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

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

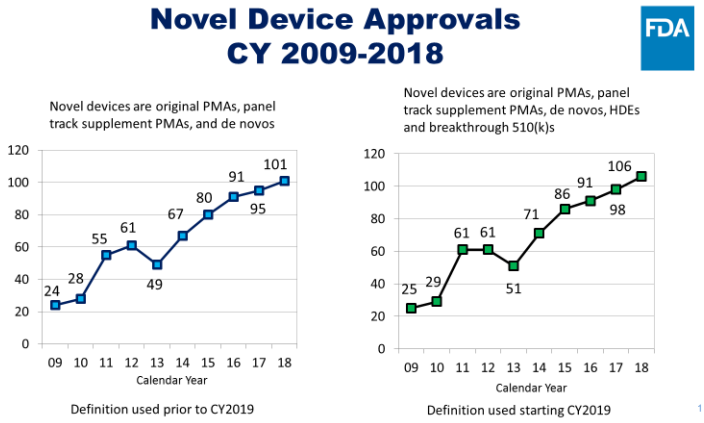
2019 #3 **February 1, 2019**

INSIDE:

FDA Reports Increase in Device Approvals and Announces Guidance on Safety and Performance Based Pathway

In April, 2018, the U.S Food and Drug Administration (FDA) released the "Medical Device Safety Action Plan: Protecting Patients and Promoting Public Health." Major themes included both patient safety and innovation, as the plan focused on the total product life cycle of a medical device using all the tools at its disposal including pre- and post-market data and expertise during development, evaluation, and marketing recognizing that oversight should be consistent and equate to the degree of risk present.

This week, the agency unveiled data that it says demonstrates increased innovation through steady growth in the number of devices approved dating back to 2008.



Courtesy of the U.S. Food and Drug Administration

"The Action Plan described some of the steps we've taken over the past few years to enhance device safety and outlined our vision for how the agency can build on these initiatives to further assure the safety and effectiveness of medical devices," said FDA Commissioner Scott Gottlieb, MD and Jeff Shuren, MD, director of the FDA's Center for Devices and Radiological Health (CDRH) in a joint statement this week. "One measure of our success in advancing device innovation is the annual number of novel, safe and effective technologies the FDA approves or clears. Last year marked another record year, supported by the new policies, processes and programs we've implemented over recent years to help efficiently promote safe and effective innovation in medical device development. [I]n 2018, the FDA approved 106 novel devices, surpassing the 40-year record we set in 2017 of 99* novel device approvals, and capping off eight years of steady improvement."

(continued on page 2)

FDA Device Approvals & Guidance (continued from page 1)

This follows publication of the final guidance for manufacturers entitled **"Safety and Performance Based Pathway**." That guidance detailed how the agency's thinking on expanding the concept of the abbreviated 510(k) Program for demonstrating substantial equivalence for premarket notification 510(k) submissions.

"In 2019, we'll continue to move forward with our plans to implement the National Evaluation System for Health Technology (NEST)," added Dr. Gottlieb and Shuren in the January 28th joint statement. We also plan to establish premarket pathways that foster innovations to enhance patient safety while continuing to build a more robust patient safety net in the U.S… We recently finalized guidance for manufacturers for an alternative 510(k) pathway initially proposed in April—the FDA's "Safety and Performance Based Pathway"—by which companies would demonstrate they meet safety and performance criteria developed by the FDA based on the performance of more modern predicate devices (cleared, U.S. legally marketed devices) when they seek to bring new devices to patients."

The final guidance further explains what devices are appropriate for the safety and performance[-]based pathway, identifies performance criteria, insights into FDA's data review process, and provides explanations for the process of modifying performance criteria.

"This option for 510(k) clearance will modernize our approach to moderate risk devices by allowing manufacturers to use objective performance criteria established or recognized by the FDA to facilitate demonstration of substantial equivalence of their new products to legally marketed devices… " said Drs. Gottlieb and Shuren in a joint statement announcing the guidance on January 22nd. "For appropriate device types, the Safety and Performance Based Pathway will ensure that the performance characteristics of new devices are evaluated against a set of objective, transparent and well-validated safety and performance metrics. It's important to note that devices using this pathway will still have to meet our current standards for reasonable assurance of safety and effectiveness before they can be marketed. The benefit of this approach is that the pathway will benchmark modern technology against modern standards while, at the same time, offering a potentially more efficient way to demonstrate that a new device is substantially equivalent to devices already on the market, and thereby ensure patients have timely access to beneficial products."

