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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Issue #25
July 14, 2017

New York Blood Center and Rhode Island Blood Center Join Forces

Strategic alliance between two premier community blood centers will bring synergies in blood and laboratory services, medical programs, cell therapies and research.

New York Blood Center (NYBC) and Rhode Island Blood Center (RIBC) announced today that they are combining their operations to enhance one of the nation's leading blood centers, serving patients and hospitals in the Northeast, Midwest and nationally.

The combination of the strengths of RIBC and NYBC provides the opportunity for greater breadth of services, efficiency and financial stability. The goal is to continue to provide the highest level of blood and hematology related products and services in a fast-changing environment for community blood centers nationwide. The new partnership with RIBC comes on the heels of NYBC's highly successful 2014 alliance with Community Blood Center of Greater Kansas City (CBC) and more recently the merger with Innovative Blood Resources (IBR) in 2016.

The NYBC network of blood centers is responsible for providing over 800,000 units of blood annually, of which RIBC is currently responsible for approximately 75,000 units. RIBC will continue to be the primary supplier of blood and blood products to the hospitals in Rhode Island and throughout Southern New England.

Christopher D. Hillyer, MD, President and CEO of NYBC said, "We're extremely pleased to be partnering with such an excellent blood center. NYBC and RIBC 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 RIBC to the NYBC family."

"Our partnership with New York Blood Center, who we have worked with for decades, allows us to grow and expand our laboratory services with the potential to add new customers. We will initially add 15 new quality medical-technical jobs to our Providence location, while allowing us to expand into exciting new areas, such as translational and applied research that NYBC specializes in to help develop better treatments for all types of diseases," said Lawrence F. Smith, President and CEO of RIBC.

Rhode Island Blood Center

New York Blood Center

Under the affiliation, Dr. Hillyer will become president of RIBC and Mr. Smith will continue as chief executive officer. RIBC's customers, donors, and volunteers will continue to receive the excellent service they've come to expect from the organization. Moreover, hospital customers will have access to an even broader range of blood products and services as a result of the partnership. The long-term goal of both organizations will be to maximize the operational synergies between the two organizations to the benefit of all members of the community.

INSIDE:

OUR SPACE

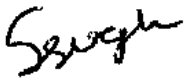
Sameer Ughade, ABC Director of Information Technology & Business Intelligence

Strengthen Your Cybersecurity Information-Sharing

Cybersecurity is again in the headlines as a result of the most recent global-spanning cyberattack named Petya and its multiple variants. This was not a typical ransomware attack, but disguised to hide its true purpose of data destruction—hence referred to as wiperware. The attack utilized sophisticated techniques to spread built-in system tools to gain credentials. After gaining users credentials, the wiperware targeted other network devices to spread and encrypt them, making them unusable. There was a unique delivery mechanism used for delivery which included infecting an accounting company's update servers to allow rapid propagation to its clients. There are multiple lessons learned here, including improving patch management, having a good backup and retention program, securing and locking down network devices, and controlling access privileges to built-in tools.

This, and the other recent cyber incidents, have highlighted the importance of increased engagement and need for cybersecurity threat information-sharing amongst various organization's and stakeholders in healthcare. The community engagement will not only help increase awareness, but also help prevent the spread and impact of such attacks in the future. Since cybersecurity is a shared responsibility between multiple organizations, the engagement needs to involve a multitude of stakeholders, ranging from both the public and private sector. Some of the stakeholder organizations include government entities like the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the Department of Homeland Security, as well as information security organizations, vendors (including medical device manufacturers), non-profit associations like ABC and AABB, and, most importantly, the healthcare delivery organizations and their information security practitioners. Government organizations, such as HHS and FDA, have already started engaging with our industry through various mediums, including workshops and guidance on medical device security, conference calls during threat events, as well as collaboration through the National Health Information Sharing & Analysis Center. It is time for blood centers to utilize these forums to demonstrate our engagement by actively participating and sharing our unique challenges and limitations. As mentioned previously, blood centers play a critical role in healthcare industry by maintaining the blood products supply chain in the country and it is time for us to embrace and engage in cybersecurity discussions as part of critical infrastructure.

Along with information sharing, there is also a need amongst the blood industry to share knowledge regarding cybersecurity best practices including tools, techniques, and programs that help maintain solid information security posture at the blood centers. Keeping this in mind the ABC planning committees have decided to make cybersecurity a critical topic of discussion at the joint ABC Finance & IT Workshop to be held in Houston, Texas, on September 27 to 28. Since cybersecurity is everyone's responsibility and knowledge is power, we welcome our fellow IT and security practitioners to share and attend the event.



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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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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.

Your Vote Counts! Vote In the ABC Members Meeting

The ABC Members Meeting during the 55th ABC Summer Meeting in Providence, R.I., will be a lively affair with a number of topics to discuss. Members will also be voting on two topics. The first is on the vacant ABC vice president of the Board of Directors position. The ABC Nominating Committee has recommended Rob Purvis, vice president of Customer Service at New York Blood Center (NYBC).

Mr. Purvis has served on ABC's board since 2014 and has worked at NYBC for the past 15 years. As VP of Customer Service, he oversees a wide range of activities at NYBC including sales and marketing, communications and public relations, development/fundraising, and volunteer leadership. He previously led two NYBC divisions: Hudson Valley Blood Services and then New York Blood Services in Manhattan. Prior to joining NYBC, Mr. Purvis spent 10 years at BloodCenter of Wisconsin (Versiti) as vice president of Blood Services. He serves on the board of directors of the Westchester Boys and Girls Club, the New Jersey Association of Blood Bank Professionals, and the National Blood Foundation.

