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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #13 **April 12, 2024**

INSIDE:

Transfusion Needs for CAR-T Cell Therapy Lymphoma Patients Studied

Researchers in *Blood Advances* sought to explore the transfusion needs for patients who received Chimeric antigen receptor (CAR) T-cell therapy to treat larger B-cell lymphoma (LBCL). They explained that blood products in the form of red blood cells (RBCs) or platelets, "have been reported in [approximately] 55 percent to 66 percent of patients after CAR T-cell infusion, but little is known about the specific needs, complications, and outcomes in this population." They also explained that the efficacy of CAR T-cells may be impacted by transfusions due to, "a phenomenon called transfusion-related immunomodulation." This study aimed to, "describe the transfusion needs in patients receiving commercial anti-CD19 CAR T-cell therapy for LBCL in the real-world setting. Secondary objectives are to search for predictive factors associated with transfusion needs after CAR T-cell therapy and to examine the potential correlation between transfusion needs and CAR T-cell efficacy and toxicity."

Patients included in this study were, "treated for relapse or refractory (R/R) BCL with commercial CD19 CAR T-cells registered in the DESCAR-T database, presenting with at least a six-month follow-up after infusion, and for whom exhaustive transfusion data were available." This database is the national registry in France for data collection for individuals who receive CAR T-cells "outside of clinical trials." The authors specified that, "[p]atients were censored for transfusions at relapse, new treatment onset, or death. We distinguished transfusions received at the early phase, meaning during the first month after CAR T-cell infusion; and at the late phase, meaning beyond the first and until the sixth month." The researchers explained that from, "August 2018 to September 2022, a total of 671 patients registered in the DESCAR-T registry [met] the eligibility criteria. They found that, [a]t the time of CAR T-cell infusion, median age was 63 years (range, 18-82) [and overall,] 82.7 percent of patients received a bridging therapy, which consisted of systemic chemotherapy in 85.2 percent of cases."

Almost 60 percent of patients (401 individuals) received a blood product transfusion at some point during the six months prior to their first CAR T-cell treatment. Specifically, 357 (53.2 percent) received RBCs, and 301 (44.9 percent) received platelets transfusion. The number of patients receiving transfusion increased month by month to reach a maximum of 228 patients (34.0 percent) within the month before treatment (30.3 percent requiring RBC and 19.2 percent platelets transfusion). The mean number of transfused RBCs and platelets units per month in the six-month period before CAR T-cell infusion also increased progressively to reach 1.0 (range, 0-15) and 0.7 (range, 0-29) during the month before infusion, respectively.

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Transfusion Needs for CAR-T Cell Therapy Lymphoma Patients (continued from page 1)

After CAR T-cell infusion, 378 patients (56.3 percent) received transfusion: 345 (51.4 percent) received RBC transfusion and 280 (41.7 percent) received platelets transfusion. The highest transfusion needs were at the early phase (i.e., within in the first month), with 359 patients (53.5 percent) requiring at least one transfusion, including 317 (47.2 percent) for RBC and 252 (37.6 percent) for platelets). During the early phase, the mean number of transfused RBCs and platelets units were 1.6 (range, 0-13) and 2.3 (range, 0-44), respectively. At the late phase (i.e., between one and six months after infusion), 202 patients (36.7 percent) received transfusion, including 172 (31.3 percent) for RBCs and 181 (32.9 percent) for platelets. The mean number of transfused units decreased over time after CAR T-cell infusion. Beyond the third month, transfusion needs were very low with only 22 patients (6.0 percent) requiring at least one transfusion (4.7 percent for RBC and 4.9 percent for platelets)."

