

2024 #19

June 7, 2024

INSIDE:

FDA Reorganization
Finalized.....2

INFECTIOUS DISEASES
UPDATES3

PEOPLE.....4

ABC Hosting Prehospital
Blood Transfusion
Programs Webinar June
18th6

Participate in the ADRP
Marketing Survey6

RESEARCH IN BRIEF6

MEMBER NEWS.....7

GLOBAL NEWS8

COMPANY NEWS10

CALENDAR.....11

POSITIONS.....12

Blood Advocacy Week Begins June 10th

[Blood Advocacy Week](#) 2024 kicks off next week. This annual America's Blood Centers (ABC) event brings together organizations across the blood community and beyond that are committed to [championing policies](#) that expand access to blood products and ensure that all patients receive blood when needed. This year's initiative includes more than 80 organizations, an increase over the more than 40 groups that participated last year.



Advocacy priorities for Blood Advocacy Week 2024 include:

- [urging Congress to provide targeted federal funding to support blood centers' local education and awareness efforts;](#)
- [establishing a demonstration program to examine the use of pre-hospital blood for traumatic injury patients;](#)
- [encouraging Congress to establish a pilot program to attract diverse and younger blood donors, and to improve testing for better patient matches;](#) and
- [establishing a demonstration program to allow reimbursement for palliative blood transfusions outside of the Medicare hospice benefit.](#)

There will be a series of engaging events aimed at advocating for policies that not only expand the donor base but also increase access to life-saving blood products. ABC, its [members](#), and [partners](#) will:

- [send a letter to Members of Congress](#) asking them to make supporting the blood supply a national priority;
- hold a briefing on Tuesday, June 11th at noon EDT on Capitol Hill in Longworth 1539 on the status of the nation's blood supply and urge action on key priorities;
- meet with key leaders from federal agencies to encourage administrative action to support the blood supply; and
- urge public action through a weeklong [Axios Politics and Policy takeover](#), press releases, [letters to Congress](#), and [social media campaigns](#).

Thank you to members of ABC's [2024 Corporate Partner Council](#) for sponsoring Blood Advocacy Week. This includes Abbott, Grifols, Terumo BCT, Roche, Cerus, Fresenius Kabi, Healthcare-ID, Macopharma, and Velico. We encourage all those interested to [take part](#). To learn more, visit BloodAdvocacyWeek.org or email bloodadvocacyweek@americasblood.org.

Contributed by Jeff Gohringer, Director of National Partnerships and Strategic Communications at ABC 💧

FDA Reorganization Finalized

The U.S. Food and Drug Administration (FDA) has [published](#) a new organizational structure. The June 3rd *Federal Register* notice described changes which aim to make the FDA, “more efficient, nimble, and ready for the future with the ever-changing and complex industries we regulate, including the emergence of new food and medical product technologies, the impacts of globalization, climate change and other factors that require FDA to quickly adapt to a consistently evolving world.” The agency anticipates the reorganization taking effect October 1st. Of note in the new structure, the Office of Regulatory Affairs (ORA) will be renamed as the Office of Inspections and Investigations (OII), “and establish new inspection and investigation offices to focus on inspections, investigations, and imports as its core mission.”

The restructuring will also:

- “realign ORA’s laboratory safety functions and resources as well as the Medical Product and Specialty Laboratories safety functions and resources to the Office of the Chief Scientist (OCS);”
- realign emergency response functions and resources from the Office of Operations’ Office of Security and Emergency Management to OII;
- realign ORA’s compliance functions to [the] Center for Biologics Evaluation and Research’s (CBER) Office of Compliance and Biologics Quality, [the] Center for Devices and Radiological Health’s Office of Product Evaluation and Quality, [the] Center for Drug Evaluation and Research’s Office of Compliance and its substructure organizations;
- merge the Office of Counter-Terrorism and Emerging Threats, and the Office of Regulatory Science and Innovation, to form the Office of Regulatory and Emerging Science. Establish the Communications and Outreach Staff, the Preparedness Research Staff, and the Regulatory Science Staff to this new organization;
- establish the Office of Specialty Laboratories and Enforcement Support and realign functions from ORA’s Office of Medical Products Laboratory Operations within the Office of Regulatory Science to this new organization which will be a direct report to OCS; [and]
- establish the Office of Science and Laboratory Advancement and realign functions from ORA’s Office of Safety within the Office of Regulatory Science to this new organization which will be a direct report to OCS.”

The announcement also explained that, “the Office of Compliance and Biologics Quality within CBER is headed by the Director for Compliance and Biologics Quality [and will include the] Blood and Tissue Compliance Branch [and] Laboratory of Blood Related Products Branch [as part of its organizational units.]”