The second vote will be to approve nominations for ABC Emeritus Membership. The ABC Membership Committee has reviewed the nominations and recommends a "yes" vote to approve Dan Connor and Don Doddridge for emeritus membership as established in the ABC bylaws.

Those member voting representatives not attending the ABC Summer Meeting should complete the proxy ballot form prior to August 3. ABC bylaws require two-thirds of ABC members to be present at the meeting, and three-fourths affirmative vote of those present to revise the bylaws. If you are unsure who the member voting representative is or your center needs to designate an alternate, please email Lori Beaston. Download the proxy ballot here.

Get Help With Your Swing: Sign Up For The Golf Clinic

Not an avid golfer, but would like to prepare for next year's Links for Life Golf Tournament while supporting a great cause? We have the perfect solution for you – come participate in this year's "Introduction to Golf" clinic at the ABC Summer Meeting on Thursday, August 3! This is a great opportunity to learn, network and have fun in a casual, mentoring environment.

During the clinic, a professional golf instructor will teach you the fundamentals, basic etiquette, and rules of the game. The package is priced at $95 per person and includes the clinic, lunch, goodie bag, and round trip transportation from the hotel. The clinic will take place at the scenic Warwick Country Club in conjunction with the 18-hole tournament. Buses will leave the hotel at 11:30 a.m. and return at approximately 3:30 p.m. All proceeds from the clinic will benefit the Foundation for America's Blood Centers (FABC). If you are interested, or have questions regarding the clinic or the full golf tournament, please contact Leslie Maundy.

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INSIDE ABC (continued from page 3)

Registration for the ABC Financial and IT Workshops Open

ABC and host member center Gulf Coast Regional Blood Center are pleased to announce registration for the 2017 ABC Financial and IT Workshops in Houston, Texas, September 27 and 28, is now open. Take advantage of early bird pricing before July 21! This year the workshop will be held at the trendy and luxurious Hotel Derek, located in Uptown Houston.

There will be concurrent sessions for the financial and IT attendees, as well as opportunities for the two tracks to come together, such as for the cybersecurity session on that Wednesday morning. Riveting presentations and break-out sessions include such topics as Costing Made Easy and Risky Business (risk-management) for financial attendees, and cybersecurity break-out sessions and interfacing with BECS for the IT attendees.

There are seven (7) $850 scholarships available for attendees as well. Funds received through this scholarship are to be used to cover the cost of the workshop registration and supplement any travel/lodging costs associated with attendance. The Financial & IT Workshop provides an exclusive opportunity for financial and IT professionals to come together for educational updates and networking events. Deadline for scholarship applications is July 26. For questions about the scholarship program, please email Leslie Maundy. To register, click here.

RESEARCH IN BRIEF

Emicizumab prophylaxis was associated with a significantly lower rate of bleeding events than the control group for hemophilia A participants with inhibitors in a new trial. Emicizumab is a recombinant, humanized, bispecific monoclonal antibody that bridges activated factor IX and factor X to restore factor VIII function. In an open-label, multi-center phase-three trial (HAVEN I), 109 males with hemophilia A with inhibitors (12 years or older), were randomized to three groups: group A consisted of 35 participants given emicizumab prophylaxis subcutaneously once-per-week for at least 24 weeks; group B consisted of 18 people given no prophylaxis; and group C was 49 patients who had previously received prophylactic treatment with bypassing agents and given emicizumab prophylaxis. A fourth group consisted of seven patients given emicizumab prophylaxis who were unable to enroll in the other groups before enrollment was closed. When comparing group A to B, there were 2.9 events per year (95 percent confidence interval [CI], 1.7 to 5.0) compared to 23.3 events (95 percent CI, 12.3 to 43.9).

Citation: Oldenburg J., Mahlangu J.N., Kim B., *et al*. Emicizumab Prophylaxis in Hemophilia A with Inhibitors. *New England Journal of Medicine*. July 10, 2017 online. DOI: 10.1056/NEJMoa1703068.

Detecting the next emerging pathogens. Scientists from the EcoHealth Alliance, a New York-based global environmental and public health non-profit organization, recently published an article in *Nature* modeling a study purporting to predict the spillover from mammals to humans of viral zoonotic diseases. Combining information gained through systematic literature reviews on all known mammalian viruses, mammal ecology, molecular taxonomy of mammals, and using geomatics—and a very sophisticated statistical analysis taking into account the research effort bias—the authors have built a roadmap allowing prioritization of surveillance efforts to detect the next emerging pathogens threatening human health. However, the authors recognize certain limitations of their work, particularly their estimate of missing viral diseases, the fact that their model explains only a portion of the total observed variation in viral richness per host, and that they cannot account for viruses or host associations that have completely eluded human detection to date. Akin to work in the area of theoretical physics, this predictive model requires validation by surveillance studies in the field in the identified areas and species to confirm its appropriateness.

Article contributed by Gilles Delage, MD, vice-president of Medical Affairs at Héma-Québec.

