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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Issue #28
August 11, 2017

ABC Summer Meeting Moves Members Into the Future

This year's ABC Summer Meeting was focused on how blood centers can move into the future and reshape themselves with presentations on alternative revenue streams for blood centers, forward-thinking relationships with hospitals, and new strategies for helping mitigate adverse reactions and iron loss in donors. Attendees enjoyed the educational presentations, roundtable discussions as well as networking opportunities that included the sites and tastes of Providence, Rhode Island.

"We're not just a blood bank anymore, that business model is no longer working," said Robert Tressler, PhD, vice president of Laboratories at San Diego Blood Bank (SDBB). "We have to find new and creative ways to support that core business."

Presentations, like Dr. Tressler's talk on T-cell mediated immunotherapy, suggested ways in which blood centers could generate new revenue to support their core mission of blood collection—their "reason for waking up in the morning" as he said. Some centers, like SDBB, have broken into the rapidly evolving and expanding industry of T-cell therapeutics by producing CAR-T cells for companies performing clinical trials.

Providing companies performing clinical trials with autologous, patient-specific CAR-T cells is not a small feat, said Dr. Tressler, but many centers today—even some of the smaller ones—have the know-how and equipment to perform such tasks. The most lucrative way to continue in this industry in the future will be if a center or affiliated partner develops an off-the-shelf allogenic CAR-T cell product. Shipping, quality, training and medical oversight are all concerns with producing and selling CAR-T cells, but it is an area worth exploring.

Another product discussed by Christopher Gresens, MD, division chief medical officer for BloodSource, as a potential stream of revenue to help support blood center's core mission is mesenchymal stem cells (MSCs). Developing these cells fits into the core mission of blood banks, said Dr. Gresens, and most centers already have the expertise and ability to produce them. Currently, only indications for MSCs are approved by the Food and Drug Administration (FDA). By supplying these cells for clinical trials and research and development companies could create new partnerships for blood centers looking to break into this emerging industry.

Other products like platelet lysate and CD34 cells were discussed during the meeting as potential revenue sources. Platelet lysate is a substitute for fetal bovine serum (FBS), which helps in the stimulus and growth of cell cultures. As blood centers are already certified cGMP manufacturers for platelet products, many centers have the ability to use their expiring platelet units to make platelet lysate as a FBS alternative. SDBB's platelet lysate product has shown to be highly effective even if not in high demand yet.

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INSIDE:

Our Space:

OUR SPACE

ABC Chief Medical Officer and interim CEO Louis Katz, MD

Business is Business

Creative Testing Solutions (CTS), the American Red Cross (ARC), and OneBlood have announced the consolidation of their donor testing services into CTS. If my eyeball is accurate, that will concentrate 75 percent of the U.S donor testing volume with a single supplier. The size of the "new" company offers the prospect of economies of scale, not just on prices, but perhaps as leverage with test builders and maybe even with the regulator. No doubt this is a good business decision by the principals of the three organizations. Time will pass and we will understand the impacts.

I fielded, in the eight hours or so after learning of the merger, perhaps a half-dozen calls or e-mails from colleagues essentially asking whether this is another "nail in the coffin" of the community blood center. The issues centered mainly on the ability of three large blood operators to advantage themselves on the costs associated with donor screening while disadvantaging "external customers," reducing the competitiveness of smaller labs and blood centers in the long run.

A concern and a comment.

The concern—really one we should have recognized and been addressing much earlier: ≥75 percent (and to grow I suspect) of a critical blood processing step, donor testing is already and will continue to be done on the nucleic acid testing and serology equipment of one company each. Recall that we have, in the past year, seen a highly disruptive blood bag and leukoreduction filter "crash," where we have limited vendors. These created substantial difficulties at substantially lower proportional volumes than 75 percent. What if that happens to one of the two systems in use by this laboratory and an assay or platform is not available for days or weeks or longer? How would that impact the short- and medium-term availability of blood? Is there an imperative that the lab maintains redundant capacity on the alternative testing systems?

The comment—this should not be a death knell for the community blood center because it is harder to farm out the donor-facing activities at the core of everything we do than very "rote" processes like donor testing and data transfer. Our most important relationships in support of the "community model" are with local donors and groups and with potential donors. I used to work for one of the principals involved in this latest announcement, who always believed there was an irreducible local imperative to putting volunteers on the beds. Is it enough to preserve our community model? Probably, but it will certainly not look like the model we are familiar with (it already does not).

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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ABC SUMMER MEETING (continued from page 1)

Clinical trials for the cure of sickle cell disease (SCD) could also help centers find a new way to fund their operations. Suchi Pandey, MD, division chief medical officer of Blood Centers of the Pacific presented on the history and the use of gene therapy for SCD patients. Using hematopoietic stem cells for treating SCD patients requires the collection and harvesting of CD34 cells from peripheral blood by apheresis.

In addition to cell extraction and production of blood products, data is another channel in which blood centers could find future revenue streams. "Data drives decisions and markets," said Bill Block, President and CEO of Blood Centers of America (BCA), which is generating revenue for its members by selling blood product ordering data. Pharmaceutical companies spend $100 to $200 million per year on clinical development, said Mr. Block. Selling anonymized data to help these drug companies make more personalized medicines and help accelerate drugs to market was an inventive way to collect funds for his organization. These data are different than the operational data the ABC Data Warehouse is collecting, but could be good for monetization efforts and is information the blood centers already have.

"Sixty percent of blood centers are not making money, this could be another way to drive revenue," said Mr. Block.

In a technological look toward the future, Marsha Bertholf, MD, medical director at Gulf Coast Regional Blood Center, and Kip Kuttner, DO, vice president and medical director at Miller-Keystone Blood Center, both discussed non-invasive devices for hemoglobin measurement. Dr. Bertholf spoke on how the fingerstick hemoglobin measurements compared to the OrSense non-invasive device and potential impacts on donor deferral rates. Dr. Kuttner discussed OrSense's device versus UltraCrit—a hematocrit analyzer, versus venous samples. Other ways to help make donors more comfortable and more likely to return for donations in the future were discussed during presentations and break-out discussions on iron mitigation strategies and predicting and preventing reactions among young blood donors.