The investigators described four categories developed for patients based on, "the time between CAR-T infusion and transfusion (early <1 month vs late ≥1 month and until 6 months) and the type of transfused product (RBCs vs platelets)." They found that, [n]either overall response rate (ORR) nor complete response (CR) were statistically different between patients who received transfusion and non-transfused patients, at early and late phase after CAR T-cell infusion. However, early transfusions were associated with a shorter progression-free survival (PFS) for RBCs (median PFS, 3.1 vs 6.0 months; P = .0042) and platelets (median PFS, 3.1 vs 5.8 months; P = .0054). Late platelets transfusion also affected PFS (median PFS, 5.6 vs 12.0 months; P = .0072), whereas late RBC transfusion did not (median PFS, 8.8 vs 8.5 months; P = .7199). Similarly, early transfusions were associated with a shorter overall survival (OS) for RBCs (median OS, 9.0 vs 21.1 months; P < .0001) and platelets (median OS, 7.8 vs 21.1 months; P < .0001). Late platelets transfusion also affected OS (median OS, 13.8 months vs not reached; P < .0001), whereas late RBC transfusion did not (median OS, 20.6 vs 24.1 months; P = .0971)." Additionally, the study showed that, "[c]umulative incidence of lymphoma-related mortality was significantly higher for patients receiving early RBC and/or platelets transfusion and late platelets transfusion but not late RBC transfusion. Cumulative incidence of non-relapse mortality (NRM) was significantly higher for patients receiving early and late platelet transfusion and late (but not early) RBC transfusion. Indeed, NRM was [approximately] two times higher for patients receiving early RBC transfusion (12.3 percent vs 8.2 percent; P = .095), early platelets transfusion (14.3 percent vs 7.6 percent; P = .008), late RBC transfusion (14.0 percent vs 6.9 percent; P = .010), and late platelets transfusion (14.9 percent vs 6.2 percent; P = .001)."

The authors concluded that, "[o]ur study provides an accurate description of transfusion needs in patients with LBCL treated with CD19 CAR T-cell therapy. We identified risk factors associated with early and late transfusion needs after CAR T-cell infusion, mainly CAR-HEMATOTOX score, pre–CAR T-cell transfusion needs, high-grade immune effector cell-associated neurotoxicity syndrome (ICANS), and tocilizumab use. Finally, our study sheds light on the potential impact of transfusions on CAR T-cell efficacy and toxicity. Our results may help inform the management of patients treated with CAR T-cell and support strategies that reduce transfusion needs after CAR T-cell therapy." They noted that limitations of this study included, "some data are missing, especially regarding baseline cytopenia and inflammatory markers that did not allow for us to calculate the CAR-HEMATOTOX score in [approximately] 10 percent of the patients. Data regarding bone marrow infiltration and duration of neutropenia were only available in very few cases. Finally, data from the DESCAR-T registry mostly include routine laboratory tests, so we were not able to analyze CAR T-cell expansion and causes of relapse that could have helped us to better understand the association between transfusion and outcome." A commentary on this paper has also been published in *Blood Advances*.

Citation: Vic, S. Jean-Baptiste, T., Bachy, E., *et al*. "Transfusion needs after CAR T-cell therapy for large B-cell lymphoma: predictive factors and outcome (a DESCAR-T study)." 2024.

WORD IN WASHINGTON

The U.S. Food and Drug Administration's Center for Biologics Evaluation Research (CBER) has published a "Calendar Year 2023 Report from the Director." The publication, attributed to CBER Director Peter Marks, MD, PhD, includes highlights from the agency over the previous year. The report notes that, "CBER made significant strides with the approval of multiple important therapeutic products and advanced important public health priorities in blood and tissue safety." It specifically references that, "CBER's Office of Blood Research and Review (OBRR) and Office of Biostatistics and Pharmacovigilance (OBPV) issued updated guidance for assessing blood donor eligibility using a set of individualized risk-based questions to reduce the risk of transfusion transmitted HIV, standardizing questions for every donor, regardless of sexual orientation, sex, or gender. The implementation of these recommendations represents a significant milestone for the agency and the LGBTQI+ community." Additionally, Dr. Marks explained in the report that, "CBER also implemented structural changes in the Office of Blood Research and Review and the Office of Vaccines Research and Review, the Office of Biostatistics and Pharmacovigilance and the Office of Regulatory Operations. These organizational changes established a structure designed to enable CBER's workforce to focus on key priorities that protect public health, improve operational efficiency, and increase professional development opportunities." The report concludes by explaining the upcoming plans for the agency in 2024 including, "addressing key challenges in the development of cell and gene therapies, especially for rare disorders. The Center is strongly committed to furthering these efforts through increased communications under the START Pilot, increasing efficiency of the regulatory process through the CoGenT Global Pilot, facilitating the use of accelerated approval of gene therapy based on surrogate endpoints that are reasonably likely to predict clinical outcomes, and issuing guidance to be transparent about our current thinking. Additionally, we will continue partnering with CDER to conduct the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) Program to facilitate CMC development of selected products under investigational new drug (IND) applications with expedited clinical development timeframes to help patients gain access to these products earlier."