Citation: Olival K.J., Hosseini1 P.R., Zambrana-Torrelio C., *et al*. Host and Viral traits predict zoonotic splillover from mammals. *Nature*. June 29, 2017; DOI:10.1038/nature22975.

Quality of Life (QoL) scores and symptom scales show promise in assessing red blood cell (RBC) transfusion outcomes in oncology. Because anemia is associated with decreased QoL and poor performance status in cancer care, this study analyzed the value of four self-reported patient questionnaires for distinguishing clinically important endpoints in relation to hemoglobin levels and transfusions. Per accepted clinical practice during the 2010 to 2013 accrual period, 133 Danish adults undergoing chemotherapy for solid tumors were randomized into two liberal transfusion arms, with the lower threshold being 9.7 g/dL. Even with high trigger points for both arms, ratings recorded prior to and one week through the post-transfusion period, clinically significant improvements were demonstrated in fatigue, dyspnea, and aggregated indices of both general and physical well-being. Likewise for the entire cohort, higher hemoglobin levels correlated directly with better performance status, well-being, and fatigue scores. As the authors indicate, their tools and approach show that for red cell therapies “high-quality [random controlled trials] are needed and should assess not only outcomes like morbidity and mortality but also functional outcomes like QoL scores.”

This article was contributed by John Armitage, MD, CEO of Oklahoma Blood Institute.

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RESEARCH IN BRIEF (continued from page 5)

Citation: Yakymenko D., Frandsen K.B., Christensen I.J., *et al*. Randomised feasibility study of a more liberal haemoglobin trigger for red blood cell transfusion compared to standard practice in anaemic cancer patients treated with chemotherapy. *Transfusion Medicine*. June 29, 2017. DOI: 10.1111/tme.12439.

Over 90 percent of men who have sex with men (MSM) believed their blood was safe to donate, reads a new study in the journal *Transfusion.* However, only 8.9 percent of these respondents met the one--year deferral criteria set by the Food and Drug Administration in December 2016. Five percent of the total respondents were willing to be abstinent for a year in order to meet the criteria. In this 33-question survey taken by 848 MSM in all 50 U.S. states, the researchers recruited subjects via social media including Facebook, Twitter, LinkedIn, and Reddit. Respondents were encouraged to share the survey with others to accrue additional participants. Of those who met the criteria, 26.7 percent admitted to donating blood during the period of the lifetime FDA ban and 57.9 percent of the subjects, who would like to donate blood, stated that they would donate without meeting the one-year criteria. Those who believed their blood would not be safe to donate were older (43.2 vs. 34.1 years old) and more likely to be African American. Of concern is that 40 percent of the subjects believed that HIV can be detected in blood 100 percent of the time and 88 percent of those preferred no deferral for MSM. Shortcomings of the study, acknowledged by the authors, included recruitment on social media and advertising the study topic as MSM donating blood and using pre-exposure prophylaxis. Both of which may not be generalizable to all MSM. "This data supports the notion of developing more individualized risk screening of blood donors that would elicit more specific risk behaviors from MSM, such as number of partners and sex with unknown partners as just a few examples," said Debra Kessler, director of Special Services at New York Blood Center.

Citation: Liszewski W., Terndrup C., Jackson N.R., *et al*. The beliefs and willingness of men who have sex with men to comply with a one-year blood donation deferral policy: a cross-sectional study. *Transfusion*. July 5, 2017 online. DOI:10.1111/trf.14217.

RECENT REVIEWS

All chimeric antigen receptor (CAR) T-cells are not created equal. CD19 specific CAR T-cells can induce remission in B-cell acute lymphoblastic leukemia (ALL). There is a significant variation in the efficacy and toxicity reported in different early phase CAR-T trials. The authors in a recently published piece in the journal *Blood*, felt that this may be due to non-standardized product formulation. Their phase-one study was to explore if a well-defined specified CD4/CD8 ratio, uniform CAR expression and less committed T-cell phenotype would be more effective. Their intent to treat (ITT) phase-one study with primary goals of feasibility and toxicity assessment evaluated 45 children and young adults with relapsed or refractory B ALL. Forty of the enrolled 45 achieved remission with a rate of 89 percent (40/43 – 93 percent in patients who received CAR-T treatment). There were no deaths. Twenty-three percent of the patients developed serious but reversible cytokine release syndrome (CRS) and/or neurotoxicity. The authors feel that their definitions for toxicity were more stringent than some of previous studies. The CAR-T cell dose ranged from 0.5 – 10 x 10(6) per kilogram body weight. Patients who had >15 percent CD19 positive B-cells (tumor and non-tumor combined) at enrollment responded better. In this study, 45 percent of the patients that achieved remission in the beginning relapsed. The authors acknowledged that methods to make bispecific CAR-T cells and augmenting CAR-T persistence independent of B-cell burden will help manage therapeutic failures.

This article was contributed by Geeta Paranjape, MD, medical director of Clinical Services at Carter BloodCare.

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RECENT REVIEWS (continued from page 6)

Citation: Gardner, R.A., Finney, O., Annesley C., *et al*. Intent to treat leukemia remission by CD19 CAR-T cells of defined formulation and dose in children and young adults**.** *Blood*. June 22, 2017. DOI: https://doi.org/10.1182/blood-2017-02-769208.