Ralph Vassallo, MD, FACP, executive vice president and chief medical and scientific officer at Blood Systems Inc., who also chairs the AABB Ad-Hoc Committee on Iron Management Among Blood Donors, discussed iron depletion intervention studies and recent discussions at AABB on how to go forward with mitigation strategies for donors—especially young and female donors. Dr. Vassallo also discussed the AABB Association Bulletin 17-02 on iron supplementation and the benefit/barriers of facilitating iron access, changing interdonation intervals, and measurement of iron stores. Breakout sessions amongst members were helpful and lively as each representative shared how their center is approaching, or not, iron supplementation. While some said they did not have enough information to make a sound decision on what strategy to follow yet and were awaiting guidance from the FDA, others were already moving forward with supplementation, measurement of iron stores and iron education plans already.

Christopher France, PhD, distinguished professor of Clinical Health Psychology at Ohio University, talked about predicting and preventing reactions in young donors, especially vasovagal reactions. The techniques reviewed were applied muscle tension, fluid loading, restriction of donors with low estimated blood volumes, and distraction techniques.

"In the media, when blood donation is depicted, it almost always involves fainting—very dramatic," said Dr. France. "We need to fight that common misconception…talk about ways to prevent it and that if it does happen, it's not a big deal."

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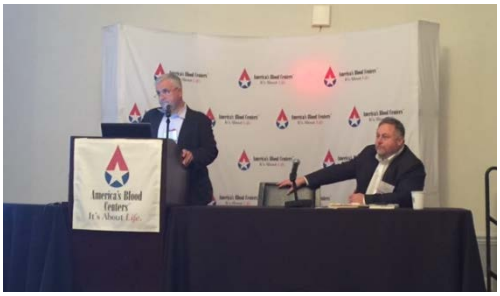
ABC SUMMER MEETING (continued from page 3)



By tracking and analyzing the data vigilantly, blood centers can develop better future outcomes.

"If you are looking toward the future—implement hemovigilance reporting first," said Kevin Land, MD, vice president of Clinical Services at Blood Systems, Inc.

"But don't gather every piece of data. If you gather everything, you have nothing. Focus less on 'best data' and see what data you can provide to start making decisions to gather more precise and accurate data."

Another form of data imperative to blood centers' operations is donor screening information. Sometimes, donors forget to tell the staff about a trip, maybe to Africa, or a "summer flu" they might have had after being in the woods for a weekend. Post donation information (PDI) occurs about one in every 600 donations, said James Shikle, MD, medical director of Shepeard Community Blood Center, in his review of the topic. When that information turns into a recall of a product, it usually has to do with information regarding a malaria infection, variant Creutzfeldt-Jakob disease risk-factors, or babesiosis. PDIs happen frequently and are "unavoidable." Improving data gathering and analysis can advance donor screening and the notification process.

The current status of the occurrence and prevention of bacterial sepsis from platelets was the subject of the presentation from James AuBuchon, MD, FCAP, president and chief executive officer at Bloodworks Northwest. Dr. AuBuchon discussed limitations and benefits to changing the timing and volume of primary platelet culture with particular reference to methods being used at NHS Blood and Transplant in the U.K. and in Canada's Héma-Québec. Dr. AuBuchon also discussed pathogen reduction and the use of cold platelets as developing strategies.

ABC CMO Louis Katz, MD, noted FDA's intent to issue a third draft platelet bacterial guidance, probably after bring the issue to Blood Products Advisory Committee, in his "Hot Topics" presentation at the meeting. He addressed blood center sustainability and activities of the Advisory Committee on Blood and Tissue Safety and Availability in the wake of the RAND report. CJD draft guidance updates, and possible guidances on other infectious diseases as well.

Something that would help the industry in the future would be more randomized controlled trials on pediatric transfusion thresholds, said Steven Sloan, MD, PhD, blood bank medical director at Boston Children's Hospital and associate professor at Harvard Medical School. Dr. Sloan discussed the outcomes of a number of historic studies, but reiterated that there is still a lack of evidence for creating solid pediatric guidelines. "The numbers do not work," he said about massive transfusions thresholds for pediatric patients.

A timely piece to help prepare blood centers for future disasters was given by Laurie Sutor, MD, vice president of medical and technical services at Carter BloodCare. In her presentation, "The Role of a Blood Center Medical Director in Internal and External Disasters," Dr. Sutor discussed the leadership, technical and safety oversight, and compliance skills a medical director needs to have in order to field a disaster scenario for their blood center. "When all else fails, call the medical director," said Dr. Sutor.

The Business Forum featured two presentations from hospital-affiliated speakers. The first was from Jack Barry, regional executive for Region One of the American Hospital Association, on common issues be

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ABC SUMMER MEETING (continued from page 4)

tween hospitals and blood centers. Mr. Barry predominantly discussed the repeal efforts of the Affordable Care Act, Centers for Medicaid and Medicare payment proposals, and cybersecurity issues as related to the hospital industry.

One of the most forward-thinking presentations of the meeting was by Andrea Y. Coleman, fellow at the American College of Healthcare Executives. As a consultant and former hospital executive, Ms. Coleman has worked extensively on contracts and hospital relationships with outside services. She provided ideas toward restructuring the blood industry and reshaping relationships with hospital executives so blood centers' needs would be more visible and clear to hospital leaders. She recognized the "blindness" of hospital executives to the realities of the blood community and our sustainability and how we might communicate more effectively with hospital executives using data on stressors affecting our services.

"I don't think they understand their actions collectively hurt a community asset—because blood is a community asset," said Ms. Coleman about the hospital's blood management programs.

Ms. Coleman recommended using lean methods in centers, finding innovative ways to remodel the industry and becoming a "marshal" to hospitals and government agencies to ensure the blood industry's declining economics don't continue their downward slope.