(Source: *Federal Register* [Notice](#), 6/3/24) 💧

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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

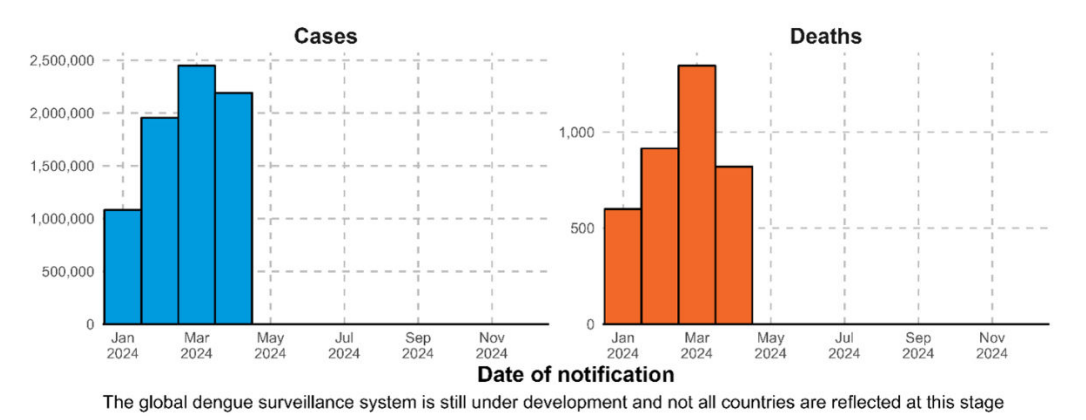
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INFECTIOUS DISEASES UPDATES

DENGUE

The World Health Organization (WHO) has [released](#) a disease outbreak news communication regarding the global situation concerning dengue. In the May 30th update, the organization explained that, “over 7.6 million dengue cases have been reported to WHO in 2024, including 3.4 million confirmed cases, over 16,000 severe cases, and over 3,000 deaths. While a substantial increase in dengue cases has been reported globally in the last five years, this increase has been particularly pronounced in the Region of the Americas, where the number of cases has already exceeded seven million by the end of April 2024, surpassing the annual high of 4.6 million cases in 2023. Currently, 90 countries have known active dengue transmission in 2024, not all of which have been captured in formal reporting. In addition, many endemic countries do not have strong detection and reporting mechanisms, so the true burden of dengue globally is underestimated. In order to control transmission more effectively, real-time robust dengue surveillance is needed to address concerns about potential undetected cases, co-circulation and misdiagnosis as other arboviruses, and unrecorded travel movements. These factors could contribute to unrecognized disease spread and establish a potential risk for local transmission in non-endemic countries. Dengue virus is transmitted to humans through the bite of infected mosquitoes. Cases are most commonly asymptomatic or result in mild febrile illness. However, some cases will develop severe dengue, which may involve shock, severe bleeding, or severe organ impairment. To strengthen global surveillance, and monitor temporal trends and disease incidence, WHO has established a global dengue surveillance system with monthly reporting across all WHO regions with a new dashboard now [live](#). The overall capacity for countries to respond to multiple, concurrent outbreaks continues to be strained due to the global lack of resources, including shortages of good quality dengue diagnostic kits for early disease detection, lack of trained clinical and vector control staff and community awareness...Given the current scale of the dengue outbreaks, the potential risk of further international spread and the complexity of factors impacting transmission, the overall risk at the global level is still assessed as High and thus dengue remains a global threat to public health.”

*Epidemic curve of dengue cases and deaths as reported to WHO from January to April 2024**

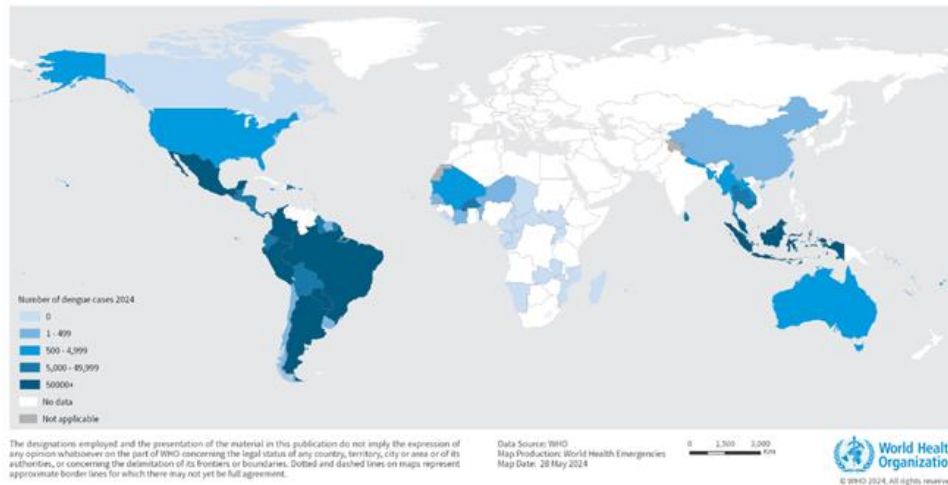


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INFECTIOUS DISEASES UPDATES (continued from page 3)

*Geographical distribution of dengue cases as reported to WHO from January to April 2024**



(Source: WHO [Announcement](#), 5/30/24)

CREUTZFELDT JAKOB DISEASE

The European Medicines Agency (EMA) has [published](#) a [revised](#) reflection paper on May 31st on “Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products.” According to the agency, “[t]he main change in this revision is that it is no longer recommended to exclude donors who have spent at least one year in the United Kingdom (UK) between 1980 and 1996 from donating blood/plasma for fractionation. Cases of variant Creutzfeldt–Jakob disease in the UK declined in the last two decades. The last known UK case was reported in 2016 and no transfusion-transmitted infections have been reported from the UK since 1999.”

