

2018 #13

April 20, 2018

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FDA Publishes New Medical Device Safety Action Plan

This week, the U.S. Food and Drug Administration (FDA) unveiled its new “[Medical Device Safety Action Plan: Protecting Patients and Promoting Public Health](#).” The themes of innovation, patient and device safety throughout the total product life cycle (TPLC) are prevalent throughout the document, as it modernizes the existing medical device framework that has been in place since the 1970s according to *Modern Healthcare*.

“This new Action Plan outlines our vision for how the FDA can continue to enhance our programs and processes to assure the safety of medical devices,” said FDA Commissioner Scott Gottlieb, MD in an agency [statement](#). “Our aim is to make sure that the new advances in technology that are enabling better capabilities and benefits are also harnessed to bring added assurances of safety, so that more patients can benefit from new devices and address unmet needs.”

The agency acknowledges that it aims to focus on the TPLC of a medical device using all the tools at its disposal including pre and postmarket data and expertise during development, evaluation, and marketing. It also makes the distinction that oversight should be consistent and equate to the degree of risk present. Commissioner Gottlieb added that “the Action Plan recognizes that safety and innovation should go hand in hand. The best technological advances should lead to more lives saved and fewer adverse events. We want to take new steps to encourage manufacturers to make even modest iterative changes to their devices, if these new advances and adaptations will lead to a reduction in risk to patients.”

The plan enumerates five goals: “establish a robust medical device patient safety net in the U.S.; explore regulatory options to streamline and modernize timely implementation of postmarket mitigations; spur innovation towards safer medical devices; advance medical device cybersecurity; and integrate the Center for Devices and Radiological Health’s (CDRH’s) premarket and postmarket offices and activities to advance the use of a TPLC approach to device safety.” It recognizes the shortcomings of reliance on medical device reports, which often are dependent on clinicians to recognize an issue, realize that a medical device could be the cause, and report it to the manufacturer and/or agency.

To assist with such challenges, plan enhancements include “improving regulatory clarity regarding use of real world evidence,” along with “developing the National Evaluation System for [H]ealth Technology ([NEST](#))”, and implementing a “signal management program.” The agency envisions NEST being a public-private

(continued on page 3)



OUR SPACE

Kevin Land, MD, Vice President Clinical Services, Blood Systems, Inc.

Documenting Value: The Role of Consultation in Blood Banking

Physicians have long practiced the art and science of the consultation where one provider reaches out to another for help. The consultant typically has expertise in some specialty, such as gastrointestinal surgery or diabetes management, that the requestor does not. The consultation can either be formal or informal. In the formal setting, the consulting physician generates a fee by establishing a relationship with the patient, taking a history, performing an examination, requesting studies, rendering a diagnosis, and detailing a treatment plan which lives in the patient's medical record. The informal "curbside" consultation is used when the primary physician needs a bit of advice on a patient but does not want a formal consultation. This is very common but unfortunately generates no direct revenue for the consultant. Oftentimes the name of the consultant is not even mentioned in the record, and it is difficult or impossible to assess its value. During my residency, the more senior residents developed a clinical pathology consultation service for primary care providers (PCPs), to help interpret a range of complicated laboratory tests seen in some of their patients. A hybrid of the two consultation models, in that while we did not charge for our service, we often chatted with the patient and always wrote a consultation note. It was successful only when we actively walked the patient wards and went on morning rounds with the PCPs, were willing to write something formal that would be placed in the chart, and provided a quick (within minutes to a few hours) response to their queries. Over time, as the PCPs began learning our names and appreciated our service, we began getting phone calls, pages, and even a few emails (a big deal back in the day).

As Lee, M.S. *et al* noted in their recent article on eConsults for PCPs, access to timely, high-quality specialty care, including specialty consultation and referral, is critical to overcoming poor outcomes, especially in underserved communities. The eConsult system described in the article helps overcome many barriers to rapid access to specialty care, by providing a portal where PCPs and specialists can openly dialogue about recommendations and treatment plans, often without a face-to-face visit with the patient. Interestingly, the positive perceptions noted by the authors are not that dissimilar to what we found years ago during residency. So, what? This article and accompanying commentary demonstrate specialists must find ways to develop a relationship with the clinicians in their area if they want to be relevant in patient care. Maybe it is routine hospital visits or writing articles for the hospital newsletter or local county medical society? Once you begin getting the calls though, the real work begins. How are you writing up your consultations? Tuan Le, MD, chief medical officer at Oklahoma Blood Institute and I started using the Situation, Background, Assessment, and Recommendation(s) (SBAR) format when we were both at Bonfils Blood Center. The Navy developed this format to improve communication between people who are experts in different domains of knowledge. It is increasingly used in healthcare environments. We found it a successful way to communicate to laboratorians, nurses, and physicians, demonstrating to administrators and supply chain professionals the blood center's value. In this competitive market, we all need to continually demonstrate our value. How are you doing it? 💧

Citations:

Lee, M.S., Ray, K.N., Mehrotra, A., *et al*. Primary Care Practitioner's Perceptions of Electronic Consult Systems. A Qualitative Analysis. *JAMA Int Med* 2018. doi:10.001/jamainternmed.2018.0738.