(Source: CBER Report from the Director, 4/5/24)

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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
Chief Executive Officer: Kate Fry
Chief Medical Officer: Jed Gorlin
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: $420

Send subscription queries to
memberservices@americasblood.org
America's Blood Centers
1717 K St. NW, Suite 900, Washington, DC 20006
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

WORD IN WASHINGTON (continued from page 3)

The Administration for Strategic Preparedness and Response (ASPR) recently announced its Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Multiyear Budget (MYB) for fiscal years 2023-2027. According to the agency, "[t]he report assesses funding needs to support medical countermeasure priorities, which would allow the U.S. Government to prepare for the next public health threat. The MYB projects an estimated overall funding need of $79.5 billion over the five-year period, an increase of $15.5 billion over the 2022-2026 report. The MYB is not a budget request and does not replace funding levels requested in the President's Budget or accompanying documents." The funding increase cited in the report is in anticipation of, "implementation of the National Institute of Health's (NIH) prototype pathogen approach for the development of candidate vaccines, ASPR Biomedical Advanced Research and Development Authority (BARDA)'s development successes enabling the transition of 13 MCMs into the stockpile, and improvements to threat-agnostic technologies and rapid response capabilities. The MYB is informed by the PHEMCE, an interagency body that reviews the current threat landscape, provides technical expertise, and makes recommendations to the Secretary of the U.S. Department of Health and Human Services to inform MCM decision-making. The 2023-2027 updated report was developed with an emphasis on addressing existing preparedness gaps and meeting goals outlined in the National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security."

(Source: ASPR News Release, 3/15/24)

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

- **ADRP Webinar: Conference 2024: Know Before You Go** – April 17th. Registration is open. More information available here.
- **ADRP Master Class** – Sept.18th-19th. More information is coming soon.

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

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

- Phlebotomy for Prisoner (MEDICAL ISSUES)
- Donors with Known Coagulopathy (MEDICAL ISSUES)
- Outdated AB Units (ALL MEMBER FORUM)
- Vein Finders (COLLECTIONS & DONOR SERVICES)
- Thermogenesis MP1100 Cascade Parts (TECHNICAL DIRECTORS)
- Low-volume RBCs (QUALITY BYTES)

ABC members are encouraged to login and join the conversations today!

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INSIDE ABC

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

ABC Economic Outlook Survey Open

ABC recently launched the Economic Outlook Survey. This new resource consolidates what were formerly known as the ABC Financial Ratio and Median Service Fee surveys while offering a comprehensive look at blood center finances, including 19 of the most frequently used ratios for benchmarking the financial health of an organization as well as median service fees for 30 different blood products and blood center procedures.

The aggregate data of this survey is important to both members and ABC as we advocate for fair and accurate reimbursement policies. Survey results are anonymized and aggregated. The ability to download final trend reports and create customized reports based on selected filters will be available to participants via ABC's benchmarking portal in early May and are complimentary to all survey participants. Non-participants may purchase the report here. The survey will remain open until April 19th. Please contact us with questions.

Meet Us in St. Louis for the ABC 2024 Quality and Technical Workshop!