**FDA defined novel devices as original PMAs, panel track supplement PMAs and de novos. In light of changes made by the 21st Century Cures Act to the Breakthrough Devices Program, the agency broadened their definition of novel devices to include HDEs and Breakthrough Device 510(k)s. Under this updated definition we approved/cleared 98 novel devices in CY 2017 and 106 novel devices in CY 2018.*

(Source: Scott Gottlieb, MD & Jeff Shuren, MD Joint Statements, 1/22/19; 1/28/19)

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

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize 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 healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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Toward A Better Understanding of Neonatal Red Blood Cell (RBC) Transfusion Risks

The authors examine the known risks of RBC transfusions in neonates and reflect on how the relative paucity of conclusive data necessitates better and more targeted work in this arena. They begin by reviewing potential adverse events reported through 26 different hemovigilance systems globally, including the United Kingdom's (UK) Serious Hazards of Transfusion (SHOT) program and the United States' National Healthcare Safety Network (NHSN) Hemovigilance Module.

The authors explore information gleaned from nine reputable observational studies that have reported associations between RBC transfusions and neonatal mortality and morbidity. Twenty-seven randomized clinical trials were analyzed along with multiple systematic meta-analyses and other reviews. Throughout their efforts, they focus not "just" on the kinds of transfusion-related complications that affect all (including non-neonatal) patients but also on the potential for transfused newborns to develop necrotizing enterocolitis intraventricular hemorrhage, retinopathy of prematurity, and chronic lung disease, among other adverse effects of transfusion. The most significant conclusions are:

1. "the main current impediments to advancement of neonatal transfusion research is a lack of registries or networks that include neonatal RBC transfusion-relevant data with outcome or donor linkage to recipients in sufficient detail;"
2. there is a "need for the [standardization] of definitions of adverse effects through international consensus;" and
3. "[multicenter] international research collaborations are also required to definitively determine the risk of RBC transfusion in neonates."

Citation: Keir, A.K., New, H., Robitaille, N., Crighton, G.L., Wood, E.M., Stanworth, S.J. Approaches to understanding and interpreting the risks of red blood cell transfusion in neonates. *Transfusion Medicine* 2019. doi: 10.1111/tme.12575.

Contributed by Chris Gresens, MD, Senior Chief Medical Officer, North & West Divisions, Vitalant

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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 staff only, unless otherwise specified.

Advocacy Agenda Input

ABC is developing its advocacy agenda for 2019 and seeking feedback from member blood centers. Please complete the brief survey linked in MCN 19-008 to share your input and make your voice heard by February 8th. The 2019 advocacy agenda will build upon the work completed over the past year. ABC thanks the many volunteers and partners who helped advance the policy issues outlined in the 2018 Advocacy Agenda. ABC members can view a summary of accomplishments and work related to the 2018 ABC Advocacy Agenda here.

(Source: MCN 19-008)

2018 Compensation and Benefits Survey Results Now Available

The results from ABC's 2018 Compensation and Benefits survey are available. Highlights include current trends in compensation and benefit programs of ABC member blood centers, with data effective as of October 1, 2018, along with salary data collected in an individualized manner, rather than organizational averages. This methodology allows the survey to present data that is more accurate, detailed, and far more reflective of the actual market. Thirty-four ABC member blood centers participated in the benefit survey, and 34 member blood centers participated in the compensation survey, which includes data representative of close to 12,000 employees and 67 positions. Participants can purchase the results for $450. Non-participant pricing is $900. This survey was designed by Gallagher Surveys, in collaboration with ABC's Human Resources Committee. To place your order, please e-mail Annmarie Flaherty. For blood centers that have already ordered the survey, an e-mail with the results has been sent.