(Source: EMA [Announcement](#), 5/31/24) 💧

PEOPLE

Hoxworth Blood Center has [named](#) **Caroline Alquist, MD, PhD**, chief transplant and cellular therapies officer and **David Oh, MD, MHA**, chief medical officer, as interim co-directors as of June 3rd. According to the blood center news release, “Drs. Alquist and Oh, who both hold appointments as Associate Professor of the University of Cincinnati (UC) College of Medicine, have extensive experience in the field of blood bank administration and together they will lead Hoxworth as they collaborate on all blood center management and strategic efforts. Dr. Alquist will ensure seamless continuity of Hoxworth’s clinical patient care. She is a leader in apheresis, transplant immunology and biotherapies with significant skill in clinical pathology, transfusion medicine, histocompatibility,



Photo courtesy of Hoxworth Blood Center: Drs. Oh (left), Cancelas (center), Alquist (right).

(continued on page 5)

PEOPLE (continued from page 4)

laboratory medicine leadership and blood management. Since joining Hoxworth in 2020, her clinical focus has been in supporting all regional solid organ and bone marrow transplants, which she will continue while serving as co-director. She has served as interim division director of Cellular Therapies since last year but will relinquish those responsibilities as soon as an ongoing search is completed to permanently fill that position. Dr. Oh possesses a wealth of experience in operational process optimization and innovative initiatives and has provided leadership to blood centers [including] the American Red Cross, San Diego Blood Bank, and Stanford Blood Center. Dr. Oh joined [the] University of Cincinnati (UC) in 2017 and will continue to focus his attention on blood supply, including blood donor recruitment, collection, processing, labeling, testing, storage, and distribution. He also will continue as the UC Medical Center Transfusion Medicine/Blood Bank Medical Director and as the director of the Hoxworth Transfusion Medicine/Blood Banking Fellowship Program while leading all medical student, resident, and fellow transfusion medicine education.” The leadership change follows the, “departure of **José Cancelas, MD, PhD**, who has served as director and chief executive officer since February 2018. Reflecting on his tenure, Dr. Cancelas expressed gratitude for the support of the community, staff, and donors, saying, ‘My time at Hoxworth has been a privilege, and I am immensely proud of what we have achieved together.’ Dr. Cancelas is joining Dana-Farber Cancer Institute in Boston, where he will be the executive director of the Connell-O’Reilly Cell Manipulation Core Facility and hold an endowed professorship at Harvard Medical School. Under his leadership, Hoxworth became the only academic unit formed by a blood center in the U.S., significantly expanded clinical activities, and conducted groundbreaking bench and clinical research.”

(Source: Hoxworth Blood Center [News Release](#), 5/29/24)



Mani Venkatesh has been [announced](#) as vice president of Digital Transformation at Terumo Blood and Cell Technologies (Terumo BCT). According to a company news release, Mr. Venkatesh will, “maximize the use of previous digital investments and oversee research and development, cybersecurity, and data privacy related to adopting emerging technologies. Previously, he held leadership positions overseeing software projects at GE Healthcare, Medtronic, and Spacelabs Healthcare.” He joined Terumo BCT in, “2020 as vice president of Global Software Engineering, where he played a critical role in driving efficiencies for customers and helping lead company growth. Some notable examples of his work include the software for the Rika™ Plasma Donation System and software for the management of Terumo BCT devices used in blood centers and by cell therapy manufacturing organizations.”

(Source: Terumo BCT [News Release](#), 5/21/24) ♦

NEW on CollABORate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC [CollABORate](#) Online Member Community include:

- [Scholarship Program Sponsored by Blood Center](#) (MEMBER RESOURCES)
- [Epi Pens](#) (MEMBER RESOURCES)
- [Product Testing](#) (MEDICAL ISSUES)
- [Water Baths](#) (QUALITY BYTES)
- [B Medical Systems Plasma Freezer](#) (ALL MEMBER FORUM)



America's Blood Centers®
It's About *Life*.