Gleason, N., Ackerman, S., Shipman, S.A. Invited Commentary: *eConsult-Transforming Primary Care or Exacerbating Clinical Burnout?* *JAMA Int Med*. 2018. doi:10.001/jamainternmed.2018.0762;

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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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MEDICAL DEVICE SAFETY ACTION PLAN (continued from page 1)

partnership led by a nonprofit medical device innovation consortium provided six million dollars in user fee funding annually for five years. The signal management program would ensure that available postmarket information makes its way back to the premarket review process for similar future devices to anticipate safety concerns.

Also, the FDA intends to “explore whether, under current statutory authorities, FDA can impose special controls, when warranted to address new or increased known risks, more quickly through the issuance of an umbrella regulation; and if not, explore what additional actions might be taken, including considering potential new authorities.” To add increased flexibility, the agency will expand the 510(k) program for “certain well understood device types to use objective performance criteria established or recognized by the Agency to demonstrate substantial equivalence” as outlined in the draft [guidance](#) entitled “Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria.”


Comments on the Medical Device Safety Action Plan can be made [here](#). More information and additional resources on the plan are available on the FDA’s [website](#).

(Sources: FDA Medical Device Safety Action [Plan](#); 4/17/18; *Modern Healthcare*, [FDA takes a long—and long-term—look at device safety in new plan](#), 4/19/18) ♦

AMERICA'S BLOOD CENTERS'

Human Resources & Employee Training/Development Workshop

Dallas, TX – May 8-10, 2018



“ABC is proud to offer this exclusive opportunity to bring both human resources and training and development professionals together in Dallas for a knowledge exchange of solutions to address the shared challenges faced by the blood community. These two disciplines play a critical role in the daily operations of community blood centers, and attendees will have the opportunity to share best practices and network, while learning from the experiences of their fellow peers and experts alike.”


– Kate Fry, Executive Director, America's Blood Centers

HOTEL INFORMATION:
Fairmont Dallas
Hotel room rate: \$195 single/double occupancy



2018 WORKSHOP SCHEDULE
Employee Training/Development: May 8
Joint HR & Employee Training/Development: May 9
Human Resources: May 10

2018 WORKSHOP FEES (EARLY BIRD/REGULAR)
2-day registration: \$410/\$465
3-day registration: \$485/\$540

Sponsorship opportunities available. Contact Leslie Maundy at lmaundy@americasblood.org for details.



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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!



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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 staff only, unless otherwise specified.

Presentations Available from 2018 ABC Annual Meeting

ABC members can access presentations from the 2018 ABC Annual Meeting on the ABC Member site by using the link below. Please note that some speakers declined to grant access to their slides. Presentations may be downloaded [here](#) for the Opening Session, Members Meeting, SMT Forum, and General Session.

(Source: [MCN 18-015](#))

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.



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



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It's About *Life*.

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

RESEARCH IN BRIEF

Implementation of orthopedic patient blood management (PBM), including a conservative hemoglobin trigger, and use of tranexamic acid are associated with improved clinical outcomes at Johns Hopkins. A before and after observational study explored the association of these interventions with selected outcomes among 2,951 orthopedic surgical patients. A 38 percent decrease was seen in the proportion of patients transfused from 16 percent to 10 percent, ($p < .0001$), and a 25 percent decrease in the mean number of units transfused from 0.34 before to 0.26 ($P < .0001$) after implementing PBM. The mean hemoglobin triggers were 7.8 gm/dL before and 6.9 gm/dL after ($p < .0001$). The hospital length of stay decreased from three to two days ($p < .0001$), and the 30-day readmission rate from 8.8 to 6.0 percent. ($p < .007$). Fewer adverse events (a composite of infectious, ischemic, renal, respiratory, and thromboembolic events) were recognized after implementation of the program, but this result was not statistically significant ($p = .08$). Mortality was not different. The study design does not permit assessment of causation.

Citation: Gupta, P.B., Scher, L.J., Yang, W.W. *et al.* Impact of a Patient Blood Management Program on Blood Utilization and Clinical Outcomes in Orthopedic Surgery. Abstract 17-SA-4722-ASAHQ. *Anesthesiology* 2017.