Rhode Island Blood Center held a splendid reception at the Biltmore hotel with a rolling dinner and live piano music. The 360-degree view of Providence had some guests audibly impressed as they entered the 17th floor grand ballroom of this historic hotel.

We would like to thank all the meeting sponsors for your continued support and the members who attended the meeting. We look forward to seeing you all again soon!

To view the presentations from the Summer Meeting, click here.

Photos from around the ABC Summer Meeting

America's Blood Centers
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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.

Members Meeting Lays Groundwork for the Future

Representatives from ABC blood centers attended a critical Members' Meeting at the 2017 ABC Summer Meeting in Providence, R.I., as the ABC leadership gave updates on their strategies and objectives, and ABC's future structure.

Rob Purvis, vice president of Customer Service at New York Blood Center, was elected as the new vice president of the ABC Board of Directors, replacing Diane Merkt who has left ITxM. Members also voted unanimously for emeritus membership for Don Doddridge, recently retired president and CEO of One-Blood, and Dan Connor, recently retired president and CEO of Blood Systems, Inc.

Pascal George, chair of the Foundation for America's Blood Centers (FABC) and CEO of Central Jersey Blood Center, listed FABC's successes and realignment to the core ABC values of Advocacy, Data and Education. Mr. George discussed the FABC's fundraising goals and value. The FY18 member grant awards were then distributed in the amount of $20,000 each and presented to the following winners at the Members Meeting:

The Louis Katz Grant Award Winning Check

- The Louis Katz Research Grant was awarded to Community Blood Center (Appleton, Wisc.) for their "High School Donor Recognition Program"

- A member grant in the area of iron mitigation messaging and strategy went to New York Blood Center for their "Use of Messaging and Action Planning to Mitigate Iron Depletion in At-Risk Donors."

- Another member grant for went to LifeStream for their iron replacement program, and

- A member grant in relation to donor health went to Versiti/BloodCenter of Wisconsin for their "Characterization of ABO titers among Group O and A donors: harmonizing an established protocol to define 'low titer' ABO blood products."

BloodCenter of Wisconsin's (Versiti) member grant award

ADRP described how the new partnership with ABC has helped them excel, including the annual ADRP conference that experienced a surge in attendance. The coming year will see ADRP working to increase their membership further and solidifying a new committee structure.

ABC Chief Administrative Officer Kate Fry gave brief advocacy strategy going forward that was inclusive of regulatory (reimbursement related), legislative and grassroots channels and noted the advocacy

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INSIDE ABC (continued from page 7)

objectives and progress that has been made for calendar year 2017. ABC Director of IT and Business Intelligence Sameer Ughade spoke again about the data warehouse (DW) and the progress he and his team have made in the 16 months since he's come onboard. He discussed the plans he has for moving the DW from a reporting and analyzing tool to a predictive and modeling asset. The focus then switched to the ABC President's report and realignment presentation.

ABC President Martin Grable, president and CEO of the Community Blood Centers of the Carolinas, presented the recommendations of the working group formed to effect the realignment of member interests across ABC, Blood Centers of America, and HemeXcel. The effort was to better align the business interests domiciled in the GPOs with the Science, Medical, Technical, Quality, Regulatory, and Advocacy efforts of ABC. Governance changes that will affect ABC bylaws as well as the size and composition of the Board of Directors, while maintaining ABC's non-profit status and blood center membership, were presented and discussed. The details of the changes will be presented in detail over the next 30 days in MCNs and webinars.

We would like to thank all the members who attended the meeting for their dedication and commitment to ABC and our shared cause of saving lives!

Special ABC Board Meeting
August 28, 2017
2:00 p.m. EDT

All ABC members are welcome to join in listen-mode. Please click here for information.

Links For Life is Par for the Course!

The Foundation for America's Blood Centers (FABC) hosted the 7th Annual Links for Life Golf Tournament at the Warwick Country Club on August 3, during the ABC Summer Meeting in Providence, R.I. The golf tournament was sponsored by Blood Bank Computer Systems, Inc. (BBCS) and was a huge success.

Golfers enjoyed an all-American lunch on the patio overlooking the beautiful Narragansett Bay and sailboats passing by. Afterwards, the foursomes hit the links while the first-ever golf clinic taught beginners, not too comfortable with golf, how to perfect their swing.

The winning foursome included: Scott Hall, MD, medical director at Blood Bank of Delmarva; Jim Shikle, MD, medical director at Shepeard Community Blood Center; ABC Director of Regulatory Services Ruth Sylvester; and Jim Decker, CEO of MEDIC Regional Blood Center. Dr. Hall also took home the award for the longest drive contest and Pete Castagna, CEO of Miller-Keystone Blood Center, was the winner of the closest to the pin contest.

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The Foundation for America's Blood Centers would like to thank BBCS, Inc., BCA and HealthAware for their generous support!

Links for Life photos (Courtesy of Eva Quinley, chief operating officer at MEDIC)

Blood Bank of Delmarva and New York Blood Center Join Forces

Blood Bank of Delmarva (BBD) and New York Blood Center (NYBC), both community-based, non-profit blood centers, announced they are merging their operations to create one of the leading blood centers in the Northeast and Mid-Atlantic regions.

The new partnership brings together the complementary strengths of BBD and NYBC to deliver a broad range of blood banking expertise that will position both organizations to deliver next generation blood banking innovations. The merger will position BBD to better serve its hospital network, expand its laboratory testing services, and create opportunities to participate in significant blood research projects operated by NYBC.

"This is an exceptional moment for our companies and the communities we serve," said BBD CEO John Ferretti. "In today's increasingly challenging and evolving blood banking environment it is imperative that like-minded organizations work together to improve access to safe blood products. This merger will ensure BBD's long-term success in a challenging healthcare environment."

Day-to-day operations at the companies will not be impacted. BBD will continue to operate under its own name and will continue to serve customers in Delaware, New Jersey, Pennsylvania, Maryland and elsewhere. Mr. Ferretti will continue as CEO of BBD. BBD's blood donors and volunteers will continue to receive the same service they've come to expect from the organization, while hospital customers will have access to a broader portfolio of blood products and services.