Registration remains open for the 2024 America's Blood Centers (ABC) Quality and Technical Workshop. Check out our program as this year's workshop is centered around highlighting collaboration amongst blood banking professionals to allow for an exchange of innovative ideas and best practices. Sessions have been developed to emphasize the important topics that are affecting you and your blood center. The workshop will feature experts in their field presenting topics that include implementation of new devices and blood products, regulatory and licensure round tables, and peer to peer strategic discussions to name a few. Don't miss the opportunity to network with your peers and gain greater insights into the challenges that the blood industry is facing now.

Schedule Available 2024 ADRP Annual Conference

The schedule is available for the 2024 ADRP Annual Conference. Register today! 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. Remember to book your hotel room by April 19th for the discounted rate. Please contact us with questions.

RESEARCH IN BRIEF

Platelets Retain Function After HLA Disruption and Storage. Researchers in *Vox Sanguinis* described a study, "undertaken to investigate the characteristics of apheresis platelets following human leukocyte antigen (HLA) disruption and subsequent storage." They explained that, "[o]n Day 1 post collection, platelet components were randomly assigned to either acid or saline (control) treatment (n=10 pairs)." Additionally, the authors noted that, "[e]ach platelet was incubat[ed] with either 15 mL citric acid solution or 15 mL 0.9 percent NaCl." The study found that, "[a]cid treatment reduced antibody binding to HLA Class-I by an average of 75 percent ($p < 0.0001$) compared to controls on Day 1. The reduction was maintained throughout platelet storage." Additionally, the investigators explained that, "[a]cid treatment resulted in significant platelet loss ($p<0.0001$). The mean platelet recovery post acid treatment was 47 percent compared to 99 percent for the controls. Over 80 percent of acid-treated platelets remained viable during storage, as indicated by calcein-AM staining. Similarly, staining of non-viable platelets with FM 4-64® showed a significantly higher proportion of dead platelets in acid-treated components." They noted that, "[p]latelet metabolism during storage was accelerated by acid treatment, with significantly higher glucose consumption and lactate production. This was not associated with a decrease in pH." In the study, "[t]he effect of HLA disruption on platelet glycans was investigated using lectin binding. Acid-treated platelets had significantly less sialic acid and galactose on their surface as measured by Sambucus nigra ($p=0.009$) and Ricinus communis agglutinin-1 binding, respectively ($p=0.029$)." The authors stated that, "[b]asal surface levels of CD62P were significantly increased in acid-treated platelets compared to controls ($p<0.0001$), indicating degranulation and platelet activation. Following TRAP-6 stimulation, maximum CD62P was blunted by HLA disruption compared to controls, although the difference was small ($p=0.0013$). HLA depletion did not affect basal activation of the GPIIb/IIIa complex in unstimulated platelets ($p=0.564$). However, activation following adenosine diphosphate stimulation was significantly lower in acid-treated platelets ($p<0.0001$)." The study also found that, "[t]he time to initiation of clot formation (R-time) as measured by thromboelastography was significantly shorter following HLA disruption ($p=0.0004$)…While RANTES and sCD40L were also slightly higher, the differences were not significant ($p=0.239$ and 0.104, respectively)." The authors concluded that, "in this study, acid treatment significantly decreased HLA antigenicity of platelet components. While platelet loss and decreased viability were observed, acid-treated platelets remained functional, retaining their ability to aggregate and form clots."

Citation: Davis, A.M., Rawson, R., Pahn, G., Daly, J., Marks, D.C. "Platelets retain function and can be stored following disruption of human leucocyte antigens." *Vox Sanguinis*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

MEMBER NEWS

Héma-Québec recently announced that it has opened its 12th donor center in Québec. The new center marks the organization's first in the Centre-du-Québec region, according to a news release. The facility is set to open in 2025. "Plasma donations made at this cent[er] will be used to produce the specialty drugs needed to treat patients at hospitals across Québec," which is an integral part of the provinces self-sufficiency strategy." Héma-Québec Chief Executive Officer Nathalie Fagnan, CPA added in the news release, "[w]e've set ourselves an ambitious plan for plasma self-sufficiency, but I know we can achieve it. Héma-Québec knows that every little bit counts—each donation becomes a source of hope for patients fighting for their health and their lives. Opening a 12th donor cent[er] in Québec is in complete alignment with our mission to efficiently meet the need for blood products, particularly plasma, while increasing our independence from foreign suppliers."