Andexanet looks effective for major hemorrhage in patients anticoagulated with factor Xa (FXa) inhibitors. An abstract presentation at the meeting of the American College of Cardiology supplies interim data from an ongoing open study of this recombinant modified FXa that acts as a decoy for FXa inhibitors by binding and neutralizing their activity. Annexa-4 is a single arm, open label study of adults with major bleeding within 18 hours of their last dose of anticoagulant. Two hundred twenty-seven patients are included in the safety report and 137 for the efficacy analysis. The patients were receiving apixaban, rivaroxaban, enoxaparin, or edoxaban. The median reduction in anti-FXa activity was 92 percent. Good or excellent hemostasis at 12 hours was achieved in 83 percent (95 percent CI 75-89) of 132 patients with adjudicated efficacy data. By 30 days, 11 percent had a thrombotic event and mortality was 12 percent, which the authors state is consistent with their expectations in the population studied.

Citations: Connolly, S.J., Crowther, M., Milling, T.J. *et al.* [Interim report on the annexa-4: andexanet for reversal of anticoagulation in factor xa – associated acute major bleeding.](#) American College of Cardiology 2018.

Mad camel disease? *In Emerging Infectious Diseases*, Algerian and Italian scientists describe a new prion disease in three dromedary camels at a single slaughter house. In the wake of the linked bovine spongiform encephalopathy (BSE)/variant Creutzfeldt Jakob epidemics, the authors speculate about its zoonotic potential. The animals were necropsied because of neurologic signs and symptoms. The neuropathology was consistent with prion disease (spongiform degeneration), immunohistochemistry demonstrated abnormal prion deposition in affected areas of the brains, and lymph nodes outside the central nervous system were affected. Western blotting suggests the abnormal prion is distinct from that of classical scrapie and BSE. A parallel retrospective study indicated a prevalence of abnormal neurologic signs of 3.1 percent in dromedaries brought to slaughter at the involved abattoir.

Citations: Babelhadj, B., Di Bari, M.A., Pirisinu, L. *et al.* Prion disease in dromedary camels, Algeria. *Emerg. Infect. Dis.* 2018. [doi: 10.3201/eid2406.172007](https://doi.org/10.3201/eid2406.172007).

Gene therapy for transfusion dependent β -thalassemia. There are almost 300,000 cases of this hemoglobinopathy worldwide with 60,000 affected births annually. Of those with severe forms (60-80 percent), chronic transfusion with the attendant morbidity of iron overload are the usual treatment. To date, the only viable “curative” treatment for the β -thalassemia patients has been allogeneic stem cell transplantation, that entails significant morbidity and for which donors are difficult to find. Results from two phase 1-2 studies

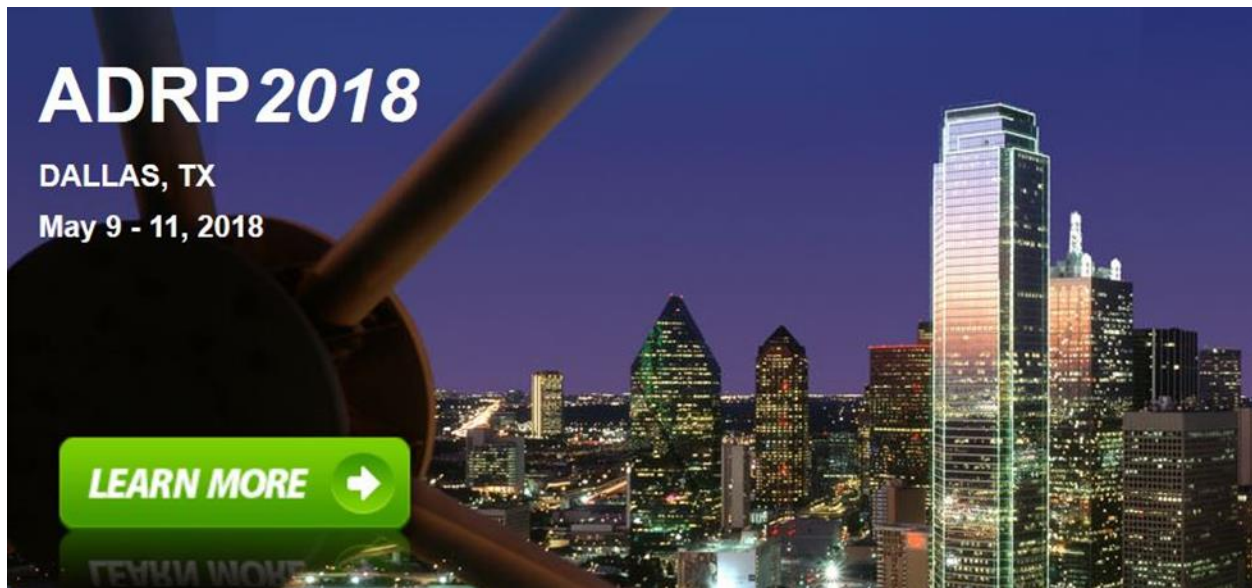


RESEARCH IN BRIEF (continued from page 5)