"We're extremely pleased to be partnering with such an excellent blood center. NYBC and BBD have a remarkable alignment of mission, vision, and talent. We look forward to working together to ensure the finest customer-focused service for our hospitals and patients. We welcome BBD to the NYBC family," said Christopher D. Hillyer, MD, president and CEO of NYBC. With this merger Dr. Hillyer will become President of BBD.

NYBC is renowned for its comprehensive, sophisticated research and product development capabilities. This will allow BBD to offer new services, skills, and products throughout its service area, including immunohematology and cellular therapy lab services that BBD currently does not offer.

The long term goal of both organizations is to identify opportunities for collaboration as they move forward.

The first-ever IT Forum Call

Wednesday, August 16
2:00 to 3:00 p.m. EDT
No registration required

The call is open to ABC member IT professionals. Discussion will be centered on: cybersecurity, IT training options, and IT resource "pool." Click **here** for more info.

RESEARCH IN BRIEF

Idarucizumab is a safe and rapid anti-coagulant reversal agent in emergency situations for patients using dabigatran. Patients at risk for developing, or being treated for thrombosis are commonly and increasingly prescribed oral anti-coagulant medications, including warfarin and newer agents like dabigatran**.** When these patients present to the hospital with life-threatening bleeding or for urgent invasive procedures, rapid reversal of the drugs is needed and can be life-saving. Reversal of warfarin with plasma or prothrombin complex concentrates is well-established. Alternatives for the new direct acting agents, which have distinct advantages over warfarin, have been fewer. Idarucizumab is a humanized monoclonal antibody to reverse dabigatran. In a two-year, multi-center, prospective open-label study of 503 individuals, 301 with uncontrolled bleeding (group A) and 202 undergoing surgery that could not be delayed for longer than eight hours (group B), the patients received 5 g of idarucizumab in two infusions. The median maximum percentage reversal within four hours after was 100 percent (95 percent confidence interval, 100 to 100). The median time to cessation of bleeding for group A was 2.5 hours, and median time to the initiation of the intended procedure for group B was 1.6 hours. Mortality rates between the two groups were similar at 30 and 90 days. No serious adverse safety signals were seen.

Citation: Pollack C.V., Reilly P.A., van Ryn J., *et al*. Idarucizumab for Dabigatran Reversal — Full Cohort Analysis. *New England Journal of Medicine*. July 11, 2017. DOI: 10.1056/NEJMoa1707278.

An international research team published a study showing application of the CRISPR-Cas9 gene editing technique to human embryos carrying a mutation for a monogenic disease. The mutation, called MYBPC3, is a dominantly inherited gene causing hypertrophic cardiomyopathy, a thickening of the heart wall with cardiac conduction abnormalities, that is responsible, for many cases of sudden death including in young athletes. This study provides proof of concept that by applying the CRISPR-Cas9 technique at the time of introduction of sperm to egg, an abnormal gene can be repaired in a large majority of embryos without the creation of new mutations, and without the generation of a mosaic state in the embryos. Its potential application to other genetic conditions, e.g. sickle cell disease or thalassemias, is obvious. The study, done primarily at Oregon Health & Science University in Portland, with collaboration from San Diego, Korea and China, was privately funded because of its work creating and altering human embryos. The embryos were not intended for implantation.
For those interested in in reading a short primer on CRISPR-Cas9, read this *JAMA* article.

Citation: Ma H., Marti-Gutierrez N., Park S.W., *et al*. Correction of a pathogenic gene mutation in human embryos. *Nature*. August 2, 2017 online. DOI: 10.1038/nature23305.

This article was contributed by Laurie Sutor, MD, vice president of medical and technical services at Carter BloodCare.

RECENT REVIEWS

3-D printing as an approach to constructing medical devices will be important moving forward. In a concise review in the *Medical Journal of Australia*, authors describe current and evolving methods and applications. This is precision medicine viewed through a different lens than the more familiar genomics perspective. The authors concluded, “an increasing number of institutions are recognizing its disruptive potential, establishing institutional hubs and pursuing collaborations.”

Coles-Black J., Chao I., and Chuen J. Three-dimensional printing in medicine. *Medical Journal of Australia.* August 7, 2017. DOI: 10.5694/mja16.01073.

BRIEFLY NOTED

Controversy about a National Institutes of Health (NIH)-funded study? The Washington, D.C.-based nonprofit consumer advocacy group Public Citizen, has called for the end of the Myocardial Ischemia and Transfusion (MINT) multicenter trial that randomizes heart attack patients to liberal (transfusion to maintain the hemoglobin >10 gm/dL) versus restrictive red blood cell transfusion (transfusion at <8 gm/dL). The primary outcome measure is a composite outcome of all-cause mortality or nonfatal myocardial reinfarction within 30 days of randomization. Public Citizen is concerned whether participants in the restrictive group are being placed in unacceptable risk, and whether the participants are receiving adequate information on standard practices or the purpose of the research. MINT started in April 2017 and is recruiting an expected 3,500 patients to the two groups.

"Our protocols have been reviewed by more than 35 institutional review boards across the country, as well as the Data Safety Monitoring Board, which is an independent organization comprised of physicians and ethicists," said Jeffrey Carson, principal investigator for the study told the *Miami Herald*. (Sources: MedPage Today, NIH Blood Transfusion Trial's Ethics Questioned. August 5, 2017; Miami Herald, Clinical trial fails to disclose risk of death, repeat heart attacks, group says. August 1, 2017).

