

2018 #17

May 25, 2018

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FDA Classifies BECS as Class II Medical Device in Guidance

The U.S. Food and Drug Administration (FDA) issued a final rule in the [Federal Register](#) classifying Blood Establishment Computer Systems (BECS) and BECS Accessories as Class II medical devices, which require special controls. The Agency also noted that they do not intend to exempt BECS or BECS accessories from premarket notification requirements (510(k)).

The classification of BECS and BECS Accessories was discussed at the Blood Products Advisory Committee (BPAC) meeting in December 2014. ABC presented [comments](#) at the BPAC meeting endorsing a Class II categorization for BECS and BECS Accessories, but requested clarifying language to clearly differentiate the two. Medical devices are classified into one of three groups (I, II, and III), based on the risk a device poses and the regulatory control necessary to “provide reasonable assurance of [their] safety and effectiveness,” according to the final rule. Class I devices pose the least risk and general controls are sufficient to provide assurance. Class II devices require additional special controls on top of the general controls to achieve such assurance. Class III devices are those that pose the highest risk or have not been classified due to insufficient information and require premarket notification submission prior to marketing.

The committee recommended that both BECS and BECS Accessories should be classified as Class II devices agreeing that general controls were not sufficient to provide a reasonable assurance of safety and effectiveness.

FDA asked for industry input in clarifying the definition of a BECS Accessory. The ABC Information Technology (IT) Committee collaborated with the AABB IT Committee and submitted comments to the FDA, which the agency incorporated and added clarifying examples into the final rule on BECS and BECS Accessories classification.

(Source: [Federal Register](#), 5/18/18) ♦

FDA to Expedite Approval Path for Certain Gene Therapies

FDA Commissioner Scott Gottlieb, MD announced that the agency will prioritize gene therapies for hemophilia with its new policy to hasten approval processes for gene therapy products. Several guidances on gene therapy are forthcoming. They will build on the promise of the 21st Century Cures Act, which seeks to foster innovation through promoting the development and speeding the approval of new drugs and medical devices such as gene therapies that can help patients.

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FDA GENE THERAPIES (continued from page 1)

Dr. Gottlieb stated that these treatments “will soon become the mainstay of how we treat a wide range of illness,” while addressing the Alliance for Regenerative Medicine according to [STAT News](#).

He envisions the FDA guiding companies with a comprehensive framework on how to evaluate therapies for various diseases. “These products are initially being aimed at devastating diseases, many of which are fatal and lack available therapy,” said Dr. Gottlieb. “In these settings, we’ve traditionally been willing to accept more uncertainty to facilitate timely access to promising therapies.”

So far, the expedited approval pathway has received 62 submissions with 19 being granted and 14 receiving orphan drug status.

“By providing clarity to developers on manufacturing parameters, safety measures, and the pathway toward clinical development, the FDA hopes to foster even greater innovative development in this field.” Opponents of the 21st Century Cures Act have expressed concerns that approvals for new drugs and devices will be more observational and potentially less subject to rigorous testing.

(Source: *STAT News*, [FDA plans to speed path to approval for some gene therapies, starting with hemophilia](#), 5/22/18)

Correction: The American Red Cross reports 15 months of Zika donor testing data

Last week, *ABC Newsletter* Issue #16 reported in the American Red Cross Zika Research Brief that “All immunoglobulin M seronegative donations (those with the highest risk for trans-fusion transmission) that were retrospectively (3 of the 4 such seronegatives) tested in minipools were negative.”

The sentence should have stated that “All immunoglobulin M seronegative donations (those with the highest risk for transfusion transmission) that were retrospectively (3 of the 4 such seronegatives) tested in minipools were positive.”

We regret this error and apologize for any confusion caused by its publication last week.

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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 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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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.

ABC Financial Ratio Survey and Blood Service Fee Survey Results Available

America's Blood Centers recently shared the results of its 2016-17 Financial Ratio Survey – completed by 93 percent of ABC's member blood centers, representing nearly all (98 percent) of member whole blood and apheresis collections. The annual survey provides participating ABC member blood centers with interesting facts and ratios that allow them to anonymously benchmark themselves against other blood centers around the country. Additionally, results from the annual Blood Service Fee Survey have been distributed to ABC

member blood centers that participated in the survey. For questions or to receive a copy of the reports please contact ABC's [Sameer Ughade](#).