(Source: Héma-Québec News Release, 4/9/24)

GLOBAL NEWS

The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has issued a national patient safety alert for reducing risks for transfusion-associated circulatory overload (TACO). The agency published the alert following a review of trend hemovigilance data from the Serious Hazards of Transfusion (SHOT). The agency stated that, "[r]eview of TACO events analy[z]ed by SHOT between 2010 and 2022 found a total of 1,336 reports. In this 13-year period, TACO contributed to 111 deaths, accounting for 39.2 percent (111 in 283) of all transfusion-related deaths reported to SHOT. The increasing trend in patient deaths and major morbidity due to TACO, with eight deaths and 25 patients with major morbidity in 2022, prompted this safety alert. In 2022, there were three cases in the under-18 age group, including neonates." Additionally, the agency explained that healthcare organizations should complete the following actions by October 4th:

- "review and update policies, procedures, and processes to ensure:
  - [a]ll transfusions are compliant with recommendations from British Society for Haematology (BSH), SHOT, and NICE;
  - [a] TACO risk assessment is undertaken utili[z]ing the SHOT risk assessment tool prior to transfusions;
  - [a]ppropriate mitigation measures are initiated for individuals at risk – see FAQ document;
  - [p]atients and carers should be informed of TACO as a significant potential complication of transfusion and likely symptoms, as part of complying with Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) consent for transfusion guidance
  - [i]nclusion of guidance on timely management of TACO, including the use of diuretics, oxygen, and other supportive measures;
  - [c]lear communications on discharge to patients and staff involved in the care of the patient about blood components and/or blood products administered and any complications such as TACO;
  - [u]se of the structured TACO incident investigation tool from SHOT;
- review, update, and implement training program[s] to include:
  - [u]se of TACO pre-transfusion risk assessment tool;
  - [a]ppropriate use of mitigation measures – FAQ document;
  - [m]anagement of severe chronic an[e]mia in non-bleeding patients using minimal/single-unit transfusion support, and an[e]mia management with iron therapy where appropriate;
  - [r]ecognition and prompt management of TACO, importance of timely interventions and escalation of care as appropriate;
  - [e]mpowerment of clinical staff and biomedical scientists to question practices of prescribing/requesting blood components;
  - [a] process for recording participation and identifying dates for re-training;
  - [k]nowledge and awareness to report TACO cases locally, as well as to MHRA and SHOT by hospital transfusion teams; [and]
- [u]ndertake regular audit on the use of the TACO risk assessment tool for adult patients*, consent practices, management of chronic severe an[e]mia, avoidable transfusions, volume of red cell transfusion and communication of information at discharge to relevant teams involved in the care pathway including patients."

(Source: MHRA Alert, 4/4/24)

A report in *The Korea Economic Daily* stated that, a startup in South Korea has "secured" $4.8 million in funding for extracorporeal blood production. According to the publication, ArtBlood has developed BioBlood, a product that is, "equivalent to actual blood cells and capable of functional expansion, using proprietary technology that implements the bone marrow's blood production process outside the body, according to the company's founder Prof. Baek Eun Jung of Hanyang University's School of Medicine." The company is marketing the product as an, "alternative solution to blood shortages, with

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GLOBAL NEWS (continued from page 7)

advantages such as transfusion compatibility regardless of blood type, prevention of infection risks associated with direct blood transfusion and longer viability *in vitro* than donated blood." The company also secured a $3.5 million federal grant from South Korean Ministry of Health and Welfare for a "cell-based artificial blood" development project.