Based on 33 years of pharmacovigilance data, authors concluded Haemate-P/ Humate -P (hereafter called Humate-P) is safe for the treatment of patients with hemophilia A or von Willebrand disease (VWD). Humate-P is the first pasteurized plasma-derived concentrate containing both factor VIII and von Willebrand factor to treat both hemophilia A and VWD patients. The manufacturing process includes a number of steps that greatly reduced the risk of virus transmission. There have been no confirmed reports of disease transmission with Humate-P to date. A search on adverse events using Embase and PubMed from January 1980 until November 2015 identified 33 thromboembolic complications in patients treated with Humate-P (one per 78,787 standard doses administered), 24 in VWD patients, and six in hemophilia A (three were unknown). Ninety-seven reports of inhibitor formation were identified in the Humate-P pharmacovigilance database: 69 cases of factor VIII inhibitors and 28 cases of VWF inhibitors (one per 26,804 standard doses). The study may be limited by underreporting, noted the authors.

Citation: Kouides P., Wawra-Hehenberger K., Sajan A., *et al*. Safety of a pasteurized plasma-derived Factor VIII and von Willebrand factor concentrate: analysis of 33 years of pharmacovigilance data. *Transfusion*. July 10, 2017. DOI: 10.1111/trf.14241.

BRIEFLY NOTED

The Food and Drug Administration (FDA) and the Bill & Melinda Gates Foundation (BMGF) released a memorandum of understanding (MOU) establishing a framework for collaboration. Their common goal is to improve public health by "stimulating and fostering medical product innovation and enabling medical product development." The non-binding agreement includes anticipated joint workshops, meetings, scientific collaborations and communications materials. (Source: FDA website)

A ruling in Pennsylvania could change the way patients give informed consent around the country. On June 20, an appeal in the Pennsylvania Supreme Court held that the duty to obtain patient informed consent for major medical procedures, including transfusions, lays solely with the physician. The case was brought to court after a patient experienced a stroke, brain injury and partial blindness after brain surgery who gave consent to a physician assistant. The patient said she did not receive full information on the risks of her surgery and if she had she would not have chosen to pursue that line of treatment. (Source: JDSupra.com, Pennsylvania Supreme Court Rules that Only Physicians – Not Their Staff – Can Obtain Informed Consent. June 30, 2017.)

The National Institutes of Health launched a study on the risks of Zika virus for pregnant women who are also HIV-positive. The study aims to determine if infection with one of these viruses might increase the risk for infection with the other virus. Other research points include whether Zika interferes with a mother's HIV prophylaxis medications to stop her baby from being infected and a heightened risk of fetal brain damage with co-infection. The study is enrolling in Puerto Rico and will recruit participants in the continental U.S. as well as Brazil and is expected to run from four to six years. (Source: NIH press release, NIH launches prospective study of Zika and HIV co-infection during pregnancy. July 10, 2017.)

AABB released its 8th edition of ***Standards for Cellular Therapy (CT) Services*****.** The Standard went into effect on July 1, 2017. All assessments performed after July 1 should follow the new edition, which contains significant changes from the previous editions. Some of those changes include

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BRIEFLY NOTED (continued from page 7)

ISBT 128 labeling and continuing education requirements. Members can purchase access to the 8th edition of CT Standards in the AABB Standards Portal. (Source: AABB Smartbrief, June 30, 2017)

The seventh edition of the American Society for Apheresis (ASFA) guidelines for apheresis therapy was published. The guidelines are published every three years with this edition providing 14 new diseases and two new indications. The guidelines removed five diseases and renamed two other diseases. Thirteen of the 16 added diseases are in category III, for which the optimal role of apheresis is not yet established. Below is the summary of three new diseases in category I and II, which apheresis is a first or second-line therapies:

N-methyl-D-aspertate receptor (NMDA-R) antibody encephalitis is one of the new category I diseases. The IgG antibodies reduce the receptor expression, leading to disinhibition of the central nervous system (CNS) excitatory pathway. In half of female patients, the disease is associated with underlying ovarian teratoma as the possible antibody stimulus. Disease activity appears to correlate with antibody levels. The guideline recommends every-other-day 1 to 1.5 total plasma volume (TPV) therapy using albumin or plasma for total of five to six procedures, although the recovery is expected to take much longer.

The only efficacious treatment for progressive multifocal leukoencephalopathy (PML) associated with natalizumab, another new category I disease, is immune reconstitution. Apheresis treatments may improve clinical outcome of PML by reducing the drug concentration, decreasing receptor saturation and restoring leukocyte transmigration into the CNS. The guideline recommends every-other-day 1 to 1.5 TPV procedures using albumin. A technical note includes often life-threatening warning about immune reconstitution syndrome.

Although the pathogenesis of Hashimoto's encephalopathy is not elucidated, it is likely to be of autoimmune etiology. Apheresis therapy is one of the second-line therapies if high dose corticosteroid fails or is contraindicated. In most cases the antibody titer is correlated with clinical improvement. Recommendation is 1 to 1.5 TPV therapy using albumin, every-other-day for three to nine procedures.

ASFA guidelines are increasingly valued by clinicians and pathologist alike. Please note that the guideline does not address the timing of procedures (e.g., emergency, urgent, and routine). The determination should be made with appropriate medical/clinical judgement by involved physicians.

This article was provided by Yasuko Erickson, MD, chief medical officer with Mississippi Valley Regional Blood Center.