ADRP Names 2018-19 Advisory Board

ADRP has announced the 2018-19 members of its Advisory Board. President Marie Forrestal (*New Jersey Blood Services, a division of New York Blood Center*), President-elect Lisa Entrikin (*Rock River Valley Blood Center*), Vice President Sylvie Daigneault (*Héma-Québec*), Vice President Mary Ann Ducedre, (*Canadian Blood Services*) Secretary Jennifer Charbonneaux (*Blood Systems, Inc.*), Treasurer Theresa Pina (*Gulf Coast Regional Blood Center*), and Executive Director Steve Bolton form the ADRP Advisory Board Executive Committee. Other members of the board include: Asuka Burge (*New Zealand Blood Service*), Amanda Farrell, (*Unyts*), Andrew Fry (*Blood Systems, Inc.*), Kate Fry (*America's Blood Centers*), Kelly A. High (*American Red Cross*), Daphne Laeijendecker (*Sanquin*), Pat Michaels (*OneBlood*), Shelly Muckerheide (*Community Blood Center of Greater Kansas City*), Patti Beamish Nagle, (*American Red Cross*), Brandye Norman (*Carter BloodCare*), Nina Salamon (*Blood Centers of America, Inc.*), and Elizabeth Waltman (*South Texas Blood and Tissue Center*). Additional information on the ADRP Advisory Board is available [here](#).

2018 Summer Meeting Registration

[Registration](#) is open for the 2018 Summer Meeting and Medical Directors Workshop in Montreal, Québec hosted by ABC member Héma-Québec July 31st – August 2nd at the Hotel Omni Mont-Royal. Don't miss an exclusive opportunity for blood community leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Medical Directors Workshop, the Scientific, Medical, and Technical Forum, and the Business Forum. Additionally, Héma-Québec will host a networking event. Please make your hotel reservations by July 9th to ensure best availability and the group [rate](#). Member and government registration rates are below:

- 3-Day Summer \$760: MD Workshop, SMT Forum, Business Forum, Members Meeting
- 2-Day Summer \$655: SMT Forum, Business Forum, Members Meeting
- 2-Day Medical \$655: MD Workshop, SMT Forum, Business Forum
- 1-Day Medical \$435: MD Workshop

You will need a U.S. Passport to enter Canada. Please be sure to check the expiration date.

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INSIDE ABC (continued from page 3)

Hospital, public, and emeritus registration rates are available [here](#). Contact [Leslie Maundy](#) for available sponsorship opportunities. Click [here](#) for additional meeting information.



AMERICA'S BLOOD CENTERS'
56TH SUMMER MEETING
July 30 – August 2, 2018 **Montréal, QC**

2018 SUMMER MEETING SCHEDULE

Monday, July 30	ABC Board Meeting
Tuesday, July 31	Medical Directors Workshop
Wednesday, August 1	SMT Forum Business Forum Host Event by Héma-Québec (off-site)
Thursday, August 2	ABC Members Meeting

All of us at Héma-Québec look forward to hosting our ABC colleagues, family and friends at the 2018 ABC Summer Meeting in Montréal. A striking union of European charm and North American attitude, Montréal seduces visitors with a harmonious pairing of the historic and the new, from exquisite architecture to fine dining. We hope you can take the opportunity to see what Montréal has to offer and discover its many colorful and vibrant neighborhoods which overflow with markets, museums, boutiques, restaurants and local cafés—diverse expressions of the inhabitants "joie de vivre."



– Luc Vermeersch,
Acting Chief Executive Officer
and Vice-President, Finance
and Strategic Project Management

Hotel Information

Hotel Omni Mont-Royal
Hotel room rate: \$234 (CAD) + tax

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

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



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ABC Has Moved

ABC moved on April 1st. Our new mailing address is, 1717 K Street NW, Suite 900, Washington, DC 20006. All telephone numbers will remain the same except the fax line which changed to (202) 899-2621. Please update your records accordingly and contact [ABC Member Services](#) with any questions.