(Source: *The Korea Economic Daily*, Bio startup ArtBlood attracts $4.8 mn investment, 4/9/24)

The World Health Organization (WHO) has published summaries of outbreaks of avian influenza and swine influenza respectively from the past year. The agency noted in the publications that, "[t]he following outbreaks, which occurred last year, illustrate the reality of zoonotic influenza, the fact that all ages can be vulnerable, that those with and without comorbidities can be at risk, and that various exposures can lead to infection[s]…The diversity of zoonotic influenza viruses that caused human infections in 2023 is alarming and infections of some types of zoonotic influenza viruses caused severe disease with a high mortality rate. In 2023 they did not transmit easily from person to person, although we never know when this may change, and therefore must be ever-ready for a pandemic."

(Sources: WHO Avian Influenza Summary, 3/30/24; WHO Swine Influenza Summary, 3/30/24)

COMPANY NEWS

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance to **Fresenius Kabi AG**'s Alyx 2RBC-LR Kit. Specifically, the April 5th letter from the FDA states that, "the Alyx component collection system is intended for use in blood collection establishments to collect and separate whole blood into its components. Depending on the ALYX Component Collection system apheresis kit used in the collection of products, the ALYX Component Collection system has been cleared for:

- concurrent collection of two units of red blood cells (2RBC), leukocytes reduced;
  - single unit recovery (one unit of red blood cells, non-leukocytes reduced) permitted;
- concurrent collection of two units of red blood cells (2RBC), non-leukocytes reduced;
  - single unit recovery (one unit of red blood cells, non-leukocytes reduced) permitted;
- concurrent collection of one unit of red blood cells, leukocytes reduced, and plasma as:
  - fresh frozen plasma;
  - source plasma;
  - plasma frozen with 24 hours after phlebotomy; and
  - plasma frozen within 24 hours after phlebotomy held at room temperature up to 24 Hours after phlebotomy;
- collection of plasma as:
  - fresh frozen plasma;
  - source plasma;
  - plasma frozen with 24 hours after phlebotomy; and
  - plasma frozen within 24 hours after phlebotomy held at room temperature up to 24 Hours after phlebotomy."

(Source: FDA Letter, 4/5/24)

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Terumo Blood and Cell Technologies (Terumo BCT) and CiRA Foundation have announced a new partnership. According to a news release, the organizations are collaborating, "to propel the broad use of induced pluripotent stem (iPS) cells for a range of new therapies. By leveraging CiRA Foundation's leading iPS cell knowledge and Terumo BCT's enabling technologies and cell therapy manufacturing know-how,

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COMPANY NEWS (continued from page 8)

the companies seek to develop an automated and clinically relevant workflow for iPS cell-derived therapies, a potential turning point for the cell and gene therapy (CGT) field." Additionally, through the partnership, Terumo BCT and CiRA Foundation intend to, "create a closed, automated, integrated process that can consistently produce high-quality iPS and iPS-derived cells at scale on Terumo BCT's Quantum Flex™ Cell Expansion System."

(Source: Terumo BCT News Release, 3/19/24)

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

April 16-17. **International Plasma Protein Congress. Athens, Greece.** Registration is open. More information available here.

April 17. **ADRP Webinar: Conference 2024 "Know Before You Go."** Registration is open. More information available here.

April 17-18. **ABC Quality and Technical Workshop. St. Louis, Mo.** Registration is open. More information available here.

May 3-4. **California Blood Bank Society (CBBS) Annual Meeting.** More information is coming soon.

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.

June 5-9. 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 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** More information is coming soon.

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.** More information is coming soon.

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.