(Source: ABC MCN 19-011)

57th ABC Annual Meeting Registration Open

Registration is open for America's Blood Centers' (ABC) 57th Annual Meeting in Washington, D.C. March 23rd – 26th, 2019 at the Ritz-Carlton (Pentagon City). Don't miss an exclusive opportunity for blood center leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Celso Bianco, MD Lectureship & Reception, the Scientific, Medical, and Technical Forum, Capitol Hill Visits, General Session, and the 22nd Annual *Awards of Excellence*. Please make your hotel reservations by March 1st to ensure best availability and the group rate. Click here for additional details. Contact Leslie Maundy for available sponsorship opportunities.

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

AMERICA'S BLOOD CENTERS'

57TH ANNUAL MEETING

March 23-26, 2019 | **Washington, DC**

2019 ANNUAL MEETING SCHEDULE

Saturday, March 23: International Blood Safety Forum
ABC Board Meeting

Sunday, March 24: General Session
SMT Forum & Celso Bianco Lectureship
Celso Bianco Celebration of Life Reception

Monday, March 25: ABC Members Meeting
General Session
22nd Annual *Awards of Excellence*

Tuesday, March 26: Advocacy Forum
Capitol Hill Visits

America's Blood Centers®
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"The ABC Annual Meeting is the premiere opportunity for individuals to explore trends amongst peers within the blood community, contribute their thoughts and ideas to important policy discussions with regulators, while sharing their stories with legislators and networking with industry partners. Value exists for professionals of all experience levels. Join us in Washington, D.C.!"

–Kate Fry, Chief Executive Officer
America's Blood Centers

Hotel Information
Ritz-Carlton (Pentagon City)
Hotel room rate: $259

For registration information, visit http://bit.ly/abc_am19.

For sponsorship opportunities, please contact Leslie Maundy at lmaundy@americasblood.org.

Upcoming ABC Webinars – Don't Miss Out!

- **SMT Journal Club –** April 3rd. Additional details forthcoming!
- **QA Education Webinar – PRT & Double Red Cell Licensure** – April 9th. Additional details forthcoming!
- **QA Education Webinar – Change Management** – July 16th. Additional details forthcoming!

RESEARCH IN BRIEF

Transfusion Medicine Reviews (TMR) launches new feature. Many journals (and Newsletters *et. al*) strive to alert their audiences to newly published work relevant to their mission. *TMR* has published a more prospective look at our literature by searching ClinicalTrials.gov for studies that are in progress and recruiting subjects that are relevant to our discipline with the aim to provide "readers a guide to emerging research for the months ahead." The editorial board hopes readers find information "useful for their clinical practice and their academic activities." The first list of 21 interventional and observational studies includes highly clinically relevant ongoing work related to the age of red blood cells, transfusion triggers in understudied cohorts, the use of plasma transfusion in patients undergoing invasive procedures, a variety of strategies to

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RESEARCH IN BRIEF (continued from page 5)

prevent or reduce bleeding in several populations, and studies on the use of pathogen reduction. Walter "Sunny" Dzik, MD, the *TMR* Editor was asked about the frequency of this feature in an e-mail interview with the *ABC Newsletter*. He responded, "given the pace of important studies... as in SLOW pace of important studies... I think for right now we might just do this annually".

Citation: Editorial Board. Emerging Research. *Transfusion Med. Rev*. 2019.

Transfusion-transmitted infections (TTIs) and the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN). From 2010 through 2016, facilities participating in CDC's NHSN reported on 7.9 million components transfused at 195 facilities that resulted in the recognition of 111 TTIs, 54 of which (37 bacteria, 16 parasites, 1 virus) met prespecified case definitions and imputability criteria. Four fatalities are included. Bacterial contamination and babesiosis, as expected, were the most frequently reported. A single transmission of hepatitis C virus (HCV) is included and none of HIV or hepatitis B virus (HBV). The CDC authors recognize the limitations of these self-reported data and their reliance on passive recognition that transfusion was a possible source of the pathogens. Further, the participating facilities are few compared to the population of eligible facilities and a large proportion are in a single state that mandates participation in the NHSN hemovigilance module, so generalizability may be limited.

Citations: Haass, K.A., Sapiano, M.R.P., Savinkina, A. *et al*. Transfusion-Transmitted Infections Reported to the National Healthcare Safety Network Hemovigilance Module. *Transfusion Med. Rev*. 2019.