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 Hosting Prehospital Blood Transfusion Programs Webinar June 18th

The ABC Education Committee will be hosting a Prehospital Blood Transfusion Programs Webinar on June 18th at 3 p.m. EDT. [Registration](#) is open. The webinar will feature Chief Adam Hagar and Daniela Hermelin, MD sharing their experiences in implementing and maintaining a prehospital blood transfusion program. Chief Hagar serves as battalion chief-EMS at Mehlville Fire Protection District in St. Louis. Dr. Hermelin is the chief medical officer at ImpactLife and an assistant professor of Pathology at the St. Louis University School of Medicine. A link to registration is available to ABC members in [MCN 24-035](#). Please contact ABC Director of Scientific and Technical Operations [Betzy Gonzalez, MS BB\(ASCP\)](#) with questions.

Participate in the ADRP Marketing Survey

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. 💧

RESEARCH IN BRIEF

Efficacy and Safety of Blood Donation in Hemochromatosis Donors. A [study](#) published in *Frontiers In Medicine*, “present[ed] the results of efficacy and feasibility of phlebotomy and erythrapheresis performed in the blood donation center in treating individuals who carry hemochromatosis (HC) and other HFE genotypes, and who potentially qualify as blood donors.” The researchers noted that individuals, “[e]ligible for the study were persons with no relevant clinical condition aged 18 to 65 years with the following: p.C282Y, p.H63D, or p.S65C HFE variants in homozygous or compound heterozygous combination [and] elevated ferritin (above 200 ng/mL in females, above 300 ng/mL in males).” The study participants were, “randomized 1:1 to phlebotomy or erythrapheresis.” They explained that, “[w]ith phlebotomies, 450 mL [of] whole blood was drawn corresponding to the removal of 200–250 mg iron... With erythrapheresis, a fixed volume of 360 mL red blood cells (RBC) corresponding to 360–370 mg iron was collected. [Phlebotomies were] scheduled weekly and erythraphereses every 14 days until ferritin was below 100 ng/mL.” The authors stated that, “[the] primary endpoint of the study was the number of phlebotomies and erythraphereses

(continued on page 7)

RESEARCH IN BRIEF (continued from page 6)

needed to reach a ferritin value below 100 ng/mL. Secondary objectives included the number of days needed to reach the ferritin target and immediate and delayed adverse events (AEs)...The HFE genotype was p.C282Y/p.C282Y in 17 subjects, p.C282Y/p.H63D in nine, and p.H63D/p.H63D in four...The median number of phlebotomies required to lower ferritin below 100 ng/mL was 1.9 times that of erythraphereses (7.5 [IQR 6.2, 9.8] vs. 4.0 [IQR 3.0, 5.8]; p=0.001)...The median duration of treatment was 59.0 days (IQR 49, 103) and 78.5 days (IQR 46.0, 139.0) (p=0.448), respectively.” The researchers explained that the, “treatment arm and HFE variant were the covariates with a significant effect on the primary endpoint (p=0.001 and p=0.007)...In total, 27 participants completed the study (90 percent)...Local hematoma was more frequent with erythrapheresis (21 percent).” That study found that, “[f]atigue was the most frequent AE and was reported after 25 percent of phlebotomies and 47 percent of erythraphereses.” One of the sites cleared “94 red blood cell concentrates, and 56 plasma units obtained from the study participants [for] transfusion.” The researchers concluded that, “[the] study shows that a tight schedule of iron removal with blood donation procedures is feasible and safe, but it is associated with side effects that are potentially relevant and that can impair compliance to treatment.”

Citation: Infanti, L., Leitner, G., Moe, M., *et al.* “[Blood donation for iron removal in individuals with HFE mutations: study of efficacy and safety and short review on hemochromatosis and blood donation.](#)” *Frontiers in Medicine*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 💧

MEMBER NEWS

The Blood Emergency Readiness Corps (BERC) recently [activated](#) to assist **Carter BloodCare** with its blood needs in wake of severe weather in the north Texas area. “As part of their on-call week, the following community-based blood centers have rushed blood to the region:

- **Blood Assurance;**
- **Bloodworks Northwest;**
- **Central Pennsylvania Blood Bank;**
- **Coastal Bend Blood Center;**
- **ConnectLife;**
- **LIFELINE Blood Services;**
- **LifeSouth Community Blood Centers;**
- **MEDIC Regional Blood Center;**
- **Our Blood Institute;**
- **Solvita Blood Center;** and
- **Western Kentucky Regional Blood Center.”**

According to the BERC news release, “Sunday’s activation marks the sixth time since its inception in September 2021 that the BERC network has been called upon to provide blood during a national emergency...BERC, a collaborative effort of over 30 community blood centers, was founded in 2021 to meet immediate transfusion needs when faced with large scale emergency situations that require blood transfusions. These blood centers commit to collecting extra units on a rotating ‘on call’ schedule to create an available supply of blood for emergency needs.”