on patients treated with gene therapy for this hemoglobinopathy are reported in the *New England Journal of Medicine*. The patients have been followed for a median of 26 months (range 15-42) after receiving with a lentiviral vector encoding adult hemoglobin A, transduced into autologous CD34 hematopoietic stem cells. All 22 patients reported reduced or eliminated transfusion requirements, without serious adverse effects other than those expected with myeloablation for autologous transplantation. In 12/13 with non- β^0/β^0 genotypes, transfusion independence was achieved. Among the 9 with β^0/β^0 , median annualized transfusions decreased by 73 percent. The approach studied eliminates the need to find histocompatible allogeneic marrow or stem cell donors. Long-term follow-up will be required to assure the absence of genotoxicity related to vector integration events. An accompanying editorial states “These results are of great importance, considering the widespread prevalence of the β^E/β^0 genotype and the major effect of reducing the transfusion needs of patients with the β^0/β^0 genotype on their overall quality of life and long-term prognosis. Notably, therapeutic efficacy was safely achieved in the absence of treatment-related adverse events or clonal expansions at the latest follow-up.”

Citations: Thompson A.A., Walters, M.C., Kriatkowski, M. Gene Therapy in Patients with Transfusion-Dependent β -Thalassemia. *N. Engl. J. Med.* 2018. [doi: 10.1056/NEJMoa1705342](https://doi.org/10.1056/NEJMoa1705342).

Biffi, A. Gene therapy as a curative option for β -Thalassemia. *N. Engl. J. Med.* 2018. [doi: 10.1056/NEJMe1802169](https://doi.org/10.1056/NEJMe1802169). ♦



RECENT REVIEWS

The human microbiome: relevant to transfusion medicine? A review in *Nature Medicine* serves as a primer (including for transfusion medicine) about the human microbiome’s composition, its interactions with human genetics, the development of the immune system, and the its putative influences on health, disease and biomarkers of disease. The microbiome could perhaps modulate our immune responses to antigens relevant to transfusion medicine. The authors

(continued on page 7)

RECENT REVIEWS (continued from page 6)


review “the challenges and propose strategies that leverage existing knowledge to move rapidly from correlation to causation and ultimately to translation into therapies.”

Citation: Gilbert, J.A., Blaser, M.J., Caporaso, J.G. *et al.* Current understanding of the human microbiome. *Nat. Medicine*. 2018. [doi:10.1038/nm.4517](https://doi.org/10.1038/nm.4517).

The platelet storage lesion. Australian authors review recent publications on characterization and potential clinical implications of changes to platelets during storage. The paper includes both impacts from cold storage and cryopreservation, as the authors note that platelet storage lesions appear to have little impact on transfusion safety though transfusion efficacy may be reduced.

Citation: Ng, M.S.Y., Tung, J-P., Fraser, J.F. Platelet storage lesions: what more do we know now? *Transfusion Medicine Rev.* 2018. [doi:10.1016/j.tmr.2018.04.001](https://doi.org/10.1016/j.tmr.2018.04.001).

One more review on the age of Red Blood Cells debate. After review of sixteen trials enrolling 31,359 patients, the authors state that “(t)he current evidence does not support a change from current usual transfusion practice.” However, they do recognize that while mortality does not appear to be influenced by storage duration, there is credible evidence supporting an increased rate of transfusion reactions and possibly infections.

Citation: McQuilten, Z.K., Frenc, C.J., Nichol, N. *et al.* Effect of age of red cells for transfusion on patient outcomes: a systematic review and meta-analysis. *Transfusion Medicine Rev.* 2018. doi: [http://www.tmrviews.com/article/S0887-7963\(17\)30159-1/fulltext](http://www.tmrviews.com/article/S0887-7963(17)30159-1/fulltext). 

BRIEFLY NOTED

The [All of Us](#) Research Program from the National Institutes of Health (NIH) will launch next month, according to testimony from NIH Director Francis Collins, MD, PhD on Capitol Hill last week. The 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. *Politico* reported that All of Us “now has more than 115 sites enrolling participants and more than 710,000 sample tubes stored in the biobank, with 10,000 arriving daily from across the country. More than 40,000 people have begun enrollment, and more than 24,000 of those already have completed the initial protocol.” ABC members BloodCenter of Wisconsin and San Diego Blood Bank were among the pilot participants.