Citation: Ipe T.S., Pham H.P., and Williams III L.A. Critical updates in the 7th edition of the American society for apheresis guidelines. *Journal of Clinical Apheresis*. June 27. 2017. DOI: DOI: 10.1002/jca.21562.

REGULATORY NEWS

The Center for Biologics Evaluation and Research (CBER) published their guidance agenda for calendar year 2017. The list of blood and blood products topics CBER is considering for the development of guidance include a third draft guidance on "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," which ABC commented on earlier this year and at which CBER is considering discussing during a future Blood Products Advisory Committee. Also under consideration for revision are draft guidances:

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REGULATORY NEWS (continued from page 8)

"Implementation of Pathogen-Reduction Measures to Reduce the Risks of Transfusion Transmissible Infections in Transfused Platelets and Plasma," and "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Product," both likely in 2018; an updated draft guidances on measures to reduce the possible risk of transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD); updates on "Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components"; "Requalification of Donors Previously Deferred for a History of Viral Hepatitis after their 11th Birthday"; and "An Acceptable Circular of Information for the Use of Human Blood and Blood Components." CBER also plans to update the May 2010 "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry."

There are also two tissues and advanced therapies guidances CBER is considering as well: "Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271"; and "Devices Used In The Recovery, Isolation, or Delivery of Regenerative Medicine Advanced Therapies." To read the full agenda, click here.

The International Council for Commonality in Blood Banking Automation (ICCBBA) announced updates to ISBT 128 Standard Technical Specification (ST-001)**.** This document is a comprehensive description of the rules for the use of ISBT 128 as well as guidance in the interpretation of these rules. A new version of the ISBT Technical Specification ST-001 document, version 5.8.0, is now available to licensed facilities and can be downloaded here.

The Food and Drug Administration (FDA) published their Biological Product and HCT/P Deviation Report Annual Summary for Fiscal Year 2016. The FDA requires certain deviations and unexpected events in biological product manufacturing to be reported to the Center for Biologics Evaluation and Research (CBER). During FY16, CBER's Office of Compliance and Biologics Quality/Division of Inspections and Surveillance entered 51,229 deviation reports into their database—a 10 percent increase in the number of reports from FY15. As is common knowledge, the FDA does not collect denominator data which prevents accurate interpretation of the data. The report notes that the bulk of the reports were from source plasma establishments (3,930 of 4,642 reports) which according to the FDA was primarily due to an increase in the number of source plasma centers (44 more than the previous year). There was no specific areas identifiable causing the increase in reports from plasma centers, just more centers reporting the same issues according to the FDA. When asked about specifics relating to bacterial detection quality control BPDs, the FDA reported they were using the code QC9404 to capture events associated with bacterial detection testing. Most of those involved a positive bacterial detection test obtained after the product was distributed, though the code also included some reports in which testing was either not performed or performed incorrectly. In FY17, the FDA has added specific codes for bacterial detection testing to capture these types of events separately. To read the full report, click here.

ABC SMT Journal Club Webinar
Date: July 25, 2017
Time: 12:00 to 1:00 p.m. EDT

The following articles and editorial will be presented and discussed:

- Obstetrics and gynecology physician knowledge of Rh immune globulin prophylaxis
- Encouraging single-unit transfusions: a superior patient blood management strategy?
- Single-unit transfusions and hemoglobin trigger: relative impact on red cell utilization
- Storage medium of platelet transfusions and the risk of transfusion-transmitted bacterial infections

To register, click here.

WORD IN WASHINGTON

The House of Representatives unanimously passed a bipartisan bill to reauthorize the Food and Drug Administration (FDA) user fee programs on Wednesday, July 12. The bill passed the Energy and Commerce Committee last month. The user fees, which make up a substantial amount of the FDA budget and used towards the review of new products, are collected from a variety of industries, including medical devices manufacturers and prescription drug makers. The user fees are negotiated every five years and must be approved by Congress. The Senate is expected to pass similar legislation prior to the current fee arrangement expiring at the end of September. If Congress fails to act, the FDA will be forced to begin sending lay-off notices at the end of this month.

The House Appropriations Committee also unanimously passed an agriculture spending bill for fiscal year 2018, which included $2.8 billion for FDA discretionary spending—the same amount as FY2017. Including industry user fees, the total FY18 FDA spending would exceed $5 billion, a nearly $500,000 increase from its FY2017 appropriation. Meanwhile the Subcommittee on Labor, Health and Human Services, Education and Related Agencies (part of the House Appropriations Committee) passed (nine to six) a 2018 funding bill that would give the National Institutes of Health (NIH) an added $1.1 billion for FY18, but would cut $5 billion from the overall Department of Health and Human Services budget, some of which includes a cut of $198 million from the Centers for Disease Control and Prevention (CDC) and a $219 million cut to the Centers for Medicare and Medicaid. These cuts are far more modest than those proposed in the President's budget. Within NIH, the National Heart, Lung and Blood Institute would receive $3.3 billion. Earlier this year, ABC requested this funding level as part of a coalition letter to House and Senate appropriators. This bill now goes up for a vote by the full House Appropriations Committee.