(Source: BERC [News Release](#), 6/3/24)

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MEMBER NEWS (continued from page 7)

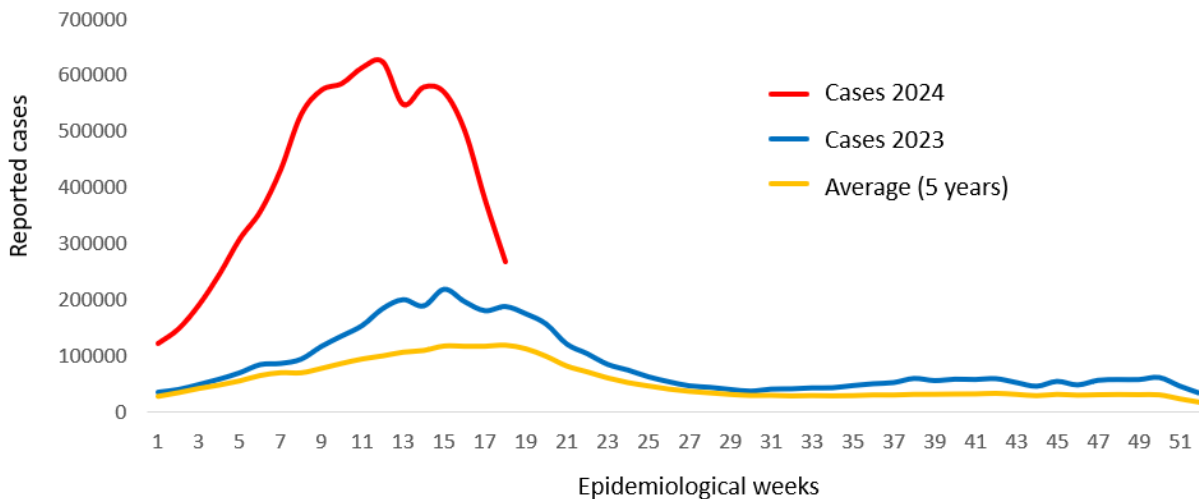
The Tarrant County Commissioners Court has [recognized Carter Blood-Care](#) for more than 70 years of service in providing “lifesaving transfusion resources” to the community with a proclamation recognizing June 14th as World Blood Donor Day. According to an announcement from the blood center, “the resolution was presented by Tarrant County Precinct 3 Commissioner [Gary Fickes](#) and read into the record at the court’s June 4th public meeting.”



(Source: Carter BloodCare [Announcement](#), 6/4/24) 💧

GLOBAL NEWS

The Pan American Health Organization (PAHO) has [issued](#) an epidemiological alert regarding the, “[Start of peak dengue season in the Central American Isthmus, Mexico, and the Caribbean.](#)” In the May 24th communication, the organization explained that, “[a]s of mid-May 2024, the Americas region has reported more than 8.1 million suspected cases of dengue, marking a 3.3-fold increase compared to the same period last year. The countries with the highest number of reported cases are Brazil, Argentina, Paraguay, Peru, Colombia, and Mexico. More than 3,600 dengue-related deaths have been reported throughout the region. Mexico has reported more than 65,000 cases of dengue, Guatemala over 12,000, Honduras over 20,000 and Panama over 5,800. This is between 2.5 and nearly six times the number of cases reported during the same period in 2023. Meanwhile, countries and territories in the Caribbean have reported over 21,000 cases, representing a 5.7-fold increase compared to the corresponding period last year. Faced with this unprecedented regional increase in dengue cases, PAHO urges countries to intensify efforts to combat the mosquito vector and the disease, for which there is no specific treatment.” The alert emphasized, “the importance of timely clinical diagnosis, early identification of warning signs, and proper management of patients to avoid serious cases and deaths. The Organization also calls on health care workers to provide clear guidance to patients and their families to monitor warning signs and seek immediate medical attention in the event of any of these signs... Since clustering of cases is common in these diseases (dengue, chikungunya and Zika), efforts should be made to analyze the spatial distribution of cases to enable a rapid response at the local level in the most affected areas. Information from the hotspots of the three diseases should be targeted for intensive vector control.”



(Source: PAHO, “[PAHO urges countries to strengthen dengue prevention in Central America, Mexico and the Caribbean.](#)” 5/24/24)

(continued on page 9)

GLOBAL NEWS (continued from page 8)

World Blood Donor Day (WBDD) 2024 will be [celebrated](#) on Friday, June 14th and mark its 20th anniversary. The World Health Organization (WHO) has revealed



that this year's theme is, "20 years of celebrating giving: thank you blood donors!" The organization is encouraging blood centers and transfusion services worldwide to,

- "thank and recognize the millions of voluntary blood donors who have contributed to the health and well-being of millions of people around the world;
- showcase the achievements and challenges of national blood program[s] and share best practices and lessons learned;
- highlight the continuous need for regular, unpaid blood donation to achieve universal access to safe blood transfusion; [and]
- promote a culture of regular blood donation among young people and the general public and increase the diversity and sustainability of the blood donor pool."

The WHO has developed and released WBDD 2024 [key messages](#) and [campaign assets](#) that can be used.