(Source: *Politico*, [All of Us launching in May](#), 4/16/18)

The *Economist* called attention to the global blood donation policies of individual countries for men who have sex with other men (MSM) in a recent [blog post](#). The author examines the controversy surrounding the current FDA MSM [guidance](#) with opponents suggesting that a 12 month deferral is medically unnecessary and discriminatory. The commentary explains that advocates in the LGBT community view the [guidance](#) as biased, while favoring a deferral based on individual behaviors. It references a 2014 University of California, Los Angeles (UCLA) [study](#) that estimated “lifting the restrictions on blood donations for sexually active gay men in America would increase the country’s blood supply by 2-4 [percent],” approximately allowing 360,600 more men to donate an additional 615,300 additional units of blood each year. America’s Blood Centers, AABB, and the American Red Cross supported moving to a one-year MSM

(continued on page 8)

BRIEFLY NOTED (continued from page 7)

deferral, as it “aligns the MSM donor deferral period with those for other activities that may pose similar risks for transfusion-transmissible infections,” according to a December 2016 [joint statement](#). ABC applauds new research initiatives to characterize the feasibility of alternative strategies like “behavior-based” as opposed to sexual orientation-based donor screening.

(Source: *Economist*, [Why some countries still ban gay men from giving blood](#), 4/16/18)

The deadline to [submit abstracts](#) for the [2018 AABB Annual Meeting](#) in Boston, Mass. is April 26th. AABB opened its call for abstracts in February and encourages members and non-members to submit abstracts online. Notification of acceptance will take place in early July. All accepted abstracts will be published in the September supplement to *Transfusion*. More information about abstract submission is [available](#).

(Source: AABB Weekly Report, 4/13/18) 💧

REGULATORY NEWS

The U.S. Food and Drug Administration has issued two final guidances on next generation sequencing (NGS). The guidances entitled “[Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics](#)” and “[Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing \(NGS\)–Based In Vitro Diagnostics \(IVDs\) Intended to Aid in the Diagnosis of Suspected Germline Diseases](#)” are follow-ups to those released in 2016 and are intended to help advance precision medicine through increased regulatory flexibility. “As disease detection technologies rapidly evolve, so too must the FDA’s approach to reviewing these new innovations,” said FDA Commissioner Scott Gottlieb, MD in an agency news [release](#). “The new policies issued today provide a modern and flexible framework to generate data needed to support the FDA’s review of NGS-based tests and give developers new tools to support the efficient development and validation of these technologies.” The FDA and other federal agencies have taken interest in the potential role that blood centers may play in conducting genomic testing of blood donors.

(Source: FDA News [Release](#), 4/12/18)

An April 12th draft guidance notice on “Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria; Draft Guidance for Industry and [FDA] Staff” from the FDA has been [published](#) in the *Federal Register*. Comments are open until July 11th. The guidance aims to “describe an optional program for certain well understood device types, where a submitter could demonstrate that a new device meets FDA-identified performance criteria instead of directly comparing the performance of the new device to a specific, submitter-identified predicate device as part of a demonstration of substantial equivalence.”

(Source: *Federal Register* [Notice](#), 4/12/18)

The Centers for Disease Control and Prevention (CDC) distributed an [outbreak alert](#) regarding potential life-threatening vitamin k dependent antagonist coagulopathy associated with the use of synthetic cannabinoids. The alert follows three deaths and more than 100 severe bleeding cases in other individuals likely linked to synthetic cannabinoids containing brodifacoum that would otherwise be unexplained. Three of the patients in Illinois reported that they had recently donated plasma prior to being admitted to the hospital. Brodifacoum is a known anticoagulant commonly found in rat poison. CDC continues to warn individuals of the potential risks associated with synthetic cannabinoids.

(continued on page 9)

REGULATORY NEWS (continued from page 8)

(Sources: CDC [Alert](#), 4/5/18; *USA TODAY*, [Fake marijuana likely tainted with rat poison kills 3, causes severe bleeding in 100 others](#), 4/11/18) ♦