The 2016 Serious Hazards of Transfusion **(SHOT) report is available.** The report from the UK Medicine and Healthcare Products Regulatory Agency (MHRA) tabulates human-factor, lab, handling and storage, and other transfusion-related errors and the adverse events reported due to such errors. There was one transfusion-transmitted infection—hepatitis E—in the year with no transfusion-related lung injury, transfusion-associated graft versus host disease or post-transfusion purpura reports in the U.K. Pulmonary complications, especially transfusion-association circulatory overload (TACO) and delayed transfusions were key sources of morbidity and mortality. Eighty-seven percent of adverse events were attributed to errors. Lack of adequate training, workload issues, and miscommunication were cited as driving the reported errors. (Source: Annual SHOT Report, July 7, 2017)

A low-cost intrauterine balloon is saving women from postpartum hemorrhage death in Africa. Postpartum hemorrhage is the leading cause of women dying during and after childbirth in developing countries. Massachusetts General Hospital developed a kit called a Postpartum Hemorrhage Implementation Package with Uterine Balloon Tamponade that costs less than $5. The kit consists of an (intrauterine) condom tied to a Foley catheter and inflated with clean water. The condom inflates and stems bleeding by tamponade. It has been used in 650 women 13 countries. (Source: MassGen press release, August, 2, 2017).

A proposed ban on payments for blood stem cell donors has been withdrawn. On August 1, the Department of Health and Human Services withdrew the pending regulation, first filed in 2013, that would have equated peripheral blood stem cells with bone marrow, which under the National Organ Transplantation Act of 1984 is classified as a human organ, for which payment is prohibited. The withdrawal of the proposal will make blood stem cell donors eligible to legally receive payment for their donations. (Source: **Office of Information and Regulatory Affairs**, August 1, 2017)

Global Healing received the Enterprise Grant award from the ICCBBA. Global Healing, a California-based nonprofit helping establish health care services in developing countries, was awarded the grant for its proposal to help strengthen the quality management system of the Hôpital Universitaire de Mirebalais (HUM) blood bank in Haiti. HUM services about 185,000 local people. The planned improvements to the blood bank include patient traceability, hemovigilance services, and data collection and evaluation.

"I can't begin to say how thrilled we are at this news," said John Donnelly, president and CEO of Global Healing. "We are very excited at the opportunity to help HUM build a strong quality management system based on real time data."

Goodbye from Dean Eller.

To my friends and colleagues in the blood banking industry,

I just wanted to say "Thank you" for your friendship over the past 18 years that I have been chief executive officer of the Central California Blood Center. I have enjoyed our collaboration in this ever-changing industry that has a mission which I have loved and will continue to love with all the passion I can muster.

Again, thank you all, and if I can be of service to any of you (speaking engagements, etc.) please do not hesitate to call me.

Sincerely,
Dean

INFECTIOUS DISEASES UPDATES

The Florida Department of Health (FDH) announced the state's first confirmed case of sexually transmitted Zika case for 2017. FDH stressed there was no evidence of local mosquito-transmitted Zika infections taking place in Florida. The individual did not travel, but the person's partner did travel to Cuba. Both tested positive for Zika. The total number of travel related incidents in the state number 90 for 2017 and 81 pregnant women have had laboratory evidence of Zika. (Source: FDH press release, August 1, 2017.)

The Centers for Disease Control and Prevention (CDC) have updated their testing guidance **for pregnant women with possible Zika virus exposure.** Providing IgM antibody testing, with relatively high false positive rates, for asymptomatic and symptomatic pregnant women is no longer routinely recommended. Rather, the CDC recommends using nucleic acid with serological testing for symptomatic pregnant women and asymptomatic women with ongoing exposure during their pregnancy. The CDC also recommends a more comprehensive screening and a shared patient-provider model to decide on if testing is needed and what type of care plans are preferred.

Citation: Oduyebo T., Polen K.D., Walke H.T., *et al*. Update: Interim Guidance for Health Care Providers Caring for Pregnant Women with Possible Zika Virus Exposure — United States (Including U.S. Territories), July 2017 *Mortality and Morbidity Weekly Report*. July 28, 2017. DOI: http://dx.doi.org/10.15585/mmwr.mm6629e1.

Ebola RNA was detectable in semen for some men infected with Ebola Virus Disease (EVD) for up to two years. A number of studies have investigated varying lengths at which EVD can survive and be transmitted via sex. A new study of 149 men who were infected with EVD and provided semen specimens was conducted in Liberia. Of the participants, 137 men provided semen specimens more than 2 years after EVD onset; and 11 of those men still had Ebola RNA detectable in their samples. The longest time Ebola RNA persisted in semen in this trial was 965 days. It is not known if the presence of the virus' RNA is an appropriate surrogate for infectious virus. The World Health Organization recommends EVD survivors use condoms or abstain from sex for a year after infection, this study calls that timeframe into question.

Citation: Fischer II W.A., Brown J., Wohl D.A., *et al*. Ebola Virus RNA Detection in Semen More than Two Years After Resolution of Acute Ebola Virus Infection. *Open Forum Infectious Diseases*. July 22, 2017. DOI: https://doi.org/10.1093/ofid/ofx155.

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INFECTIOUS DISEASES UPDATES (continued from page 13)

West Nile Virus (WNV) continues to spread this summer. A total 159 confirmed WNV cases, with six deaths, have occurred in the U.S. and 40 possibly viremic blood donors. The Centers for Disease Control and Prevention wrote on their website that while most people infected with WNV will not have noticeable symptoms, about 1 of every 150 infected people will develop a serious, sometimes fatal, illness. By the end of 2016, the total number of WNV cases were over 2,000 in the U.S. (Sources: CDC WNV statistics site; NBC10, Pennsylvania's First Human Case of WNV in 2017, August 8, 2017)

REGULATORY NEWS

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research released a list of user fee billable biologic products. The list also contains product's potencies levels and the fee is assessed accordingly. Some licensed products are not assessed and are put on the "Discontinued List," which the manufacturers request to be on. (Source: FDA email alert, August 3, 2017)

PEOPLE

Jerome Adams, MD, was approved as the next surgeon general. The full Senate consented to his appointment last week. Dr. Adams is the current state health commissioner for Indiana and is an assistant professor of clinical anesthesia at the Indiana University School of Medicine. Prior to his approval, he said one of his first priorities would be to tackle the opioid epidemic. With President Trump recently focusing on the law enforcement approach to the epidemic, rather than a health-related strategy, it will be interesting to see if Dr. Adams' priority shifts. (Dr. Adams was also written about in ABC *Newsletter* #24)