Gene therapy for severe, transfusion-dependent beta-thalassemia reported from small phase 1-2 clinical trial. Sixty thousand infants are born annually, worldwide, with severe thalassemia. Building on animal models, a lentiviral-vectored autologous hematopoietic stem cell containing the functional beta-globin gene was given to three adults and six children resulting in rapid engraftment of vector-containing cells. Transfusion requirements fell in adults, and three of the four evaluable pediatric subjects were transfusion independent at last follow-up. The stem cells were infused into bone, to avoid trapping in "filter organs" (e.g. spleen and liver).

Citation: Marktel, S., Scaramuzza, S., Cicalese, M.P. *et al*. Intrabone hematopoietic stem cell gene therapy for adult and pediatric patients affected by transfusion-dependent ß-thalassemia. *Nat. Med*. 2019.

Cumulative U.S. incidence of West Nile virus(WNV) infection reported. Investigators in Houston, Texas use data from the CDC ArboNET national surveillance system for arboviral infections and published data to make the "conservative estimate" that there have been 7 million WNV infections in the continental U.S. since the virus was introduced in 1999.

Citations: Ronca, S.E., Murray, K.O., Nolan, M.S. Cumulative incidence of West Nile Virus infection, continental United States, 1999-2016. *Emerg. Inf. Dis*. 2019. doi:10.3201/eid2502.180765. ♦

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

PEOPLE

The Héma-Québec Board of Directors announced **Nathalie Fagnan, CPA, CA** as president and CEO. "The board of directors and I are very pleased to welcome Nathalie Fagnan," said board chair Martine Carré. "She will have no trouble quickly immersing herself in Héma-Québec's culture to carry on the transformation of the organization. Ms. Fagnan has a strategic mind and a solid background in operations management and finance. She has worked for major corporations in Canada and the United States and has many accomplishments in organizational transformation to her credit. Her experience will be a major asset in achieving the ambitions of our organization and meeting the many challenges that it faces today." Ms. Fagnan previously served in executive roles at Publicis and Raymond Chabot Grant Thornton.

(Source: Héma-Québec News Release, 1/30/19)

ABC 2019 Meetings & Workshops

Meeting/Workshop	Dates	Location	Hotel/Hotel Rate	Registration Dates & Fees
Annual Meeting	March 23-26	Washington, DC	Ritz-Carlton (Pentagon City), $259/night	Register here by Mar. 1 $760
Technical & Quality Workshop	April 30-May 2	Minneapolis, Minnesota	Embassy Suites, $139/night	Mid-Feb. (Early Bird TD or QA or TD + QA) $360/$435; Feb. 23-Apr. 5 (TD or QA or TD + QA) $420/$495
ADRP Annual Conference	May 14-16	Indianapolis, Indiana	Hyatt Regency, $179/night	Register here now Subscribers $575/$695 non-subscribers
Medical Directors Workshop	July 30 (precedes Summer Mtg)	Denver, Colorado	Grand Hyatt, $239 CAD/night	Late April - July 5 MD Workshop $435 MD+Summer $760
Summer Meeting	July 31-August 1	Denver, Colorado	Grand Hyatt, $239 CAD/night	Late April - July 5 Summer $655 Summer+MD $760

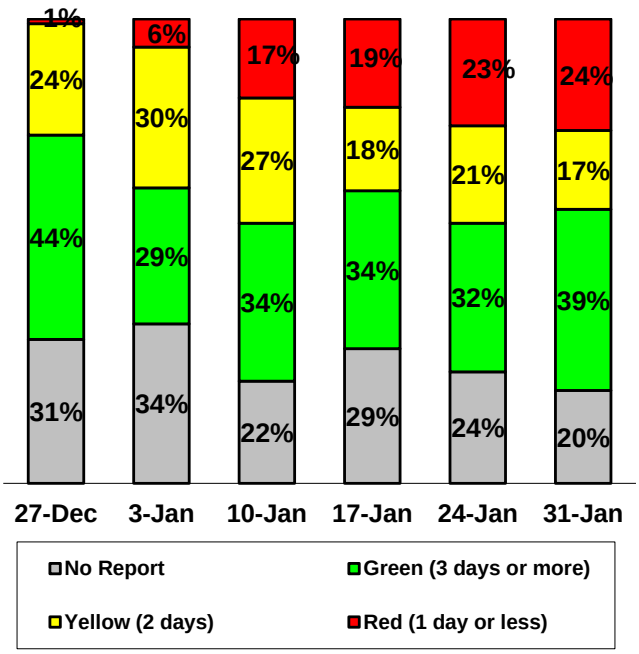
Notes:

For the most up-to-date information on all events, members of ABC may check the calendar on ABC's Member Site.

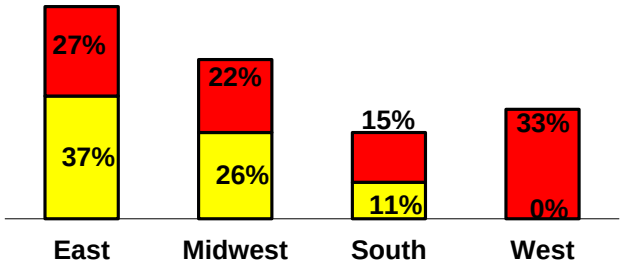
Non-members may attend all events; information will be updated on ABC's Public Site.

STOPLIGHT®: Status of America's Blood Centers' Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, January 31, 2019



Percent of Total ABC Blood Supply Contributed by Each Region
East: 20%; Midwest: 25%; South: 24%; West: 31%

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2019

March 6-7. **IPFA 4th Asia Workshop on Plasma Quality and Supply, Hanoi, Vietnam.** More details available here.

March 23. **2019 International Blood Safety Forum, Washington, D.C.** More details available here.

March 24-26. **2019 ABC Annual Meeting, Washington, D.C.** More details available here.

April 23-24. **15th Annual FDA and the Changing Paradigm for HCT/P Regulation, Washington, D.C.** More details available here.

April 30-May 2. **2019 ABC Technical & Quality Workshop, Minneapolis, Minn.** More details coming soon.

May 14-16. **ADRP Annual Conference, Indianapolis, Ind.** More details available here.

May 22-23. **IPFA/PEI 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens", Krakow, Poland.** More details available here.

July 30-Aug. 1. **2019 ABC Medical Directors Workshop & Summer Meeting, Denver, Colo.** More details 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 institutional 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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Chief Medical Officer (America's Blood Centers). Reporting to the Chief Executive Officer (CEO), the Chief Medical Officer (CMO) is responsible for implementing strategies and tactics, consistent with the best scientific and medical evidence and regulatory requirements, that support America's Blood Centers' (ABC) mission, maintain our values, and realize our vision. The CMO works as part of the ABC Senior Executive Team (SET) to communicate ABC's issues to members, regulators, legislators, and external groups and mobilizes ABC members and professional staff to achieve the strategic goals of the organization. The CMO serves as a public advocate for ABC, maximizing the organization's public presence as a national leader in shaping the future of blood banking, transfusion medicine, and cell therapies. Responsibilities: Represent independent non-profit community blood centers on scientific, medical, and technical matters as well as donor and patient safety concerns before federal agencies, industry and other business partners, allied domestic and international organizations, scientific societies, the media, and the public. Advise the CEO, ABC Board of Directors, and ABC member centers on medical, scientific, technical, safety, and policy issues germane to blood banking. Stay appraised of pertinent regulatory developments and develop effective strategies to achieve success on regulatory issues affecting ABC members. Education & Experience: Medical Degree required. U.S. medical license required with board certification in a medical specialty. Board certification in pathology, transfusion medicine, hematology, or infectious disease preferred. Ten or more years' experience related to blood banking or transfusion medicine. Three or more years' experience with healthcare and/or blood banking issues at a national level via committee work, offices held, or other appropriate experience. Administrative experience in a leadership role preferred. Please click here to view the full job description. To apply, please submit a resume and cover letter to Kate Fry.