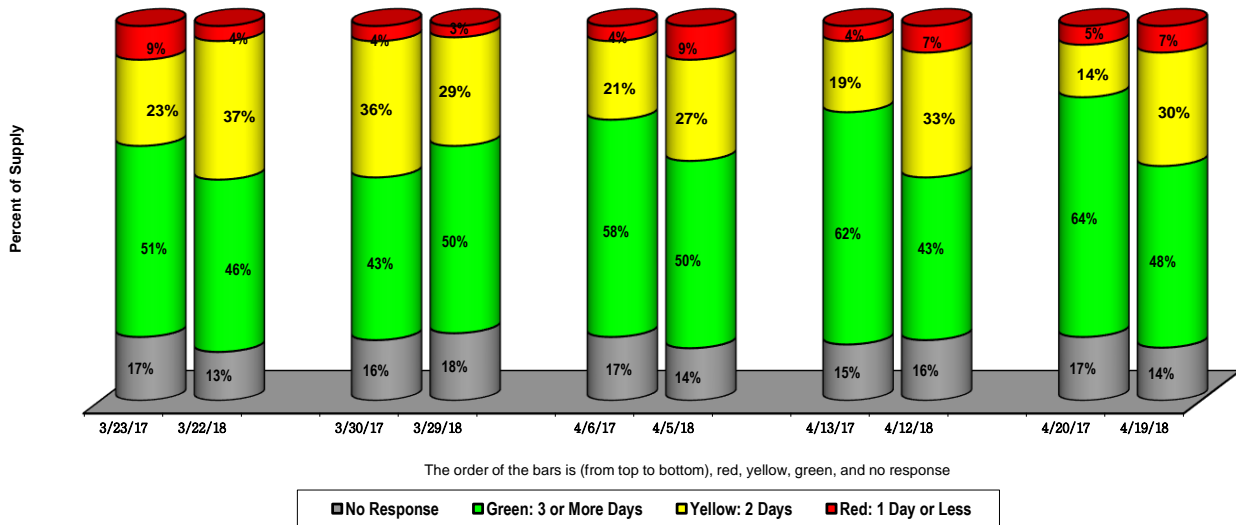
PEOPLE

Versiti has named Brian Bautista, MBA executive vice president and chief operating officer. Mr. Bautista has more than 18 years of healthcare experience, most recently serving as the area vice president at Shire, formerly Baxalta. “Inspiring leaders light the flame to ensure we build and sustain a winning Versiti culture, while also courageously delivering on our noble mission,” said Chris Miskel, MBA president and CEO of Versiti in a news [release](#). “Brian is a proven leader that has the heart, spirit and experience necessary to lead our high performing operations team well into the future.” In this role, Mr. Bautista will be responsible for blood center operations across all Versiti blood centers. “I am thrilled to join an organization that holds such a deep commitment to its mission and to ensuring it can serve its hospital customers at the highest level,” said Mr. Bautista. “I look forward to empowering the team to standardize excellence across all of Versiti while preserving our commitment to the local communities we serve.” Mr. Bautista received a Doctor of Pharmacy degree from the University of Illinois at Chicago College of Pharmacy and an MBA from Lake Forest Graduate School of Management.



(Versiti News [Release](#), 4/17/18) ♦

STOPLIGHT®: Status of the ABC Blood Supply, 2017 vs. 2018
Daily updates are available at:



www.AmericasBlood.org

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. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 393-1282. 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.



MEMBER NEWS

Mississippi Valley Regional Blood Center (MVRBC) has received approval by the U.S. Food and Drug Administration (FDA) to distribute Intercept pathogen reduced platelets. “We are excited about our [biologics license application] approval as it will enable us to supply and improve patient access to Intercept-treated platelets to hospital customers across our service region.” said MVRBC Chief Executive Officer Mike Parejko, MS, MT(ASCP) in a news release. “This aligns with MVRBC’s mission to ensure the safety and availability of blood components; with increased availability of pathogen reduced products, we can help protect patients from transfusion transmitted infections.”

(Source: Mississippi Valley Regional Blood Center News Release, 4/17/18)

The Blood Connection, Inc. (Greenville, S.C.) held a grand opening on April 9th for its new donation center in Easley, S.C. Community leaders, board members, hospital partners, blood donors, and blood drive sponsors gathered together to celebrate during an open house and ribbon cutting ceremony. “Although The Blood Connection has had a donation center in Easley for more than 15 years, the new donation center will enable us to better serve our donors,” said President and CEO Delisa English, MBA. “Our newly designed facility has more room, for a comfortable, relaxing donor experience. It will help us expand our ability to collect blood and support the Easley community, while strengthening sustainable relationships with our hospital partners, drive sponsors, volunteers and donors.” Gwendolyn Mayes, board chair at The Blood Connection, Inc. became the first blood donor at the new Easley center.



The Blood Connection Board Chair Gwendolyn Mayes donates during the Easley center grand opening.

(Source: The Blood Connection, Inc. Announcement, 4/13/18) 💧

COMPANY NEWS

Cerus announced earlier this month that Baylor St. Luke’s Medical Center is the first in the continental U.S. to enroll in the Intercept Blood System for Red Blood Cells in Regions at Potential Risk for Zika Virus Transfusion-Transmitted Infections (RedeS) study, a phase 3 study examining the efficacy and safety of red blood cells (RBCs) collected via Cerus’ Intercept compared to RBCs in Zika-prevalent areas. “We are pleased to be part of this very important study,” said Elizabeth Hartwell, MD, Clinical Pathologist and Principal Investigator for RedeS at Baylor St. Luke’s Medical Center. “The risk of Zika transmission through blood transfusions remains a key concern in states along the gulf coast such as Texas given the prevalence of the *Aedes* mosquito, a known vector for several viruses.” Funding for RedeS has been provided in part by the Biomedical Advanced Research and Development Authority (BARDA) and the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response. “Expansion of RedeS into the continental U.S. is a key step in moving our U.S. red cell program forward. In addition to Baylor St. Luke’s, we expect several more sites to begin enrolling patients in the coming months,” said Richard Benjamin, MD, PhD Cerus’ Chief Medical Officer.

