roles at Abbott, as well as previous leadership positions at the Ortho Clinical Diagnostics division of Johnson & Johnson, Eastman Kodak, and General Motors." He obtained his MBA with a concentration in finance from the Rochester Institute of Technology and a Bachelor of Sciences in Mechanical Engineering Technology from the University of Dayton."

(Source: QuidelOrtho News Release, 5/2/24)

Terumo Blood and Cell Technologies (Terumo BCT) has received 510(k) clearance from the FDA for the "Rika Plasma Donation System™ with the iNomi™ Nomogram," according to a company news release. Terumo BCT explained in the announcement that the iNomi, "innovation means that plasma collection volume can be determined by an individual donor's height, weight, and hematocrit level on the day they donate plasma…The individualized nomogram is anticipated to increase collection volume without increasing collection time. The clinical trial to support the recent FDA clearance showed an average 10 percent increase in the volume of plasma collected per donation with an average collection time of less than 35 minutes."

(Source: Terumo BCT News Release, 5/9/24)

CALENDAR

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

2024

May 14-16. **2024 ADRP Annual Conference. St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Aarhus, Denmark.** Registration is open. More information available here.

(continued on page 10)

CALENDAR (continued from page 9)

May 22. **America's Blood Centers (ABC) Body Interact Training Webinar.** Registration is open. More information available to ABC members here.

May 23. **Centers for Disease Control and Prevention (CDC) Public Webinar: National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in People.** More information available here.

May 29. **America's Blood Centers (ABC) Blood Advocacy Week Partners Briefing (Virtual).** More information and link to registration available to ABC members here.

May 29-30. **U.S. Food and Drug Administration (FDA) Regulatory Education for Industry (Redl) Annual Conference 2024: Innovation in Medical Product Development (Hybrid).** More information available here.

June 4. **U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Town Hall: Chemistry, Manufacturing, and Controls (CMC) Readiness for Gene Therapy Biologics License Applications (BLAs) (Virtual).** More information available here.

June 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** Registration is open. More information available here.

June 13. **FDA Public Meeting: Optimizing FDA's Use of and Processes for Advisory Committees (Virtual).** Registration is open. More information available here.

June 23-27. **38th International Society of Blood Transfusion (ISBT) Congress. Barcelona, Spain.** Registration is open. More information available here.

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

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

Sept. 30-Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** More information is coming soon.

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

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

2025

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

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

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

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Immunohematology Reference Laboratory Manager. LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Immunohematology Reference Laboratory team in Atlanta, GA. This position is responsible for providing mentorship and leadership to laboratory staff. The IRL Manager is expected to provide onsite day-to-day supervision of testing personnel and reporting of test results under the direction of the Laboratory Director. This position is also responsible for performing laboratory procedures and reporting of test results, ensuring compliance with company policies and procedures, ensuring compliance with regulatory requirements from agencies such as CLIA, FDA, AABB, and HIPAA. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

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

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

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

Chief Administrative Officer. The Chief Administrative Officer (CAO) is accountable for the development of integrated marketing strategies, plans, and activation via internal and external partners. The CAO oversees brand strategies, campaigns, social media, and donor and corporate marketing programs to drive brand relevance, growth, and mission impact. The CAO serves as a spokesperson for the organization. The CAO must have a contemporary approach to data and analytics and understand how to support decision-making by integrating data intelligence. This position maintains leadership for East Texas operations and oversees large-scale capital projects through administrative oversight of Facilities and Fleet Management. The CAO manages a team that provides the full range of operations support, including client relations, community outreach, blood donor recruitment, communication services, and the implementation and analysis of the tactics needed to execute these strategies and promote continuous improvement. This position collaborates with the Chief Operating Officer (COO) in assessing the organization's market performance and identifying opportunities for growth as well as competitive threats. Education: Master's Degree in a business, healthcare, or other industry-related field. Experience: 7 years of industry-related work experience. Five years of upper management level experience. Carter BloodCare is an EEO/Affirmative Action employer. Apply at www.carterbloodcare.org/careers.

Regional Director, Blood Services. Vitalant is seeking a passionate and results-driven Regional Director to lead all operational activities at our regional blood center in Spokane, Washington. As the driving force behind our daily operations, you will lead by example, ensuring strict compliance with Vitalant' s policies and directives while overseeing every facet of the blood center operations. In this pivotal role, you will thrive in a collaborative environment, working closely with Blood Service Leadership

(continued on page 12)

POSITIONS (continued from page 11)

throughout the organization to realize strategic objectives and exceed collection targets. This role will encompass a wide range of responsibilities, including upholding policy compliance, driving performance metrics, and maintaining stringent standards. The primary focus will be spearheading impactful community outreach initiatives to increase exposure and engagement, as well as cultivating new partnerships and accounts to expand our reach and impact in the region. If you are ready to lead with purpose and make a vital impact through your work you will experience a career built on purpose, an organization created to care, and a team committed to lead – together. Please click here to view the full job description and apply.

Director, Donor Marketing. The Director, Donor Marketing is a pivotal leadership role within New York Blood Center Enterprises (NYBCe), overseeing a team of seasoned marketing professionals tasked with driving donor engagement and donor acquisition across various Blood Operations divisions. Working closely with divisional Donor Recruitment and Collections teams to ensure alignment with overarching marketing strategies. As the senior-most authority in donor marketing, the Director, Donor Marketing operationalizes Enterprise Donor Engagement strategies at the local level, guiding and empowering divisional marketing managers to execute targeted initiatives that meet product and service objectives across all divisions. Reporting directly to the Executive Director, Strategy and Planning, Donor Engagement, this role carries significant responsibility in steering local marketing efforts in line with enterprise goals. Candidates must be able to report into one of the following NYBCe locations: New York City, NY; Providence, RI and Newark, DE. New York Location: For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $160,00.00 p/yr. to $170,00.00 p/yr. Rhode Island Location: For applicants reporting into Rhode Island, the proposed annual salary is $150,00.00 p/yr. to $160,00.00 p/yr. To apply: https://careers-nyblood-center.icims.com/jobs/6268/director%2c-donormarketing/job?mode=view.

Donor Recruitment Manager. Blood Assurance is seeking a Donor Recruitment Manager to lead field recruitment efforts that build new and existing business in our Chattanooga and North Georgia region. Primary responsibilities include direct leadership of Account Managers in expanding blood drive activity on mobiles primarily, and in facilities as needed, based on growth strategy in a specific type of blood product recruitment and collection. Assist in developing long-term community business partnerships, and coordinating internally with all leadership levels to support or expand Blood Assurance recruitment efforts. Work closely with Donor Services leadership to ensure recruitment and collection teams are working together toward meeting overall product collection goals. Qualified applicants will have: Bachelor's degree-preferably in business, marketing, or related field. Seven to 10 years sales experience, preferably in blood banking. Three to five years sales staff management. Advanced communication skills. Public presentation and networking skills. Advanced organizational, customer service and teamwork skills. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Paid Time Off, 401K, a Wellness Program, and Relocation Assistance. Qualified candidates are encouraged to submit an online application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco-Free Environment.

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources for our operations based out of Augusta, GA. This position will be responsible for monitoring progress to goal proactively, and effectively coaching and managing their team to success. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources – Augusta, GA.

Manager of Donor Services. The Blood Connection is seeking a Manager of Donor Services for our operations based out of Raleigh, NC and Rock Hill, SC. These positions will oversee donor collection operations within their assigned divisional territory. These positions provide leadership and discipline to direct reports, interviews, and hire staff, and ensure staff are appropriately trained. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Services – Raleigh, NC.