(Source: WHO [Announcement](#), 5/30/24)

A cyberattack this week temporarily [forced](#) NHS, the national health service, in the United Kingdom to cancel operations and blood transfusions. According to *Daily Mail*, the incident occurred on an information technology (IT) system that "serves NHS pathology labs." Specifically, the ransomware attack targeted, "Synnovis [which] is run by SYNLAB UK & Ireland and performs more than 32 million pathology tests a year...NHS officials said they were working with the National Cyber Security Cent[er] to understand the impact of the ransomware cyberattack."

(Source: *Daily Mail*, "[NHS cyberattack cancels operations and blood transfusions: Hackers target Guy's and St Thomas' and Kings College Hospital as health service declares 'critical incident'](#)," 6/4/24)

Valneva SE has [received](#), "a positive opinion recommending authorization of Valneva's single-dose vaccine for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older." According to the news release, "[the] European Commission (EC) will review the Committee for Medicinal Products for Human Use (CHMP) recommendation, and a decision on the marketing authorization application of [the vaccine,] IXCHIQ®, in the European Union (EU), Norway, Liechtenstein and Iceland is expected in the third quarter of 2024. If approved, it will become the first chikungunya vaccine available in Europe to address this unmet medical need. In accordance with the International Reliance Procedure (IRP), Valneva is also preparing a Marketing Authorization Application (MAA) for submission to the UK Medicines and Healthcare products Regulatory Agency (MHRA). The CHMP opinion follows the November 2023 approval of IXCHIQ® by the U.S. Food and Drug Administration (FDA). Two additional marketing authorization applications are currently under review by Health Canada and the Brazilian Health Regulatory Agency (ANVISA) with potential approvals in 2024."

(Source: Valneva SE [News Release](#), 5/31/24)

The World Health Organization (WHO) has [announced](#) publication of new data that indicates an increase in sexually transmitted infections (STIs) worldwide. The data appears in the WHO report titled, "[Implementing the global health sector strategies on HIV, viral hepatitis and sexually transmitted infections, 2022–2030](#)." According to the agency, "[i]n 2022, WHO Member States set out an ambitious target of

(continued on page 10)

GLOBAL NEWS (continued from page 9)

reducing the annual number of adult syphilis infections by ten-fold by 2030, from 7.1 million to 0.71 million. Yet, new syphilis cases among adults aged 15-49 years increased by over one million in 2022 reaching eight million. The highest increases occurred in the Region for the Americas and the African Region. Combined with insufficient decline seen in the reduction of new HIV and viral hepatitis infections, the report flags threats to the attainment of the related targets of the Sustainable Development Goals (SDGs) by 2030...In 2022, around 1.2 million new hepatitis B cases and nearly one million new hepatitis C cases were recorded. The estimated number of deaths from viral hepatitis rose from 1.1 million in 2019 to 1.3 million in 2022 despite effective prevention, diagnosis, and treatment tools. New HIV infections only reduced from 1.5 million in 2020 to 1.3 million in 2022. Five key population groups — men who have sex with men, people who inject drugs, sex workers, transgender individuals, and individuals in prisons and other closed settings — still experience significantly higher HIV prevalence rates than the general population. An estimated 55 percent of new HIV infections occur among these populations and their partners. HIV-related deaths continue to be high. In 2022, there were 630,000 HIV related deaths, 13 percent of these occurring in children under the age of 15 years.” Strategies recommended by the WHO to mitigate the increase in STIs include:

- “implement policy and financing dialogues to develop cross-cutting investment cases and national-level sustainability plans;
- further consolidate and align disease-specific guidance, plans, and implementation support within a primary health care approach;
- accelerate efforts to address ongoing criminalization, stigma, and discrimination within health settings, particularly against populations most affected by HIV, viral hepatitis, and STIs;
- expand multi-disease elimination approaches and packages, drawing from lessons learned from the triple elimination of mother-to-child transmission; and
- strengthen the focus on primary prevention, diagnosis, and treatment across the diseases to raise awareness especially for hepatitis and STIs.”

(Source: [WHO Report](#), 5/21/24)

The United Kingdom’s (UK) “Infected Blood Inquiry” report has been [published](#). The inquiry examined the crisis in the 1970s and 1980s that resulted in more 30,000 individuals being infected with HIV and hepatitis C from contaminated blood products. The report includes:

- [an] overview and recommendations;
- what happened and why; and
- the response of government and public bodies.

UK Prime Minister Rishi Sunak [issued](#) a statement apologizing to the victims and their families following the release of the report.