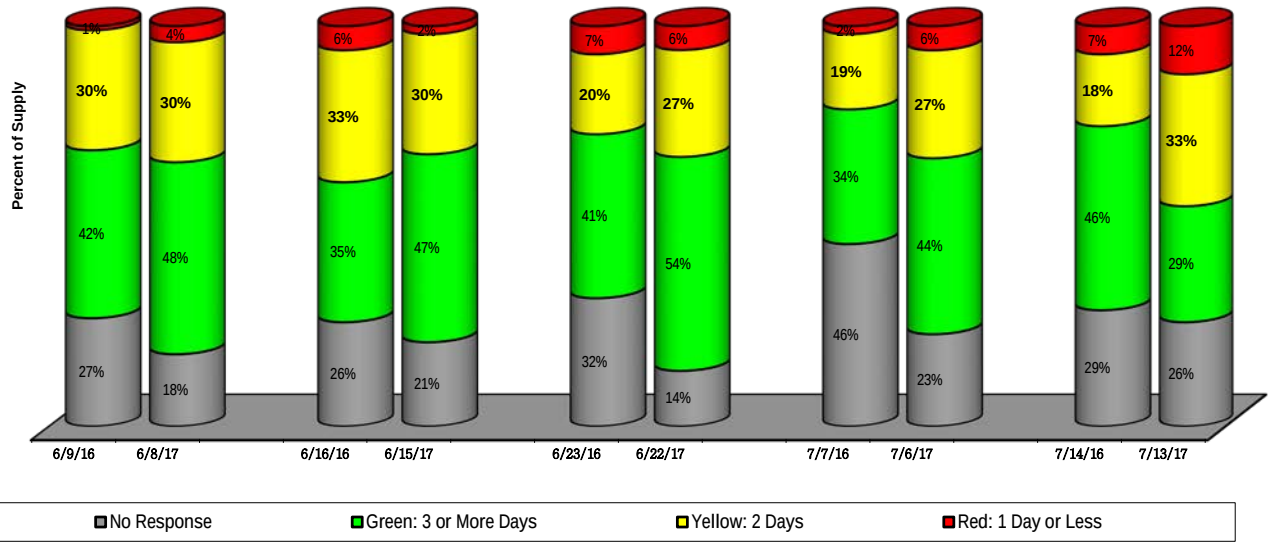
The NIH "is one our priorities," Rep. Tom Cole (R-Okla.), chairman of the labor-health panel, told Bloomberg BNA. "We want to keep supporting the work they do." (Sources: Regulatory Affairs Professional Society site, House Passes Bill to Reauthorize FDA User Fee Programs, July 12, 2017; *Reuters*, FDA fees for product review would more than double under Trump budget. March 16, 2017)

Senate Republicans released a new health care bill on Thursday aimed at repealing and replacing the Affordable Care Act (aka Obamacare). The latest bill included a total of approximately $70 billion for states to use to help lower premiums in addition to the $112 billion already included in the first version of the bill; reduce out-of-pocket costs; and make health care generally more affordable, while keeping taxes on those making over $200,000 to help fund the program. Medicaid would still be converted into a fixed payment plan to the states—per capita caps. Other changes would include a fund from which payments to insurers would be made to cover high-risk patients enrolled in their plans to help lower the cost for those low-risk patients. People who enroll in catastrophic health insurance plans would be eligible for federal tax credits to help pay premiums. Those with health care flexible spending accounts (HSA) could also use their HSAs towards covering health insurance costs in this bill. (Source: New York Times, Senate G.O.P. Leaders Unveil Health Care Bill to Try Winning Over Skeptics. July 13, 2017; Business Insider, Republicans just released a new healthcare bill — here are all the changes. July 13, 2017)

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 ABC Publications Editor Lisa Spinelli 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.

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

PEOPLE

Gregg Boothe retires after more than 20 years at Hoxworth Blood Center. Mr. Boothe most recently served as the associate director/chief operating officer at Hoxworth and held that title since March 2012. He has over 32 years of blood banking experience, beginning as an undergraduate student at the University of Cincinnati College of Allied Health and then graduate student at the College of Medicine. Following his college graduation, he began his career at St. Elizabeth's Medical Center in Dayton, Ohio. He then continued on at the University of North Carolina Hospitals, Chapel Hill, N.C., and the last 24 years have been dedicated to Hoxworth Blood Center, University of Cincinnati.

Mr. Boothe holds certifications as a specialist in blood banking and as a Six Sigma Black Belt. He has served as an assessor for AABB, and a member of the Hoxworth Blood Center Medical/Technical Advisory Committee and the Community Advisory Board. He is also a member of the Cincinnati Rotary Club #17.

"We wish Gregg all the best in his retirement and we thank him for the leadership and dedication that he brought to the industry for just over three decades," states Dr. Ronald Sacher, MD, director Hoxworth Blood Center.

Taking over for Mr. Boothe, as of July 3, is Christopher M. Nare. Mr. Nare most recently serviced as the vice president of Laboratory Sales and Service at Blood Bank of Delmarva (BBD) in Newark, Del. "Chris' tenure at BBD has demonstrated strong leadership, operational knowledge and skill. I have great confidence that he will be an asset to our organization," said Dr. Sacher. Mr. Nare is a native of Kentucky and holds a bachelor's degree from Northern Kentucky University and a master's degree in Human Relations and Business from Amberton University. He also holds certification as a Six Sigma Green Belt and American Medical Technologist.