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WASHINGTON, DC 20006

202.393.5725 | 202.899.2621 FAX | www.americasblood.org

RESEARCH IN BRIEF

Should red blood cell (RBC) transfusion triggers be higher for “mature” patients? Conservative transfusion triggers validated in randomized, controlled trials (RCTs) have, in part, driven declining RBC use in the U.S. and worldwide, but persistent questions about their appropriateness in patient subgroups remain. An Australian systematic review and meta-analysis suggests that patients 65 years of age and older may have higher mortality when randomized to restrictive transfusion in these studies. Thirteen eligible papers selected from 723 included data from nine RCTs (five orthopedic surgery, three cardiovascular surgery,

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RESEARCH IN BRIEF (continued from page 4)

and one oncologic surgery). Thirty- and 90-day mortality were the primary outcomes. Risk ratios were 1.36 (95 percent CI 1.05-1.74) and 1.45 (1.05-1.98) respectively, favoring liberal transfusion strategies. Risks of myocardial infarction, infection, and hospital length of stay were not different. The authors characterize their work as exploratory, noting that the paper is limited by the small number of studies focused on older patients, potential publication bias, exclusion of studies where the enrollee mean age was less than 64 years old, and the inclusion of studies with varying transfusion strategies.

Citation: Simon, G.I., Craswell, A., Thom, O., *et al.* Outcomes of restrictive versus liberal transfusion strategies in older adults from nine randomised controlled trials: a systematic review and meta-analysis. *Lancet Haematology*. 2017. [https://doi.org/10.1016/S2352-3026\(17\)30141-2](https://doi.org/10.1016/S2352-3026(17)30141-2).

Can mosquito “spit” influence the pathogenesis of transfusion-transmitted arthropod-borne (arbovirus) infections (TTIs)? It has been interesting to follow the emergence of arboviruses as transfusion risks since the 2002 emergence of West Nile Virus (WNV). The blood community has subsequently considered dengue, chikungunya, and Zika virus as potential pathogens and intervened regarding the latter with individual donation nucleic acid testing. WNV is an important pathogen causing significant morbidity after TTI. Dengue, chikungunya, and Zika transmission are rarely recognized and even more rarely clinically significant despite reasonable evidence that the virus can circulate in otherwise well donors. Baylor College of Medicine scientists published a paper that might provide a partial explanation for this disconnect, noting that “mosquito saliva is a very complex concoction of >100 proteins, many of which have unknown functions.” They speculate that “mosquito saliva may enhance pathogenicity of arboviruses by manipulating the host's immune response.” Effects were measured on the innate and acquired immune responses of mosquito bite transmitted infections, in contrast to less natural models, in mice with humanized immune systems. Significant changes in immune responses that persisted from six hours to seven days after the bites were observed. They speculate that “the possibility remains that even though mosquito saliva increases some subsets of immune cells typically associated with a Th1 human immune response, these cells could be responsible for increased disease severity in humans.” Conversely, one might speculate that their absence could influence the pathogenicity of TTI.

Citation: Vogt, M.B., Lahon, A., Arya, R.P. *et al.* Mosquito saliva alone has profound effects on the human immune system. *PLoS Neglected Tropical Diseases*. 2018. <https://doi.org/10.1371/journal.pntd.0006439>.

Automated RBC and platelet typing using whole-genome sequencing moves forward. The ability to provide very closely antigen-matched cellular blood products offers promise to improve transfusion compatibility, safety, and effectiveness, especially for chronically transfused populations. Conventional serologic methods suffer from the breadth of antigens of interest (e.g. more than 300 RBC antigens) the absence of appropriate reagents, and genotyping methods that detect single nucleotide polymorphisms (SNP), but do not detect critical ABO and Rh variants. Collaborators (including participants from New York Blood Center) in the MedSeq Project have published their iterative experience with an automated whole genome sequencing platform (bloodTyper) to develop algorithms that provide a predicted antigen phenotype from the genotype. They describe three rounds of testing sequences compared with conventional and SNP phenotypes and show 99.2 percent concordance across 200 comparisons.

Researchers from Brigham Women’s, New York Blood Center, and the United Kingdom INTERVAL trial were involved in the development, design, and validation of this study. “Our vision is that as more people have their genomes sequenced as part of medical care, the algorithm we’ve developed could be applied to type everyone for all relevant blood groups at a low cost using existing data from their electronic medical record,” said New York Blood Center’s Connie Westhoff, PhD to the *ABC Newsletter*. “With current technology, it isn’t cost effective to do blood typing for all 300 or more RBC and platelet antigens. But as more

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RESEARCH IN BRIEF (continued from page 5)

people get whole-genome sequencing, it may be possible to modernize our approach to transfusion therapy by having a complete profile for the individual prior to transfusion.” An accompanying comment describes the paper as “a landmark in the application of genotyping because it provides a basis for integration of whole-genome sequencing into a high-throughput workflow, a prerequisite for automation.”