Director, Fixed Site Operations. We Are Blood serves over 40 hospitals and medical facilities in a 10-county area. We are currently hiring a Director, Fixed Site Operations. Responsibilities: Subject matter expert for Donor Services: Develop and sustain complete familiarity with all industry guidelines, cGMP, technical skills, departmental SOPs, quality policies and procedures, human resources policies and procedures, mainframe donor database, document management software, operator manuals, training plans and other materials as appropriate. Administration of managerial functions: Direct, manage, and evaluate work activities of the Lamar Operations and Satellite Managers; ensure compliance with all applicable industry, federal and organizational guidelines, protocols, policies, and procedures. Employee development: Function as a mentor to fixed site and support staff; providing leadership, guidance, training and counsel; investigate and rectify employee performance and/or behavioral inadequacies with timely counseling; conduct fair, effective, unbiased and factual performance appraisals of department managers and ancillary staff. Project Management: Work with Donor Services Quality Assurance Manager to establish, implement and validate new processes, protocols, procedures, and technologies; draft and revise SOPs; record keeping and organizational leadership. To view the full posting, click here. EEO Employer: Minorities/Women/Veterans/Disabled

Director, Mobile Operations. We Are Blood serves over 40 hospitals and medical facilities in a 10-county area. We are currently hiring a Director, Mobile Operations. Responsibilities: Subject matter expert for Donor Services: Develop and sustain complete familiarity with all industry guidelines, cGMP, technical skills, departmental SOPs, quality policies and procedures, human resources policies and procedures, mainframe donor database, document management software, operator manuals, training plans and other materials as appropriate. Administration of managerial functions: Direct, manage, and evaluate work activities of the Business Integration Services (BIS) manager and mobile operations managers; ensure compliance with all applicable industry, federal and organizational guidelines, protocols, policies, and procedures. Employee development: Function as a mentor to mobile operations and BIS support staff; providing leadership, guidance, training and counsel; investigate and rectify employee performance and/or behavioral inadequacies with timely counseling; conduct fair, effective, unbiased and factual performance appraisals of department managers and ancillary staff; project management, record keeping, and organizational leadership. To view the full posting, click here. Check us out at www.WeAreBlood.orgto find out how you else you can be a part of our family. EEO Employer: Minorities/Women/Veterans/Disabled

Chief Information Officer. LifeShare Blood Center is currently seeking a Chief Information Officer. The Chief Information Officer (CIO) is responsible for directing the

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POSITIONS (continued from page 9)

information technology (IT) and communication strategy, and data integrity of LifeShare. The CIO oversees and manages the Project Management Office. This scope includes all data centers, technical service centers, production scheduling functions, help desks, data communication networks, computer program development, and computer systems operations. The CIO provides overall management, definition, and strategic planning of all computer and communication activities within the organizations; and provides insight to the C-suite and Board of Trustees on Information Technology and systems. Bachelor's degree in Computer Science or Business with emphasis in information management systems is required. A graduate degree is preferable. Ten plus years' experience in successive leadership with knowledge of contracting, negotiating, organization development, accounting, strategic planning, and supervision. Five plus years in an FDA regulated environment is highly desirable; blood-banking experience is advantageous. This position will be in our Shreveport, LA location. Review complete job description and submit applications at www.lifeshare.org/careers.

Medical Technologist, Clinical Laboratory Scientist, or Medical Laboratory Scientist (*MT/CLS/MLS; 2nd or 3rd Shift Available).* The Community Blood Center/Community Tissue Services is located in Dayton, OH. We are looking for a **Medical Technologist, Clinical Laboratory Scientist, or Medical Laboratory Scientist** to join our team of blood/tissue bank laboratory professionals. Our microbiology department is growing! We are expecting a volume of 437,000 tests this year. This position will be on either 2nd or 3rd shift. We perform sterility testing on all tissue grafts, and leukoreduced apheresis units, culture other blood products as needed and provide environmental surveillance cultures. If you haven't thought about working at a blood center or tissue bank give us a call. We'd be glad to give you a tour and tell you more about how we operate. The job consists of performing clinical microbiology testing. BS Required. ASCP certified as a Medical Technologist (MT), Clinical Laboratory Scientist (CLS), or Medical Laboratory Scientist (MLS). We offer a highly competitive benefit package including medical, vision, dental, life and supplemental insurance options, 401(k) with employer contribution and match, tuition assistance and generous paid time off (PTO). *CBC/CTS is an Equal Opportunity Employer/Protected Veteran/Disability. Drug-Free Workplace.* Visit our website to apply www.cbccts.org.