Dr. Tedros Adhanom Ghebreyesus started his five-year term as the new director-general of the World Health Organization (WHO) on July 1, 2017. Dr. Ghebreyesus was elected to the seat by the WHO member states on May 23, 2017 during the World Health Assembly. Serving as Minister of Foreign Affairs in Ethiopia from 2012 to 2016, Dr. Ghebreyesus also served as Minister of Health for his home country from 2005 to 2012. He has also served as chair of the Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria; as chair of the Roll Back Malaria (RBM) Partnership Board; and as co-chair of the Board of the Partnership for Maternal, Newborn and Child Health. (Source: WHO site, July 1, 2017)

Department of Health and Human Services Secretary Tom Price, MD, named Brenda Fitzgerald, MD, as the new director of the Centers for Disease Control and Prevention (CDC). If approved, she will also serve as the Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR). Dr. Fitzgerald, a board-certified obstetrician-gynecologist, was formerly the commissioner of the Georgia Department of Public Health (DPH) and state health officer since 2011. She has held numerous leadership positions in the Georgia OB-GYN society, and other organizations and worked as a health policy advisor to House Speaker Newt Gingrich and Sen. Paul Coverdell (R-Ga.). Dr. Fitzgerald replaces Rear Admiral Anne Schuchat, MD, who was acting CDC director and ATSDR administrator since the change in the White House administration. (Source: FDA press release, July 7, 2017)

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PEOPLE (continued from page 12)

Serge Maltais, President and CEO of Héma-Québec, has resigned after finalizing the blood center's 2017 to 2020 strategic plan. Héma-Québec Board of Directors has commenced the necessary steps to recruit another CEO. In the interim, Vice-President of Corporate Affairs Smaranda Ghibu, BCL, LLB, will be acting as president and vice-president of Finance and Administration and Luc Vermeersch, CPA, CA, will be acting as CEO. We wish Mr. Maltais the best! (Source: Héma-Québec email)

Steve Ferraiuolo (left) and Tom Choi (right) were appointed as division presidents for the West and Southwest Divisions of Blood Systems, Inc., respectively. The appointments became effective on July 11. Mr. Ferraiuolo began his blood banking career with BloodSource more than 20 years ago. He held leadership roles in operations and logistics and, most recently, served as the senior director of Hospital Services and Laboratories in the West Division following BloodSource's 2015 merger into Blood Systems. Mr. Ferraiuolo is president of the California Blood Bank Society and a past president of Blood Centers of California. He replaces Rob Van Tuyle in the role as Mr. Van Tuyle was recently named president of Blood Systems Blood Services.

Mr. Choi has been with Blood Systems nearly 30 years, and served as executive director of the United Blood Services center in Reno, Nevada, for 13 years. Since 2014, he has been the vice president of Hospital Services and Inventory/Order Management. He is a past president of the South Central Association of Blood Banks. Mr. Choi replaces Dirk Johnson, who was recently named executive vice president for Blood Services Operations.

"Steve and Tom share a strong customer experience and focus. They will continue the tremendous work already accomplished by our strong West and Southwest teams," Mr. Van Tuyle said.

MEMBER NEWS

BloodCenter of Wisconsin (Versiti) launched a new assay to more accurately measure von Willebrand (VWF) factor activity. The test, VWF GPIbM Activity, employs patented technology that detects qualitative VWF defects, reducing variability, and providing more precise and sensitive test results. The technology was not previously used in a U.S. clinical laboratory setting, noted the BCW press release. "As a physician caring for individuals with inherited bleeding disorders, this development is an exciting advancement in von Willebrand disease diagnostics," said Johnathan Roberts, MD, Associate medical director of Bleeding & Clotting Disorders Institute, Peoria, Ill. "This assay will reduce some of the diagnostic challenges in caring for individuals with von Willebrand disease."

San Diego Blood Bank (SDBB) hosted their first annual Padres Summer Blood Drive. The blood drive was held on June 27 at Petco Park in partnership with the Major League Baseball team San Diego Padres. The drive collected more than 300 pints of blood and featured appearances by Padres players, alumni, and hosted kid activities as well as a special ribbon cutting ceremony celebrating the newest SDBB bloodmobile. Donors received a pair of tickets to a future Padres game, VIP access to the autograph booth and a meal voucher for the day. The partnership with the Padres came as the San Diego Chargers, moved their team up to Los Angeles. The Padres blood drive was not created as a replacement for the Chargers blood drive, which occurs in the fall, but to help supplement during the summertime shortage. (Source: *San Diego Union Tribune*, Padres score with first 'Summer Blood Drive'. June 27, 2017).

COMPANY NEWS

New York-based cord blood banking company Americord is kicking off a social media campaign called #BankonBaby. The social media campaign is to celebrate National Cord Blood Awareness Month (July) and raise awareness about umbilical cord blood and tissue benefits. The company is seeking cord blood ambassadors, who will earn points for each time they share a post across the various social media channels. The two ambassadors earning the most points will each win a $500.00 Amazon gift card. To find out more information, click here. (Source: Americord press release, June 30, 2017.)

GLOBAL NEWS

A new startup in Israel was selected as a "Cool Vendor" for artificial intelligence (AI) in health care by Gartner Inc., a U.S.-based technology research and analyst company. The startup, Medial EarlySign, analyzes blood tests with AI and develops algorithms that help identify and predict patients with a higher likelihood of risk for certain cancers like colon cancer, metabolic, and other diseases. (Source: Medial EarlySign press release, June 13, 2017.)