(Source: Cerus News [Release](#), 4/2/18) 💧

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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

Apr. 24-25. **International Consensus Conference "Patient Blood Management," Frankfurt, Germany.** More details available [here](#).

May 8-10. **ABC Human Resources & Training/Development Workshop, America's Blood Centers, Dallas, Texas.** More details available [here](#).

May 9-11. **ADRP Conference & Expo., Dallas, Texas.** More details available [here](#).

May 15. **2018 NJABBP Spring Seminar & Annual Conference, Woodbridge, NJ.** [Join](#) NJABBP by March 15th to be eligible to receive benefits. More details available [here](#).

May 16-17. **IPFA/PEI 25th Workshop on "Surveillance and Screening of Blood-borne Pathogens," Athens, Greece.** More details available [here](#).

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

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

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) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Compliance/Quality Assurance Director. The Community Blood Bank of NWPA & WNY is seeking a Compliance/Quality Assurance Director. He/she must be thoroughly knowledgeable in AABB, FDA, CLIA, OSHA, and State Health Department regulations and standards. Must be familiar with the principles of risk management, corporate compliance and quality assurance. The incumbent must be available during outside agency inspections and maintain a positive professional rapport with inspectors. Candidates should have a minimum of a bachelor's degree in Medical Technology, Clinical Laboratory Science, or related science field,

Masters or advanced certification (e.g.: SBB, ASQ) a plus; five years of blood bank quality and regulatory affairs experience preferred. Experience should include participation in FDA site inspections, experience with GMP requirements and application of quality assurance principles; three years of supervisory experience preferred. Must possess excellent conceptual, communication, and analytical skills, and be competent with Microsoft Office (Word, Excel, PowerPoint) and Crystal Reports. Office 365 knowledge a plus. To apply,

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POSITIONS (continued from page 11)

please send a resume and any relevant documentation to: Deanna Renaud, Interim Executive Director, Community Blood Bank, 2646 Peach St., Erie, PA 16508; or email Deanna.renaud@fourhearts.org.

Associate Director, Donor Recruitment. Memorial Blood Centers in St. Paul, Minnesota, is looking for an Associate Director of Donor Recruitment Department. This role will be a leader to our leaders, as it oversees the Donor Recruitment and Contact Center Teams! The role is also responsible for maintaining and growing our donor base. Benefits include: Medical, Dental Vision, PTO/EST, 401K and more! Please click [here](#) to apply.

Director, Finance. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Finance position. This position is responsible for managing the daily activities of the general accounting/finance function. Scope of responsibilities include overseeing the completion of ledger accounts, payroll, A/P, A/R, fixed assets and financial statements; directing and supervising general accounting personnel; evaluating and making appropriate improvements to internal accounting processes ensuring that practices are in line with the overall goals of the organization. Must be familiar with a variety of the field's concepts, practices, and procedures and relies on extensive experience and judgment to plan and accomplish goals. Bachelor's degree in Accounting preferred or other closely related business degree may be acceptable. A CPA is highly desirable. Minimum ten (10) years combined experience in Public Accounting and/or private industry; good understanding of accounting and business systems; prior management/supervisory experience required. Relocation package is available for qualified candidates. This position reports to the Vice President/CFO. 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/>.

Clinician Educator Line/Medical Center Line. The Department of Pathology seeks an outstanding new faculty member to join Stanford Blood Center Histocompatibility, Immunogenetics, and Disease Profiling Laboratory at Stanford Medicine, for appointment in the Clinician Educator Line (Clinical Assistant Professor, Clinical Associate Professor, or Clinical Professor), or in the Medical Center Line (MCL) (Assistant Professor, Associate Professor or Professor). The individual will share oversight responsibilities with Directors of the Laboratory including clinical reporting, clinical consultation, research and development, implementation and validation of novel tests, administrative duties, and teaching of clinical residents and fellows. Service responsibilities include reviewing and reporting clinical cases, clinical

consultation, methods development, safety, quality assurance, regulatory compliance, and management of personnel and budget. Participation in weekly clinical meetings with transplant services is required. Requirements for the position include an MD or PhD or MD, PhD with demonstrated and recognized experience in human clinical histocompatibility testing and demonstrated expertise in novel test development and/or experience in desensitization programs. Licensure, or eligibility for such licensure, by the State of California as a Histocompatibility Laboratory Director and Board certification at the Diplomate level, or eligibility for such certification, by the American Board of Histocompatibility and Immunogenetics (ABHI) are required. Please see full description at <https://stanfordbloodcenter.org/about/sbc-careers/current-job-openings/>