Medical Director. Provide transfusion medicine (TM) clinical care at Heartland Blood Center (HBC) and its associated hospitals in the scope noted below, as well as effort in leadership of the Immunohematology Reference Laboratory (IRL) as Medical Director at HBC/Versiti. Key components of this position would comprise TM consultation and oversight of blood management at HBC and Versiti partner hospitals, as well as participation in educational initiatives and clinical/applied research within both Versiti blood centers and their affiliated health systems. Primary Responsibilities: Oversees blood donor center collections in the Chicago-land and various areas of Indiana. Provides medical direction, including compliance with local, state, and federal regulations and accreditation agencies, for blood center and transfusion services at Versiti affiliated hospitals in Illinois and Indiana. IRL Medical Director for HBC, providing oversight of IRL laboratory staff technical duties and working with Versiti and HBC laboratory management to provide education and skill advancement. Education and Licenses: M.D. or D.O. Degree. Board certified in pathology (AP/CP or CP only), internal medicine, or pediatrics (with subspecialty boards in hematology). Board certified/board eligible in Blood Banking/Transfusion Medicine (American Board of Pathology—ABP). Current or eligible for medical licenses in Illinois, Wisconsin, Indiana, Michigan and Ohio. Experience/Certifications: Demonstrated experience in both 1) pathology/laboratory medicine or hematology and 2) transfusion medicine. Ability to write lectures and articles using original or innovative techniques or styles; excellent presentation skills with capacity to present to varied audiences. Click here to view the full job description and to apply.

Medical Director. LifeShare Blood Center is currently seeking a Medical Director. The Medical Director provides oversight for LifeShare Blood Center, and LifeShare Cellular, Molecular, and Tissue Services and provides medical support and consultation to centers when requested concerning donors, donor reactions, physician or hospital requests, apheresis services or any related procedures. Additional responsibilities include investigating suspected transfusion transmitted diseases and submitting required reports, reviewing reports of transfusion reactions and taking appropriate action, reviews reports of post-donation illnesses and makes decisions concerning product disposition, reviews abnormal donor test results and all positive infectious disease test results and makes appropriate notifications. Medical Doctor with appropriate specialty, such as hematology or pathology required. Louisiana license must be in good standing. Experience or fellowship in blood banking helpful. Demonstrated excellence as a physician or medical practitioner, either in private practice or in association with a major hospital or medical teaching institution. Knowledge of all regulations, laws, statutes and standards (e.g. FDA, AABB, CLIA, FACT) pertaining to blood donation, transfusion transmitted disease testing, blood compatibility and transfusion, cellular therapies, molecular testing, blood components, and patient or donor reactions. This position will be in our Shreveport, LA location. Review complete job description and submit applications at www.lifeshare.org/careers.

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POSITIONS (continued from page 10)

Vice President of Blood Services (Bloodworks Northwest). The incumbent will: Serve as an active member of the leadership team, providing strategic and operational expertise to achieve Blood Services goals. Manage the operational activities of a large technical and support staff engaged in the collection of donated blood and its preparation, testing, labeling and distribution. Assure compliance with policies, programs, and directives set forth by regulatory agencies and the organization. Establish and execute meaningful continuous improvement, coordinate laboratory functions with Transfusion Services to achieve efficient and effective blood resource management within the region. Responsible for preparing, recommending and subsequently executing a departmental profit and loss budget, inclusive of all relevant financial and operational performance measures. Serve as the strategic analyst and integrator of evolving healthcare information and delivery trends. Lead the effort to provide blood donors with an optimal experience. Develop and maintain a highly engaged workforce. Hire and retain successful team. Serve on boards, committees and task forces that promote Bloodworks within the community. Education & Experience: Medical, technical or nursing degree or equivalent combination of education and experience. Ten or more years of progressive leadership experience in blood collection and manufacturing (strongly preferred), or equivalent. Apply online here.