Citations: Lane, W.J., Westhoff, C.M., Gleadhall, N.S. *et al.* Automated typing of red blood cell and platelet antigens: a whole-genome sequencing study. *Lancet Haematology*. 2018. doi: [http://dx.doi.org/10.1016/S2352-3026\(18\)30053-X](http://dx.doi.org/10.1016/S2352-3026(18)30053-X).

Flower, R., Roulis, E., Hyland, C. Whole-genome sequencing algorithm for blood-group typing. *Lancet Haematology*. 2018. doi: [http://dx.doi.org/10.1016/S2352-3026\(18\)30064-4](http://dx.doi.org/10.1016/S2352-3026(18)30064-4).

Mixed results comparing the hemostatic efficacy of pathogen-reduced (PR) platelets in two randomized, clinical trials. Two RCTs from international investigators have evaluated amotosalen/ultraviolet treated platelets and riboflavin/ ultraviolet treated platelets respectively in patients with thrombocytopenia complicating hematologic malignancy. The first study (EFFIPAP), a non-inferiority trial, at thirteen French centers assessed 790 evaluable patients for clinical bleeding (World Health Organization (WHO) grade 2 or higher) for up to 30 days after enrollment. One hundred twenty-six patients received amotosalen/UV platelets in additive solution, 114 platelets in plasma, and 120 platelets in additive solution. Non-inferiority was not demonstrated for PR platelets in additive compared with platelets in plasma, but was when comparing PR platelets in additive solution to platelets in additive solution. The occurrence of more severe bleeding (grades 3 and 4) did not differ among the study arms. In the second paper (PREPAREs), 469 patients with hematologic malignancy and thrombocytopenia were randomized to 567 treatment periods comparing riboflavin/UV platelets to control (283 control and 284 PR periods). The primary outcome was WHO grade 2 or higher bleeding. In the intention-to-treat analysis, non-inferiority was demonstrated but was not in the per protocol analysis. The authors in both trials speculate that the clinically modest hemostatic differences were likely related, in part, to off-target effects of the PR processes on the transfused platelets.

Citations: Garban, F., Guyard, A. Labussiere, H. *et al.* Comparison of the hemostatic efficacy of pathogen-reduced platelets vs untreated platelets in patients with thrombocytopenia and malignant hematologic diseases a randomized clinical trial. *JAMA Oncology*. 2018. doi: [doi:10.1001/jamaoncol.2017.5123](https://doi.org/10.1001/jamaoncol.2017.5123).

Van der Meer, P.F., Ypma, P.F., vanGeloven, N. *et al.* Hemostatic efficacy of pathogen-inactivated- versus untreated- platelets: a randomized controlled trial. *Blood*. 2018. doi: [10.1182/blood-2018-02-831289](https://doi.org/10.1182/blood-2018-02-831289). 

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has approved the first drug (Doptelet) in the treatment of thrombocytopenia (low platelet count) in adults with chronic liver disease that are scheduled to undergo a medical or dental procedure. “Patients with chronic liver disease who have low platelet counts and require a procedure are at increased risk of bleeding,” said Richard Pazdur, M.D., director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research, in an agency news [release](#). “Doptelet was demonstrated to safely increase the platelet count. This drug may decrease or eliminate the need for platelet transfusions, which are associated with risk of infection and other adverse reactions.” Patients taking Doptelet as part of the ADAPT-1 and ADAPT-2 trials, demonstrated increased platelet counts and did not need platelet transfusions during the procedure or up to seven days afterwards. Doptelet received priority

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REGULATORY NEWS (continued from page 6)

review in which FDA aims “to take action on an application within six months where the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.”

(Source: FDA News [Release](#), 5/21/18)

FDA has announced the dates for the next meeting of the Blood Products Advisory Committee (BPAC). The meeting will take place on June 22nd at the FDA’s White Oak Campus in Silver Spring, Md. BPAC will discuss research programs in the Laboratory of Emerging Pathogens, Laboratory of Bacterial and TSE Agents, the Laboratory of Molecular Virology in the Division of Emerging Transfusion-Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), FDA. The afternoon session will include presentations on research in the Hemostasis Branch, in the Division of Plasma Protein Therapeutics, Office of Tissues and Advanced Therapies, CBER, FDA. The meeting will be [webcast](#) for those unable to attend. More information is available on the FDA’s [website](#).