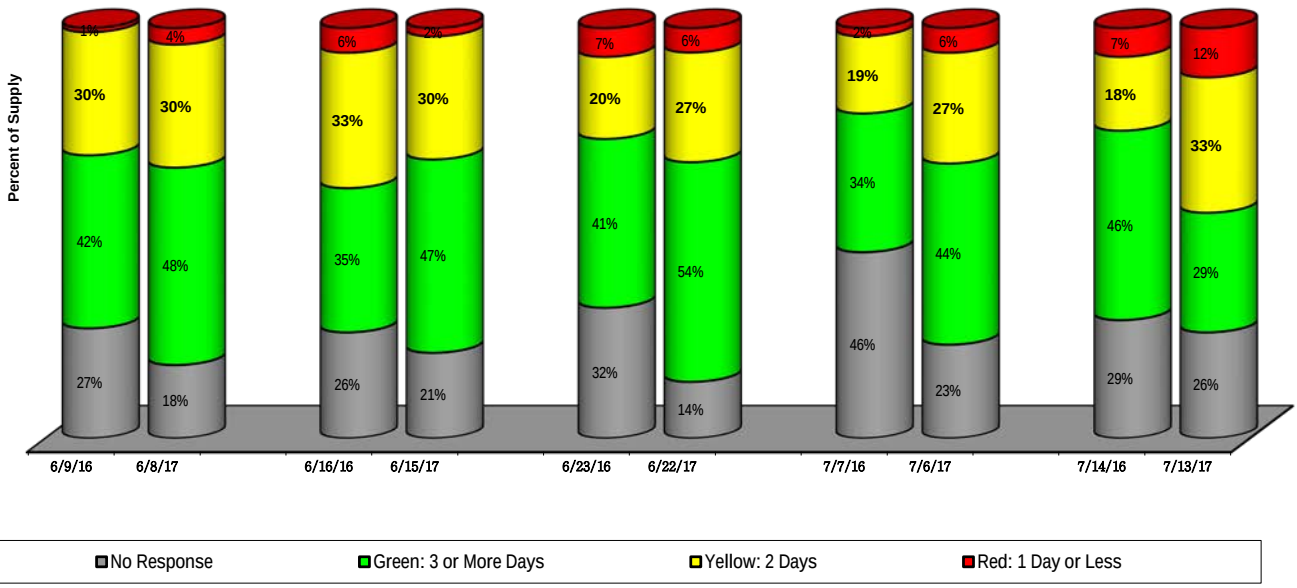
Other approvals to federal health offices include. Robert Kadlec, MD, Department of Health and Human Services (HHS) assistant secretary for preparedness and response and Lance Robertson as HHS assistant secretary for aging. (Source: MedPage Today, Senate Confirms Surgeon General, Other HHS Picks.

WORD IN WASHINGTON

Prior to adjourning for their August recess, the U.S. Senate passed legislation reauthorizing the FDA's user fee program. The House had passed identical legislation earlier this year and the bill is now awaiting the President's signature. H.R. 2430, the FDA Reauthorization Act of 2017, reauthorizes the FDA user fees programs which accounts for a substantial part of the FDA's overall budget, through Fiscal Year 2022. The fees collected from industry under the program help pay for reviews of new medical products and devices, some of them expedited. Last month, President Trump urged Congress to overhaul the agreements FDA had with industry partners and to entirely fund the agency with user fees. The idea was not well-supported by either party. (Source: Regulatory Affairs Professionals Society, Trump to Sign FDA User Fee Reauthorization Bill. August 3, 2017)

A few hours after the passage of the fee bill, another bill dubbed the "Right to Try Act," was passed in the Senate. If the bill passes the House of Representatives, it will allow terminally ill patients to try experimental therapies that passed phase one trials, but are still not approved by the Food and Drug Administration. Currently, 37 of the 50 states already have similar laws on their books. (Source: New York Times, Senate Passes F.D.A. Funding and 'Right to Try' Drug Bills. August 3, 2017)

STOPLIGHT®: Status of the ABC Blood Supply, 2016 vs. 2017



The order of the bars is (from top to bottom), red, yellow, green, and no response

MEMBER NEWS

Central California Blood Center collaborates with Cerus on pathogen-reduction (PR) cryoprecipitate (cryo). Cryoprecipitate is a blood product derived from blood plasma and contains coagulation factors VIII and XIII, fibrinogen, von Willebrand factor, and fibronectin to help control bleeding for patients with acquired fibrinogen deficiency. Current cryo products have a short shelf-life which leads to significant waste. CBCC will manufacture the PR cryo, not yet approved under the Food and Drug Administration for use in people, for Cerus to study. "We are very pleased to be working with the Cerus team in developing a next-generation cryoprecipitate product. We recognize the unmet need in the clinical community for a cryo product with an extended post-thaw shelf life, given the challenges faced by hospital blood banks today in regard to the high wastage rates associated with the short expiry of conventional cryo," said Christopher Staub, president and CEO of CCBC, in a statement. The new product, if approved, will become an extension of the already-approved INTERCEPT system for plasma. (Source: Cerus press release, July 27, 2017)

The South Texas Blood and Tissue Center (STBTC) celebrated a unique 100-gallon donor last week, Marco Perez. The 57-year-old postal worker was born prematurely and required a blood transfusion. In repayment for his gifts of life as a baby, he has spent the last 34 years of his life visiting STBTC every other week to donate platelets. The blood center celebrated with a cake and a plaque honoring Mr. Perez and his donations. (Source: *Miami Herald*, He got a blood transfusion as a baby. He donated 100 gallons of blood in return. August 4, 2017)