CALENDAR

2017

July 13: **Meeting Global Blood Needs with Rotary's Help, Chicago Marriott O'Hare.** Blood center executives and interested parties discuss current projects and engage attendees on ways to have a meaningful impact with blood collection abroad through Rotary International and associated organizations. Contact Chris Bollmann for details.

July 26. **Transfusion Safety Officer & Patient Blood Management Seminars (Advanced Program), Ft. Lauderdale, Fla.** 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.

July 31-Aug. 1. **The Center for Medicare and Medicaid Services (CMS) Advisory Panel on Clinical Diagnostic Laboratory Tests annual public meeting, Baltimore, Md.** For more information and registration click here.

Aug. 1-4. **Summer Meeting, MD Workshop & Golf Tournament, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; Register here or e-mail: meetings@americasblood.org.

Aug. 4. **Board Meeting, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

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.** Register here. Contact: ABC Meetings Dept. for questions. 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 BloodCenter 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.

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CALENDAR (continued from page 14)

Sept. 28. **36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md**. Advance registration is encouraged. Contact Karen Byrne or click here.

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

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

Immunohematology Reference Laboratory (IRL). The San Diego Blood Bank (SDBB) is looking for an evening shift IRL. The IRL performs essential job duties while providing guidance and expertise for the laboratory to meet the needs of SDBB customers, in accordance with accepted standards and regulations. Essential duties include: participates in the Reference Lab on call rotation; performs red cell blood grouping and antibody identification on donor and referred patient blood samples; determines suitability for transfusion of donor units with discrepant ABO or Rh groups and unexpected red cell antibodies; performs molecular procedures and platelet compatibility work; provides verbal and written reports, technical assistance and consultation to customers; assist in maintaining rare donor files; investigate and review non-conformances through quality incident reporting; perform supervisory reviews and tasks as needed; perform validations and new process development; perform controlled document writing and revisions; assists with staff training and competency when applicable. The applicant must have an MT (ASCP) or equivalent experience; a California Clinical Laboratory Scientist License (CLS) or Calif. Clinical Immunohematologist Scientist License (CIS); specialist in Blood Banking (SBB) or equivalent education/experience. The evening shift is from 2:30 p.m. to 11:00 p.m. (hours may vary). EOE/Minority/Female/Disability/Vets. To apply, click here.

Assistant Manager Donor Testing Laboratory. Memorial Blood Centers in St. Paul, Minnesota, is looking for a full-time Assistant Manager of our Donor Testing Laboratory (Laboratory Supervisor). This day shift, Monday through Friday, 9:00 p.m. to 5:30 a.m. role manages the staff at the testing laboratory during the third shift. Benefits include medical, dental, vision, PTO/EST, 401K and more. This is a great next step for a lead technologist who is ready to take on more leadership duties. To apply, follow the link: https://home2.eease.adp.com/recruit/?id=19192882.

Quality & Regulatory Affairs Specialist. The Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the general supervision of the Director of Quality and Regulatory Affairs, this position will perform the quality and regulatory affairs duties and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, validations, and assist with development, as necessary. Develop, perform and report departmental, system audits, and safety inspections. Perform Good Manufacturing Practice (GMP) and safety training, trend analysis of events and quality indicators, root cause analysis, process improvement, corrective and preventive actions; maintain compliance by enforcing applicable regulations and standards set by regulatory

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POSITIONS (continued from page 15)

agencies and submit appropriate reports, when required. Candidate must have a four-year college degree and a combination of three or more years of experience in blood banking\laboratory or manufacturing with solid familiarity of GMP, safety in a manufacturing setup, and CAL-OSHA regulations. Must have exceptional attention to detail, able to exercise flexibility, and prioritize tasks; strong collaboration and effective communication skills both verbally and in writing, able to problem solve, analyze and evaluate complex situations; work independently and initiate improvement ideas to enhance QRA program; proficient in Microsoft Office applications especially Word and Excel; be able to prepare and perform training of staff. MT or Specialist in Blood Banking (SBB) certification, CQA certification, Registered Nurse, knowledge of quality improvement concepts and quality management tools, are all highly desired. For more information about us, visit our website at http://bloodcenter.stanford.edu/. Apply online at http://www.stanfordhealthcarecareers.com, ref. job# 42175.

Clinical Laboratory Scientists (technologists). Stanford Blood Center Histocompatibility Lab has several openings for Clinical Laboratory Scientists (technologists) to perform highly complex human histocompatibility testing for organ transplantation, including molecular typing, HLA antibody identification, and crossmatch testing including both machine and manual assays. Test specimens, analyze, interpret, and report results. Clinical test results are used directly to inform patient care decisions, with errors potentially leading to adverse events. Experience in HLA is a plus, but we will train. The candidate must have a bachelor's degree in medical technology or a life science, and a 12-month internship in medical technology or 12 months of work in an approved histocompatibility laboratory. The applicant must also hold or qualify for California license: Clinical Histocompatibility Scientist (MTR) license (qualify if you are certified by ABHI as CHS or CHT), or Clinical Laboratory Scientist (MTA) license (qualify if you are certified by ASCP or AAB as medical technologist). If currently out-of-state, California license must be obtained within six months of start date. For more information on Stanford Blood Center, click here. Please apply online at: https://www.stanfordhealthcare.org, reference job codes 41863, 41845, 41994, and 41995. Note: Specific work schedules are indicated on the individual job postings.