(Source: FDA [Announcement](#) 5/21/18)

The National Institutes of Health (NIH) has begun accepting funding applications for genome centers as a part of the All of Us Research Program. The agency will award up to two genome centers. Applicants can “request funds to generate and analyze genotype data from 100,000 participants in the first year while beginning to also employ whole genome sequencing methods. In remaining years of the anticipated five-year project period, applicants may request funds for whole genome sequencing for as many as 200,000 participants annually.” Additional details are available in the [funding announcement](#). Applications are due July 12th with a webinar taking place on May 31st. Questions or RSVPs for the webinar should be sent [here](#). The All of Us initiative began in 2016 with \$130 million earmarked to NIH with the stated goal of bringing precision medicine to all in the U.S. by recruiting and examining health data from 1 million individuals to assist with disease prevention and treatment.

(Source: NIH [Announcement](#), 5/23/18) ♦

BRIEFLY NOTED



Courtesy of CNBC

The Federal Aviation Administration (FAA) has approved 10 states to participate in a three-year pilot program that will examine the use of commercial drones to assist with federal regulations and potential policy development surrounding the use of commercial drones. The pilot program fosters relationships between the public and private sectors and includes Zipline, a California-based company that has been using drones to deliver blood in Africa including more than 5,000 units over the past year. “Our country is on the verge of the most significant new development in

aviation since the emergence of the jet age,” said Elaine Chao, secretary of Transportation during a press conference announcing the selections. “We’ve got to create a path forward for the safe integration of drones if our country is to remain a global aviation leader and reap the safety and economic benefits drones have to offer.” Zipline is partnering with the North Carolina Department of Transportation as part of the pilot, which intends to launch the pilot in Charlotte, Raleigh, and the Outer Banks.

(Sources: CNBC, [The most important delivery breakthrough since Amazon Prime](#), 5/22/18; Inc.com, [Apple Uber among companies approved for federal drone pilot program](#), 5/9/18; FAA News [Release](#), 5/9/18) ♦



WORD IN WASHINGTON

The Senate Appropriations Committee unanimously voted in favor of a 5 percent increase to the U.S. Food and Drug Administration (FDA) budget for 2019. The bill provides the agency with an additional \$159 million in funding, which would bring the FDA budget to \$2.9 billion with \$70 million earmarked for precision medicine and \$20 million for rare disease innovation. The House Appropriations Committee voted in favor of a 10 percent increase to the FDA budget last week, which the two sides may reconcile in conference in the coming weeks.

The Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing this week to address the shortage of healthcare workers. “It is my hope that the committee will soon begin working on solutions to address these shortages,” said Committee Chair Lamar Alexander (R-Tenn.). A report appearing in the *Medical Laboratory Observer’s LABline* earlier this month noted the need to recruit the next generation of medical laboratory professionals, for which ASCP has several initiatives underway to recruit new individuals to the field. A recording of the Senate [hearing](#) is available.

The Senate HELP Committee approved the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPA) (S. 2852) this week. ABC, AABB, and the American Red Cross submitted [joint comments](#) to the committee that recommended recognizing the role that blood centers play in emergency preparedness and response, in addition to the financial costs incurred to ensure availability of a safe and robust blood supply when needed. Also, the comments asked the committee to include blood centers in incentive programs that help implement planning measures, and to consider “policies that support and finance the implementation of new technologies that are required for blood safety.” The bill would reauthorize PAHPA through 2023. 💧

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MEMBER NEWS

The Blood Centers of California recently announced that **Houchin Community Blood Bank** has been selected as a Nonprofit of the Year for 2018 by Sen. Jean Fuller (16th Senate District). Houchin will be recognized in a California State Senate and Assembly resolution for their outstanding work on behalf of individuals in the 16th District. President and CEO Greg Gallion will be in Sacramento on June 6th to receive the award on behalf of Houchin during a luncheon celebrating California Nonprofits Day.