(Sources: [UK Infected Blood Inquiry Report](#), 5/20/24; PM Rishi Sunak [Statement](#), 5/20/24) 💧

COMPANY NEWS

Be Biopharma, Inc. recently [announced](#) the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug application (IND) for its engineered B cell medicine (BCM) to treat hemophilia B. According to a company news release, the BCM is, “engineered to insert the human F9 gene into primary human B cells, allowing for expression of active factor IX (FIX) for the treatment of hemophilia B. [The therapy] has the potential to express sustained therapeutic FIX activity levels with a single infusion with the flexibility to be re-dosed, if needed. The potential to maintain therapeutic FIX activity levels while

(continued on page 11)

COMPANY NEWS (continued from page 10)

reducing dosing frequency associated with current FIX replacement regimens would address the considerable infusion burden associated with current therapies and potentially drive significant reductions in the annualized bleeding rates and FIX usage.” The company anticipates dosing the first patients in a phase I/II clinical trial (BeCoMe-9) later this year. The clinical trial will be, “a multi-center, first-in-human dose escalation study designed to assess the safety and preliminary efficacy of BE-101 in adult participants with moderately severe to severe hemophilia B.” According to Be Biopharma, preclinical study data showed that, “a single dose of [the therapy] has demonstrated the ability to deliver active and sustained FIX levels. The data confirmed the expected biodistribution of FIX-expressing BCMs in bone marrow tissue, where they engraft stably over time. Additionally, the redosability of [the therapy] has been demonstrated, resulting in a predictable increase in plasma FIX levels.”

(Source: Be Biopharma, Inc. [News Release](#), 5/28/24) 💧

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

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 18. **ABC Prehospital Blood Transfusion Programs Webinar.** More information and link to registration available to ABC members [here](#).

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

June 27. **U.S. Food and Drug Administration (FDA) Webinar: Final Guidance: remanufacturing of Medical Devices.** More information available [here](#).

July 24. **ADRP Webinar: Marketing Insights to Drive Change.** [Registration](#) is open. More information available [here](#).

Aug. 12-14. **National Institutes of Health (NIH) National Heart, Lung, and Blood Institute’s (NHLBI) Annual Sickle Cell Disease Research Meeting. (Hybrid) Bethesda, Md.** More information available [here](#).

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

Sept. 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.

(continued on page 12)

CALENDAR (continued from page 11)

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

2025

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

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

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

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

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

CLASSIFIED ADVERTISING

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POSITIONS

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 \(recruitingbypaycor.com\)](#)

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. Education: BA or master's degree in marketing, communications, or public relations. Experience: Minimum 10 years of demonstrated leadership experience in marketing and/or communications, including at least seven years of team management. Demonstrated experience managing budgets. Demonstrated experience evaluating media opportunities and buying. Licenses / Certifications: Valid driver's license. Click [here](#) to apply.

(continued on page 13)

POSITIONS (continued from page 12)

Director of Quality Assurance. Sheppard Community Blood Center in Augusta, Georgia, seeks an ambitious leader to promote product safety and compliance. A generous benefits package, including up to a 9 percent employer 401(k) contribution, relocation expenses, and ample PTO, are available for a successful candidate. Sheppard serves several communities in rapidly growing communities in Georgia and South Carolina. The ideal candidate will have at least six years of experience in blood banking, quality assurance, or compliance. Responsibilities include serving as the subject matter expert in regulatory compliance; working with operational leaders to help advance Sheppard's strategic plan; and overseeing the review and implementation of SOPs, validations, maintenance, reporting, and other related processes. The person selected for this role must see themselves as an integral member of the Sheppard leadership team and dedicated to furthering the organization's long-term goals. Those interested can apply at sheppard-blood.org.

Donor Services Operations Director (Our Blood Institute, Fort Smith, AR). This position will provide leadership and direction over all aspects of the Donor Services collection team for both mobile and fixed site operations. It is responsible for assessing, developing, and implementing strategic plans to achieve donor services objectives and goals. Create a friendly competitive environment to motivate staff to achieve high system wide standings on all key performance metrics (loss rates, errors, 2RBC conversion, Global Blood Fund, etc.). Conduct routine meetings to communicate organizational vision, updates, and changes and recognize outstanding staff performance keeping morale high. Maintain adequate staffing levels. Make frequent visits to both fixed and mobile collection sites. Actively participate in internal and external assessments/inspections including corrective action plans and effectiveness checks as needed. Track and monitor inventory and collection goals, which include whole blood, automation rates, and WB conversion data. Analyze data and make adjustments to increase productivity. This includes working closely with recruitment to ensure projections are met. Prepare and manage department annual budgets. Qualifications: Bachelor's degree in management or medical field. Minimum of five years' leadership/management experience, and valid driver's license. Salary: Competitive salary and excellent benefits <http://obi.org/careers/>.

Operations Coordinator – Mobile Collections (Carter BloodCare). Principal Accountability: The Operations Coordinator-Mobile Collections position is crucial within the Collection Management team. Key responsibilities include ensuring daily production objectives and standards are met, maintaining high levels of compliance and customer service, and serving as the primary contact and

acting manager in the manager's absence. Duties also involve hiring collection staff, conducting investigations, fostering employee development, and providing feedback on termination decisions. The role requires promoting team spirit within the department and collaborating with all CBC personnel to ensure maximum efficiency. Education: High School diploma or equivalent. College degree preferred. Bilingual skills are a plus. Special licensure such as CDL driver a plus. Experience: Two (2) years of supervisory/management experience. Background in a highly regulated field. Previous blood banking or apheresis experience required. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job **Ops Coord Mobiles**.