Director, Hospital Services. The Blood Connection (Greenville, SC) seeks qualified applicants for its Director of Hospital Services position in Eastern North Carolina. This position will provide administrative support, technical guidance, and supervision to Hospital Services personnel. Must possess a broad knowledge of procedures routinely performed in the donor-testing laboratory, component processing and distribution and a working knowledge of all procedures performed. The job primarily involves the application of this knowledge through the supervision of staff as well as the performance of analytical related tasks, solution of testing problems, and the continued development of operational skills through daily workload responsibilities. High school diploma or technical or vocational school (four years) plus up to two years of specialty training OR up to two years of college. Associates degree MLT, BSMT (ASCP), or BS/BA in biological science strongly preferred. Licensure/Certification Requirements: ASCP certification required for associate level degree (MLT) Experience Requirements: Two years related supervisory experience, extensive blood banking and transfusion service experience strongly preferred, including three to four years in a technical or laboratory setting. Work experience in a regulated environment (FDA, AABB, CLIA): strongly preferred. Blood center experience preferred. The Blood Connection (TBC) is an Equal Opportunity Employer. EEO/Minority/Female/Disability/Vets. To apply, please go to <http://thebloodconnection.org/everify/>.

Director, Donor Resources. The Blood Connection (Greenville, SC) seeks qualified applicants for its Director of Donor Resources position in Eastern North Carolina. This position directs the Donor Resources Department in activities related to donor recruitment efforts. This position is responsible for engaging in TBCs visibility and community outreach through various recruiting, public relations and communication efforts. This position will plan and implement effective strategies to recruit and retain and manage sponsor organizations and relation

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POSITIONS (continued from page 12)

ships to achieve established blood collection goals. This position is responsible for managing all staff assigned to the recruitment department to oversee their production and relation efforts. The Director of Donor Resources will represent TBC as a role model that positively reflects the values, ethics and culture of the organization. The position requires the ability to handle difficult situations and ways to arrive at an agreement amongst diverse groups of stakeholders. Bachelor's degree required. Minimum of three (3) years managerial responsibility in public relations, marketing or sales or five (5) years of technical experience in sales or marketing-related role. The Blood Connection (TBC) is an Equal Opportunity Employer. EEO/Minority/Female/Disability/Vets. To apply please go to <http://thebloodconnection.org/everify/>.

Director, Donor Services. The Blood Connection (Greenville, SC) seeks qualified applicants for its Director of Donor Services position in Eastern North Carolina. This position Provides leadership, administrative guidance and direction to staff of the Donor Services Department. Proficient in: Preparing and monitoring budgets, planning, organizing, leading and controlling departmental operations, goal setting, disciplining, counseling, and communication with patients or donors who have problems. The ability to perform statistical analysis to track and trend pertinent data, oversight of current good manufacturing practices (cGMPs), and current good tissue practices (cGTPs) and the effectiveness and efficiency of the Donor Services department. Experience requirements: Bachelor's degree required. Four (4) or more years' experience in blood banking preferred or at least three (3) years in a healthcare management position. Licensure/Certification Requirements: Registered Nurse certification and license. The Blood Connection (TBC) is an Equal Opportunity Employer. EEO/Minority/Female/Disability/Vets. To apply please go to <http://thebloodconnection.org/everify/>.

Blood Center Professionals. OneBlood is looking for individuals that want to learn, grow and establish a career path. Be part of a team that supports the community and hospitals by executing blood drives at community, promotional, and corporate events. We provide paid training for Donor Services and Recruitment staff. We offer competitive salary, shift differential for weekend schedules (Friday-Sunday), mileage reimbursement, medical benefits, dental, vision and a retirement plan. Position requirements: flexible schedule, morning, afternoon and evening schedules, weekends and holidays, working indoor/outdoors. Supporting Recruitment and Collections department we have available positions as: Donor Services Specialist (Phlebotomists), Blood Donation Recruiter, Senior Sales Associate and Territory Account Representative. In Dade/Broward County, Lantana, Lakeland FL, Orlando and Tampa/St. Pete. Some positions require the use of personal transportation and a valid driver's license. Interested candidates please apply via our website www.oneblood.org/careers. OneBlood is an equal opportunity employer.

Division Director. Hoxworth Blood Center seeks a Division Director to direct operations of the Components & Distribution, Immunohematology Reference, and Donor Testing laboratories. This individual will streamline workflow, increase efficiency while increasing Hoxworth's ability to deliver existing and new products and services. Primary responsibilities: Eliminate inefficient processes; Provide weekly order fulfillment, TAT data; Reduce products lost (waste) in manufacturing; Ensure test results are uploaded and product labeling is completed by 8 a.m.; Resource share \$650,000 in products end of first year; Increase recovered plasma sold; Support Donor Recruitment, Donor Operations to implement Source Plasma; and Resource share \$650,000 in products first year. Requirements: MT (ASCP) SBB Certified or master's degree in Immunohematology; or bachelor's degree with seven (7) years of experience; or associates degree with nine (9) years of experience. Degree must be in science. Experience requires at least five years supervision. Apply [here](#). 💧