GLOBAL NEWS

Kite Pharma, Inc., announced their initiation of chimeric antigen receptor (CAR) T-cell therapy for non-Hodgkin lymphoma patients clinical program in the E.U. Kite's investigational CAR-T therapy, axicabtagene ciloleucel, was studied in the ZUMA-1 trial as a treatment for patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL) ineligible for autologous stem cell transplant. The therapy is currently under review by the U.S. Food and Drug Administration (FDA), and the FDA has set a Prescription Drug User Fee Act action date of November 29, 2017. In the E.U. the first patient was dosed in a safety expansion cohort of Zuma-1 and Kite is currently enrolling at multiple E.U. medical centers for the investigational candidate. (Source: Kite press release, August 7, 2017)

The Yemen national blood bank may be forced to shut down due to lack of funds. A medical charity organization that has been delivering funds and assistance to the blood bank recently decided to end its support, leaving the blood bank without enough funding to survive. The World Health Organization said they are trying to stabilize the situation and find more money for the blood bank. Patients of the blood bank have risen in the few years as civil war ravages the country and a cholera outbreak is underway. More than 3 million people have been displaced due to the conflict and over 10,000 people have died, with thousands more wounded. (Source: Reuters, Yemen blood bank may be forced to shut due to lack of funds. August 8, 2017)

COMPANY NEWS

American Red Cross is using Grifol's Procleix Babesia assay under an investigational new drug (IND) protocol. The ARC testing lab (soon to be Creative Testing Solutions lab) in Charlotte, N.C., will be screening blood samples from New Jersey, Pennsylvania, Maryland, Maine, Vermont, and New Hampshire—areas endemic for the tick that carries Babesia—with the Procleix Babesia assay under this IND. The IND is for in vitro nucleic acid testing of whole blood and the data collected will be used in the submission

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COMPANY NEWS (continued from page 16)

process seeking the Food and Drug Administration's approval. The assay will become part of the Procleix Panther system, which is designed to fully automate nucleic acid testing for blood donations. (Source: Grifols press release, August 1, 2017)

The Food and Drug Administration (FDA) approved the first treatment for chronic graft versus host disease (cGVHD). cGVHD is a condition some stem cell transplant recipients develop after receiving hematopoietic stem cells for blood or bone marrow cancers. The symptoms of the condition can be debilitating and/or fatal. The FDA expanded approval for Imbruvica, a kinase inhibitor, to include the treatment of cGVHD. Imbruvica was previously approved for certain indications in treating chronic lymphocytic leukemia, Waldenström's macroglobulinemia, and marginal zone lymphoma, as well as under accelerated approval status for mantle cell lymphoma. Forty-eight percent of the 42 patients with cGVHD in a single-arm study experienced improvement lasting up to five months or longer after using Imbruvica. After the study and the maker's application, the FDA granted a "priority review" and "breakthrough therapy" status to the product. (Source: FDA press release, August 2, 2017)

The Food and Drug Administration (FDA) approved the first treatment for certain types of poor-prognosis acute myeloid leukemia (AML). AML is a rapidly-developing blood cancer that starts in the bone marrow and quickly moves throughout the blood and body. The American Cancer Society estimates 21,380 new cases of AML will be diagnosed this year, and 10,590 deaths from AML will occur. Vyxeos was approved for the treatment of therapy-related AML (T-AML)—which occurs after a patient has been treated with chemotherapy or radiation; and for patients with AML with myelodysplasia-related changes (AML-MRC)—which occurs in patients with a history of certain blood disorders and other significant cancer cell mutations. Vyxeos was approved after a randomized trial of 309 patients showed a longer overall median survival rate using the drug over separate chemotherapy drugs (9.56 months vs. 5.95 months). This drug was also granted Priority Review and Breakthrough Therapy designations; as well as an Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases. (Source: FDA press release, August 3, 2017)

CALENDAR

2017

Sept. 11-12. **IPFA/BCA 3rd Global Symposium on The Future for Blood and Plasma Donations, Atlanta, Ga.** Registration is open.

Sept. 18-19. **Public Workshop- Advancing the Development of Pediatric Therapeutics (ADEPT): Application of "Big Data" to Pediatric Safety Studies, Silver Spring, Md**. For more information, click here.

Sept. 27-28. **Financial Management & IT Workshops, America's Blood Centers, Houston, Texas.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 27. **7th Annual Symposium Red Cell Genotyping 2017: Patient Safety, Bethesda, Md.** The Department of Transfusion Medicine, NIH Clinical Center, National Institutes of Health, and the Blood Center of Wisconsin are co-hosting this symposium on the NIH campus. For information, registration fee and advance registration contact Phyllis Kirchner.

Sept. 28. **36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** No registration fee. Advance registration is encouraged. Contact Karen Byrne or visit the website.

Oct. 7-10. **AABB Annual Conference, San Diego, Calif.** More information and registration here.

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CALENDAR (continued from page 17)

Oct. 19-20. **Austrian Red Cross Content Marketing Workshop, Vienna, Austria.** Email for more information.

Nov. 7-8. **Transfusion Safety Officer & Patient Blood Management Seminars (Basic & Advanced Programs), Jacksonville, FL.** If you are interested in taking part in one of these new and engaging programs, please contact: Cathy Shea, Executive Assistant or call (727) 568-1151.

Nov. 8-10. **10th World Federation of Hemophilia Global Forum, Montreal, Canada.** For more information and to register, click 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 Lisa Spinelli at the ABC office. Phone: (202) 654-2982; fax: (202) 393-1282; e-mail: lspinelli@americasblood.org.

POSITIONS

Positions also available on our website

Donor Testing Lead Technologist. Memorial Blood Center in St. Paul, Minn., is looking to add a Donor Testing Lead Technologist to their Donor Testing Department. This full-time role will supervise donor testing technical staff and coordinate all operations on either a second or third shift schedule. Benefits include: medical, dental, vision, PTO/EST, 401K and more! Candidates with four or more years of laboratory experience are encouraged to apply with the following link: https://home2.eease.adp.com/recruit/?id=19228782.