Senior Vice President (SVP). Reporting to the Chief Operating Officer, the Senior Vice President (SVP) will function as the top executive leader of Enterprise Laboratory Services and will be responsible for overseeing the day-to-day operations, developing strategy, implementing business plans, managing the department's P&L (including revenue and operating margins), developing budgets and financial plans, and fostering a high-performance, customer-oriented culture. Education: BS/MS/PhD in Medical Technology or Applied Science, or MD with background in transfusion medicine, medical laboratory, or related specialty. An assorted business degree (MBA, MPA, MHA or equivalent) is highly desirable. Experience: Ten (10) years of blood banking or comprehensive laboratory experience, with five years at managerial level. Relevant published research in peer reviewed journals is highly desirable. For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is \$ 350,000.00 p/yr. to \$375,000.00 p/yr. For applicants who will perform this position outside of New York City or Westchester County, salary will reflect local market rates and be commensurate with the applicant's skills, job-related knowledge, and experience. Please click [here](#) to apply.

Transfusion Lab Supervisor Needed! Join Florida's leading blood center, OneBlood, as a Blood Bank Lab Supervisor in Lakeland, FL. Bring your leadership, technical expertise, and management experience to support the transfusion testing procedures on patient and/or donor samples. Qualified candidates should possess three (3) or more years' experience in a clinical laboratory, preferably blood banking environment, including one (1) or more years' experience in supervision and management experience, as well as a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Supervisor license strongly preferred. To apply and view a complete Job Description of this Lab Supervisor position, visit www.oneblood.org/careers. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

(continued on page 14)

POSITIONS (continued from page 13)

Assistant/Associate Director Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology, or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. We collaborate closely with clinical colleagues in bone marrow and solid organ transplantation, CAR-T cell therapy, cardiac surgery, trauma and critical care, neurology, and pediatrics. Our faculty also work closely with transfusion medicine faculty within the MGB network. Service and teaching responsibilities will be shared with two full and several part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ148, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Director, Division of Cellular Therapies (Hoxworth Blood Center, University of Cincinnati). Hoxworth Blood Center (HBC) is seeking a Stem Cell Transplant/Cellular Therapies Medical Director and Processing Facility Director. This is an open rank/track, faculty position, with opportunities for collaborative clinical and basic research, and an active clinical trials program in stem cell transplantation and immunotherapies, supporting four different stem cell transplantation programs in Ohio. Candidates with expertise in transfusion medicine, hematology, hematopoietic biology and therapy, immunology and/or immunotherapies could use this opportunity to build a translational/clinical research program. HBC has established connections with world-class research departments that offer access to a wide variety of shared facilities. Minimum Requirements: Applicants must have an MD or DO to be considered as the processing facility director and processing facility medical director, and licensed or eligible for unrestricted license in the State of Ohio. Applicants must have a PhD to be considered solely as the processing facility director. Position and track will depend on academic accomplishments and programmatic expectations. At least two years' relevant experience in the preparation and clinical use of cellular therapy products is required. For full description and to apply, visit <https://bit.ly/3woC42L>. The

University of Cincinnati is an Equal Opportunity Employer.

Associate Director – Process Excellence Design and Field Support. This position is charged with eliminating waste and standardizing operations to enable optimization of the collection staff and donor experience across Enterprise Divisions allowing for improved efficiency and productivity. The position will own and drive projects to completion, have the ability to build complex models for the validation of new procedures and technology that inform decision-making in donor and product management and support all other pillars of the Enterprise Collections Center of Excellence (ECCOE) in the identification of metrics for performance management. The position interacts with multiple verticals within the Enterprise Collections Center of Excellence departments and other departments within New York Blood Center Enterprise such as Information Technology, Laboratories, Quality/Regulatory Affairs, Recruitment, and Logistics. Candidates must be able to report into one of the following NYBCe locations: New York City, NY; Kansas City, Missouri; St. Paul, Minnesota; Providence, RI and Newark, DE. For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is \$130,000.00 to \$140,000.00. For applicants who will perform this position outside of New York City or Westchester County, salary will reflect local market rates and be commensurate with the applicant's skills, job-related knowledge, and experience. Click [here](#) to view the full job description and apply.

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

(continued on page 15)

POSITIONS (continued from page 14)

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/48917G1>. The University of Cincinnati is an Equal Opportunity Employer.

Immunoematology Reference Laboratory Manager.

LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Immunoematology 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!](#)

Immunoematology 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 Immunoematology 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 immunoematology 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!](#)

Immunoematology 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 Immunoematology 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 immunoematology 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!](#)

Immunoematology 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 Immunoematology 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 immunoematology 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!](#)

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. [Click here](#) to apply. 💧