(Blood Centers of California Announcement, 5/17/18)

San Diego Blood Bank is partnering with Seqster to allow blood donors and their families integrated accessibility and management of their own available health data securely through the RedConnect portal. “We are honored that San Diego Blood Bank selected Seqster’s platform for their donors and their families,” said Ardy Arianpour, CEO and co-founder, Seqster in a news [release](#). “We both want to support healthier communities and today we are taking a major step forward. The future of health happens when you empower people to break down data silos and take ownership and control of their health information.” San Diego Blood Bank will allow patients to share electronic medical records, genomics and DNA data, and

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MEMBER NEWS (continued from page 8)

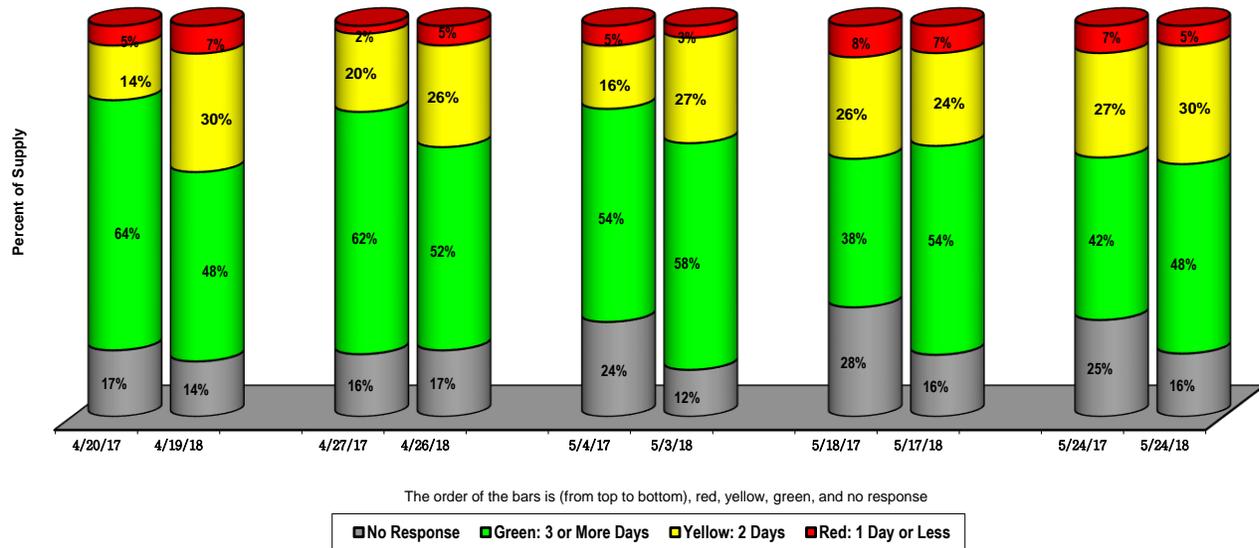
the ability to share health data with family members now and in the future through a legal trust. Additionally, individuals can opt-in to participate in research studies. “The health of our blood donors is critical to us at [San Diego Blood Bank],” said David Wellis, PhD, CEO at San Diego Blood Bank. “Blood donors provide local hospitals and patients a precious resource that saves lives. Our objective is to ensure our donors are well taken care of. This includes providing access to the most cutting-edge tools to maintain their own health. Our entire community’s wellness is our priority.”

(Source: San Diego Blood Bank and Seqster News [Release](#), 5/7/18)

Coastal Bend Blood Center (Corpus Christi, Texas) recently honored local students at the annual “High School Heroes” award ceremony. They presented 26 awards in a show of appreciation for the lifesaving work of the students and schools that held more than 235 blood drives at 53 area schools, “[i]t is something [students] look forward to. It’s an opportunity for them to be in competition with other schools. So, again it’s exciting and it’s an opportunity for us to recognize these local high school students and show our appreciation for everything they’ve done throughout the year for us,” said Coastal Bend’s Ashley Ramirez.

(Source: KZTV News, [Area high school students honored donating blood](#), 5/16/18) 💧

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



Daily updates are available at:
www.AmericasBlood.org

COMPANY NEWS

Cerus [announced](#) that the Biomedical Advanced Research and Development Authority (BARDA) is providing an additional \$15 million in funding for the ReCePI acute anemia clinical trial and SCient

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COMPANY NEWS (continued from page 9)

chronic anemia clinical trial. “BARDA is an important partner in our mission to establish INTERCEPT as the standard of care for all transfused blood components globally,” said Richard Benjamin, MD, PhD Cerus’ Chief Medical Officer. “Our collaboration with BARDA provides Cerus with the support and non-dilutive funding anticipated to complete the clinical development, regulatory submission, and commercial scale-up activities for INTERCEPT red blood cells (RBCs) in the U.S.” ReCePI evaluates the safety and efficacy of INTERCEPT RBCs for cardiac surgery patients as part of a phase 3 study, while SCient is a randomized study of INTERCEPT RBCs in sickle cell patients in the United Kingdom.