Medical Director. LifeShare Blood Centers is looking for a Medical Director (MD or DO) with appropriate specialty, such as hematology or pathology. Prior blood banking experience helpful with 15+ years of experience as a physician or medical practitioner, either in private practice or in association with a major hospital or medical teaching institution. Must have knowledge of regulations, laws, statutes and standards pertaining to blood donation, disease testing, and blood compatibility, transfusion of blood and blood components, and patient or donor reactions. The Medical Director is responsible for providing medical support and consultation to all LifeShare Blood Center locations as needed concerning donors, donor reactions, physician or hospital requests, apheresis services and related procedures. The Medical Director investigates all suspected TTD's and submits reports; reviews transfusion reaction reports and takes appropriate action; reviews all post-donation illness reports and makes decision concerning product disposition. The Medical Director reviews abnormal donor test results, including all HIV positive test results and makes notification to the donor. To apply, please go to http://www.lifeshare.org/careers.

Component Manufacturing Manager: MEDIC Regional Blood Center is looking for a Component Manufacturing Manager with demonstrated ability to lead others and prior supervisory experience. The Component Manufacturing Manager is responsible for supervision of employees and blood production within component manufacturing to ensure the well-being of our community by providing a safe, adequate and economical supply of blood products. The Manager will ensure inventory and production levels are maintained in coordination with Hospital Services and Distribution Manager. Responsible for staff schedules, daily work flow, inventory levels and supply/equipment maintenance. Excellent verbal and written communication and organizational skills. Basic computer experience, familiar with Microsoft office suite. Prefer health care and/ or blood banking experience MEDIC offers a competitive compensation and benefits package including medical/dental coverage, company-matched 401(k), and PTO (Paid Time Off). To apply, please go to http://medicblood.org and select the Jobs tab.

Vice President of Medical Affairs/Medical Director. Mississippi Blood Services (MBS) is seeking the right candidate to assume the role of Vice President of Medical Affairs/Medical Director. From this highly visible position, you'll provide medical guidance to the organization, and continuing education to hospital customer transfusion services encompassing immunohematology, therapeutic apheresis, cellular therapy, and other activities. In this position you'll have the ability to impact the health of MBS blood donors and

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POSITIONS (continued from page 18)

hospital patients. MBS is the only blood service headquartered in Mississippi and currently serves nearly 50 hospitals across Mississippi, Tennessee, Arkansas and Louisiana. The right candidate should be a board certified/board eligible physician with three to five years of experience, preferably in hematology, transfusion medicine, cellular therapy, clinical pathology or related fields; comfortable communicating in a manner that will motivate and persuade others, while being aware of their needs and concerns; strategic, big-picture thinking backed by an added focus on the tactical aspects of the work; cooperative and comfortable working as a member of a team, building appropriate relationships with donors, MBS associates, the Mississippi medical community, and medical directors across the country. To apply: Submit a letter of interest with a CV to Human Resources, attention K. Lee, 115 Tree Street, Flowood, MS 39232, email klee@msblood.com, or upload here.

Reference Laboratory Manager. Kentucky Blood Center, located in Lexington, Ky., is seeking a proactive professional responsible for the oversight and management of the reference laboratory (AABB IRL). Responsibilities will include the development of short- and long-term plans; budget preparation and monitoring; oversight of compliance with staff training, processes, and procedures; workload of reference laboratory including staff supervision, employee evaluation, and other standard management functions. Qualified applicants must have a four-year degree, MT(ASCP)SBB, with a minimum of three years management experience preferred. Proof of education/certifications required during the interview process. Must have a working knowledge of industry regulations including the Food and Drug Administration, AABB Standards for Immunohematology Reference Laboratories and AABB Standards for Blood Banks and Transfusion Services. Must be proficient with MS Office products; have proven data analysis skills; be highly organized, reliable, and have outstanding interpersonal skills. Strong written and oral communication skills, a do-what-it-takes work ethic, and a team player attitude are required. Competitive salary, comprehensive benefits including health, dental, vision, life, STD, LTD, paid time off/holidays, EAP, 403(b) retirement savings plan, and pension plan. For more information or to apply online, please visit www.kybloodcenter.org. Drug-free and EOE/AAP.

Clinical Laboratory Scientist, Technical Services Processing Lab. The Stanford Blood Center is seeking a Clinical Laboratory Scientist in the Technical Services Processing Lab to independently perform complex clinical testing, including both machine and manual assays, of bodily fluids for patient care purposes. Clinical test results are used directly to inform patient care decisions, with errors potentially leading to adverse events. This position is a full-time, benefitted, evening shift 6:00pm to 2:30am, Monday through Friday with rotating weekends and holidays. Qualifications include: a four year college degree in medical technology or a life science, and one year relevant experience in a blood center or clinical laboratory setting required. 12 month internship in medical technology or certification as technologist. Current California clinical laboratory technologist license (MTA/MTR) required. For more information and to apply, please go to: http://www.stanfordhealthcarecareers.com/search-jobs and search for job # 42443.

Clinical Laboratory Scientists, SBC Histocompatibility Lab. Stanford's Histocompatibility Lab seeks HLA technologists to perform histocompatibility testing for transplantation. You will perform high complexity HLA testing including determination of antibody specificity, crossmatching, and DNA-based typing, and produce clinical reports. Come work with Director Marcelo Fernández-Viña in beautiful Palo Alto! Join an outstanding team of technologists in an exciting and innovative environment. Prior experience in HLA is a plus, but we will train. Qualifications include: a BA/BS degree in medical technology or related life science. Must hold or qualify for California Clinical Laboratory Technologist or Clinical Histocompatibility Specialist license. OUT OF STATE: You qualify for a license if you are ABHI CHT or CHS certified, or you are a board certified medical technologist. More information about licensure can be found at https://www.cdph.ca.gov/programs/lfs/Pages/ClinicalLaboratoryPersonnel.aspx.We are increasing our staffing, and several shift options are available: days, evenings, and nights. All are regular, full-time positions with full benefits. Apply at http://www.stanfordhealthcarecareers.com/search-jobs and search for job # 41845, 41994, 41995, and 41996.