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CALENDAR (continued from page 9)

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

Mobile Site Supervisor – Donor Centers (Carter BloodCare). The Site Supervisor position provides a vital link in the procurement of a safe quality blood product. Essential functions are to assist in smooth and efficient donor flow, determine donor acceptability, perform sterile venipuncture for the collection of blood, provide excellent customer service, and ensure compliance with regulations and standard operating procedures throughout the donation process. This position oversees and assigns duties to staff and may be involved in the following processes: discipline, performance reviews, hiring and terminations. This includes effectively and discreetly solving personnel and donor issues, addressing procedural or behavioral problems, and making verbal or written reports to management. Additionally, this role requires completing annual leadership training and assisting with on-the-job development of employees. Education: High school diploma or equivalent. Some college a plus. Experience: Minimum 2 years general work experience. Customer service experience required. Minimum 6 months to 1-year supervisory experience. Previous Phlebotomy 2, blood banking experience, or medical field experience. Background in a highly regulated industry. Fluency in English/Spanish skills and CDL driver a plus. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job # Mobile Site Supervisor Donor Center.

Phlebotomist 2 – Donor Centers (Carter BloodCare). The Phlebotomist 2 assists in smooth and efficient donor flow, determine donor acceptability, performs sterile venipuncture for the collection of blood, provides excellent customer service and ensures compliance with regulations and standard operating procedures throughout the donation process. In the absence of a supervisor, you will oversee and assign responsibilities to staff. This includes effectively and discreetly solving personnel and donor problems, addressing procedural or behavioral problems, and making verbal or written reports to management. Additionally, the Phlebotomist 2 will be required to attend and complete annual development training resources and assist with on-the-job development of staff. Education: High school diploma or equivalent. Some college a plus. Experience: 1-year general work experience, preferably working with the public, or education that includes comparable experience such as an internship or externship. Customer service experience required, intern and/or externship experience will satisfy this requirement. Previous Phlebotomy 1, blood banking experience or medical field experience. Background in a highly regulated industry. Fluency in English/Spanish skills and CDL driver a plus. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job # Phlebotomist 2.

Immunohematology Reference Lab (IRL) 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

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POSITIONS (continued from page 10)

need. Visit our careers page to learn more about this position, and apply here!

Immunohematology Reference Laboratory (IRL) 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!

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

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

Sr. Policy & Documentation Specialist (San Diego Blood Bank). The Senior Policy and Documentation Specialist proactivity guides and oversees policy management and technical documentation needs of San Diego Blood Bank. Creation, implementation, and maintenance of a document management system that can manage both internal and external controlled documents. This role provides relevant training on document control procedures and good documentation practices, assists Quality Assurance and Compliance Department in creating quality plans and procedures. The Sr. Policy & Documentation Specialist assists in the initiation, investigation and closure of product and process deviations/non-conformances. This position will author and revise policies, procedures, and manage document processes and systems to ensure control and availability of documentation to personnel. This role requires a bachelor's degree in a related field from an accredited college or university, or equivalent combination of education, training and experience. Click here to view the job description and apply.

Marketing Manager (Blood Centers of America). This position develops and executes a marketing strategy for BCA and for individual business units including budget planning and measurement of success. The position manages the social media accounts and website content and supports the needs of the Advanced Therapy Network including newsletter, search engine optimization, and maintaining a record of member capabilities. Other responsibilities include press releases, presentations with input from internal stakeholders and trade show participation. A bachelor's degree in business is required; major in marketing preferred. Requires three (3) or more years of marketing experience with a proven track record of success. Social media management experience required. Blood center or related industry experience preferred. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 10 percent-20 percent of overnight travel required. Please click here to view the full job description and apply.

Supply Chain Contract Manager (Blood Centers of America). This position is responsible for the day-to-day activities specific to BCA and national GPO supplier contract relationships. Position will identify, develop, coordinate, and implement supplier contracts working with blood center Materials Directors and Purchasing Managers driving contract savings and increased revenue. A primary responsibility will be to oversee and manage the Third Party Logistics (3PL) operations, adding new product categories to be distributed in this

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program to increase overall program value and efficiency. A bachelor's degree in a related field is preferred. Requires 3-5 years of supply chain experience in a related industry. Ability to travel regularly throughout the year to meet member needs. Remote work is available for a candidate who does not reside within a reasonable commuting distance of BCA's headquarters in West Warwick, RI; 20 percent-30 percent of overnight travel required. Please click here to view the full job description and apply.