(Cerus News [Release](#), 5/16/18) ◆

Learn • Grow • Lead Shed Light on Your Future



This Month's Featured API Resources

- 1. Jerry Haarmann Leadership Program**
Six courses on leading teams

“This course gave me many ideas on how to work with the team in my department as well as working with other teams outside my department.”

- API pilot participant
- 2. Strategic Leadership Program**
Six courses on change management and communication challenges

Effective Leadership: How Do You Rate?

Check your leadership effectiveness by answering yes or no to the following questions:

- Do you know exactly what you want employees to understand, think, and do in response to your communications?
- Are trust and commitment part of your team's DNA?
- Do you know what motivates your employees?



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CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) 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.)

2018

June 2-6. **35th International Congress of the ISBT, Toronto, Canada.** More details available [here](#).

June 22. **FDA Blood Products Advisory Committee Meeting, Silver Spring, MD.** More details available [here](#).

June 25-26. **FDA 2018 Center for Biologics Evaluation Research Science Symposium, Silver Spring, MD.** More details available [here](#).

July 18-19. **FDA Blood Products Advisory Committee Meeting, Silver Spring, MD.** More details available [here](#).

July 31 – Aug. 2. **Summer Meeting & MD Workshop, Montreal, Québec.** Contact: ABC Meetings Dept. Phone: (202) 654-2917; e-mail: meetings@americasblood.org.

Sept. 5-7. **3rd European Conference on Donor Health and Management, Copenhagen, Denmark.** More details available [here](#).

Sept. 12. **8th Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD.** More details available [here](#).

Sept. 28. **36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available [here](#). ♦

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

Lead Laboratory Technologists. SBBs wanted for Immunohematology Reference Labs (IRL) serving one of the largest population of sickle cell patients in the Southeast. LifeSouth's SBBs provide results of complex serologic investigations, compatibility testing and consultation services to hospitals. The LifeSouth IRLs have access to an extensive database of African American blood donors who have been previously typed by molecular methods. Positions are available in **Atlanta, GA** and **Gainesville, FL** for qualified individuals to join our dynamic interdisciplinary team. Specialty in Blood Banking (SBB) certification required. Bachelor's degree in clinical laboratory, chemical or biological science required. Clinical laboratory training program and five years of clinical laboratory experience at a licensed, certified or accredited facility required. Current certification [MT (ASCP), CLS (NCA), MT (AMT), MT (AAB) and/or NRCC] required. Relocation package negotiable. Follow

this link to apply: <https://lifesouth.careerplug.com/jobs/750712/apps/new>

Director, Information Services. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Information Services position. This position is responsible for all Information Technology (Voice and Data) functions of the company. Primary responsibilities include Information Technology Administration duties, system security, cost control, systems hardware and software architecture, and support thereof. Supervision of Software Test Engineer, Programmer Analysts, Network/Telecommunications Administrator, and Help Desk Technicians. Ensures department provides excellent customer service. Ensures activities of the

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POSITIONS (continued from page 11)

department are aligned with organizational goals. Four-year bachelor's degree (BA / BS) in Computer Science, Applied Math, or related Degree. Five or more years of a history of progressive experience and responsibilities culminating in advancement to a similar position. Five or more years' direct supervision/management of employees is required. Current California Driver's License. This position reports to the Vice President/Technical and Clinical Affairs. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal government E-verify program to determine employment eligibility. Apply online at <https://www.lstream.org/open-positions/>.

Account Consultant I (Ada, Oklahoma, USA). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How To Apply: <http://obi.org/careers/>.

Executive Director. The European Blood Alliance (EBA) is seeking an Executive Director who will be based in/close to Brussels and whose key goals include building the organizational capability and capacity and supporting the membership; contributing to EBA strategy and policies and implement these in close collaboration with the President and Executive Board of EBA; representing the EBA in contact with other organizations and the EU institutions (Commission, Parliament, Council etc.) and to manage the EBA office/secretariat, and supervising staff. The successful candidate must be able to demonstrate achievements in leadership positions, in the ability to build organizational capacity for a membership organization, and in content knowledge of blood banking. A track record of networking and interacting with EU bodies is a bonus. The full job description and person specification can be read on the EBA-website: <https://wp.me/p413nF-2aF>. Applications should be received by **31 May 2018**. 💧