Lab Technical Director. The Central California Blood Center (CCBC) is seeking a Laboratory Technical Director for our operations based out of Fresno, California. This position provides exceptional, mission-focused leadership to the blood component manufacturing, testing lab, research, and immunohematology reference laboratory and assures cost-effective, lean operations and compliance with all regulatory agencies and best practices as defined in AABB Standards and AABB Technical Manual. Assures that the department strives for optimal performance by providing the necessary resources and developing a highly competent team. This position works in close collaboration with CCBC senior leadership and the Medical Director, who holds the CLIA licensure for the organization. The ideal candidate must have a current California Clinical Laboratory Scientist (CLS) license or eligible, a minimum of six (6) years of experience working in a blood center, and a minimum of three (3) years of direct supervisory experience managing teams and assets. Certified as an SBB/BB or equivalent is preferred. We offer a generous benefits package including a great 401k matching program, PTO, paid sick leave, medical, dental, vision, electronic vehicle charging, wellness program, and employee assistance program (EAP). Prospective candidates may be eligible for relocation assistance. For full description and to apply click here. The Central California Blood Center is an Equal Opportunity Employer.

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. Manager of Donor Services – Rock Hill, SC.

Director, Quality Assurance & Regulatory Affairs (Hoxworth Blood Center). The University of Cincinnati College of Medicine (COM) has a reputation for training best-in-class health care professionals and developing cutting-edge procedures and research that improves the health and clinical care of patients. Hoxworth Blood Center (HBC) is located within the College of Medicine and is the only Regional Blood Center owned and operated by a University in United States. The HBC is seeking a **Director of Quality Assurance & Regulatory Affairs**. This position will oversee and direct the coordination of quality assurance and regulatory compliance for the Cellular Therapy, Therapeutic Apheresis and Transplantation Immunology divisions. Required Education & Experience: Bachelor's degree in Medical Technology, Biology, Chemistry, or related field. Seven (7) years of experience in a clinical laboratory, blood banking or other related experience. Additional Qualifications Considered: Previous experience in a FACT, AABB and HCT/P (21 CFR 1271) and GMP (21 CFR 211) for Phase I/II clinical manufacturing, Regenerative Medicines, Cleanrooms, and Aseptic Processing is ideal. Understanding of CAP requirements for histocompatibility (HLA) laboratories which includes disciplines of sequencing, molecular, serological, immunology, flow cytometry, and cellular analysis is preferred. For full description and to apply, visit https://bit.ly/489l7Gl. The University of Cincinnati is an Equal Opportunity Employer.

Division Director, Core Operations (Hoxworth Blood Center). Hoxworth Blood Center is recruiting for Division Director, Core Operations, to provide leadership, vision, and oversight of programs related to donor center core operations, including Biomedical Engineering, Materials Management, Physical Operations, and computer software informational systems. Experience in daily production of cleanroom environments, as well as recruitment and training of new employees with knowledge in cleanroom environment and regulatory framework in accordance with cGMP, FDA, and ISO regulations pertinent to the environmental control in ISO7/8

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facilities is crucial. Enforce current strategic planning initiatives; develop new activities and establish goals in support of blood center strategic plans. Direct and facilitate cross functional activities that support the interdepartmental communications, productivity, and quality between various operating units. Develop innovative processes for monitoring operations to ensure high quality customer service and successful delivery of outputs. Required Education and Experience: Bachelor's Degree in related field of healthcare, biological or computer sciences. Seven (7) years of relevant experience in equipment management, computer and software information systems, blood banking, biotherapies, transfusion medicine, or scientific research. Three (3) years of direct supervisory experience managing employees, teams, and assets. For full description and to apply, visit: https://bit.ly/3OHlZet. The University of Cincinnati is an Equal Opportunity Employer.