

ABC Submits Statement at

#### EWSLE R URRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2018 #10

#### March 16, 2018

### ABC Comments to CMS Regarding Potential Revisions to CLIA Regulations

America's Blood Centers (ABC) has responded to the Centers for Medicare and Medicaid Services (CMS) request for information (RFI) to assist in revising the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The ABC Quality Blood Regulatory Review Committee reviewed the RFI and used feedback provided by ABC member blood centers via a survey of the entire membership to assist ABC staff in formulating a response that represented the views of the membership.

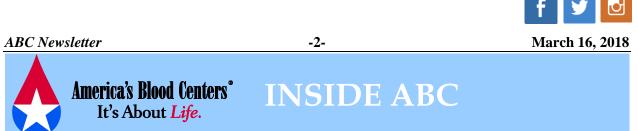
On the possible amendment of educational requirements to recognize the bachelor of science degree in nursing as equivalent to a biological science degree, ABC stated "[g]iven the information provided above, we do not agree with CMS's proposal that a [bachelor of science in nursing] should serve as a qualifying degree, nor is it equivalent to a biological sciences degree, for the purposes of meeting the educational requirements for high complexity testing personnel or technical consultants. With sufficient training and adequate oversight, a BSN should provide an adequate educational foundation for the performance of moderate complexity testing." ABC added that the organization "does not believe that a physical science degree, not related to or combined with a biological science, should be considered appropriate for qualifying to meet the CLIA educational requirements for laboratory personnel. It would be more appropriate to specify minimum curriculum requirements as is done by [the American Society for Clinical Pathology]."

CMS also sought comments on proficiency testing (PT) referral and applying discretion in cases when a lab refers PT samples to another lab and reports the other lab's findings as its own. ABC pointed out that "PT referral can inadvertently occur such as when there are multiple laboratories within an organization with different CLIA certificates or when organizations are undergoing merger/consolidation. If there is no malicious intent to defraud the system, the agency should have the flexibility to allow it without the need for extensive appeals. ABC fully endorses the maximum flexibility with regard to any testing activity that could inadvertently result in fines or the suspension or termination of certification."

ABC acknowledged and supported CMS in recognizing advancements in histocompatibility and endorsed integrating virtual crossmatches into regulations but urged the agency to continue to "engage subject matter experts and industry representatives in developing regulatory criteria." The comments added that regulations must be careful not to stifle innovation or the adoption of new technologies.

(Source: ABC <u>Comments</u> to CMS, 3/12/18)

### INSIDE:



*The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.* 

### **ABC Submits Statement at House Hearing on Disaster Preparedness & Response**

America's Blood Centers (ABC) highlighted the role of ABC member blood centers in emergency planning and response in a statement to the House Homeland Security Committee. Specifically, ABC called on the committee to "recognize the vital role of community blood centers in collecting and distributing blood products, and [to] consider [community blood centers] as essential partners in emergency preparedness planning." The statement came in response to the Committee's hearing on "Preparedness, Response, and Rebuilding: Lessons from the 2017 Disasters." The hearing focused on hurricanes Harvey, Irma, and Maria and discussed lessons learned in hopes of better preparation for future disasters. ABC noted that through "extensive planning and collaboration, the blood community responded swiftly and effectively to Hurricanes Harvey, Irma, and Maria. Additional action is needed however to prioritize and coordinate the need for blood products in federal, state, and local emergency planning efforts." Specifically, ABC suggested to the committee that community blood centers should be fully integrated into emergency management planning efforts to ensure a safe and robust blood supply is appropriately prioritized during disasters.

(Source: ABC Statement, 3/14/18)

### ABC Launches 2017 Employee Turnover and Retention Survey

ABC's Human Resources Committee recently launched the annual Employee Turnover and Retention Survey for calendar year 2017. ABC hopes to achieve a 100 percent response rate this year. Member blood centers are encouraged to participate in this survey to ensure that this will be a valuable tool for the entire ABC membership. Survey results will be reported in aggregate and made available on ABC's member website (the 2016 report is available <u>here</u>). ABC members can find more information and survey details in <u>MCN 18-013</u>. Questions regarding the survey may be directed to <u>Judy Hunter</u>.

(Source: <u>MCN 18-013</u>)

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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. America's Blood Centers

Executive Director: Kate Fry Chief Medical Officer: Louis Katz Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$390

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#### **INSIDE ABC** (continued from page 2)

# Human Resources and Training/Development Workshop Registration

ABC invites all human resources and training and development professionals to <u>register</u> for the 2018 ABC Human Resources and Training/Development Workshop in Dallas, Texas May  $8^{th} - 10^{th}$  at the <u>Fairmont Dallas</u>. Attendees will have the opportunity to discuss industry challenges and trends with their peers and partake in joint sessions that will explore the current state of the blood industry, critical thinking skills, and disaster training/preparedness. View the workshop schedule <u>here</u>. Time will also be devoted for separate sessions focusing on hot topics specific to each discipline such as Human Resources as a Business Partner, Intermittent FMLA/ADA/LOA, Training Video Production, and Mobile Learning/Micro-Learning. HRCI and P.A.C.E. credits will be offered. Please contact Leslie Maundy for additional details and sponsorship opportunities. Registration rates are below:

- 3-day HR/TD Workshop (Tue-Thu) \$540
- 2-day Training & Development (Tue-Wed) \$465
- 2-day Human Resources (Wed-Thu) \$465

### (Source: <u>MCN 18-011</u>) •





# **REGULATORY NEWS**

**ABC** Newsletter

The Director of the Center for Biologics Evaluation and Research and Commissioner of the Food and Drug Administration discuss regenerative medicine and the agency. Peter Marks, MD, PhD and Scott Gottlieb, MD review the promise of cell-based approaches in replacement, engineering, and regeneration of cells, tissues, and organs for the establishment, restoration, and enhancement of normal function. They highlight their expanding use, the proliferation of early investigations, and the risks for adverse events associated with their use. Drs. Marks and Gottlieb emphasize that even without serious adverse events, "therapies that are of unproven efficacy is [sic] a disservice to patients and the public health." Their critical focus is "on efforts to facilitate the development of such therapies, rather than propagating products with dubious clinical efficacy and possible risks." The article outlines in some detail, with appropriate graphics, the agency's new policy framework for regulation of these products, including relevant sections on the expedited pathway included in the 21<sup>st</sup> Century Cures Act.

**Citation:** Marks, P., and Gottlieb, S. Special Article: Balancing Safety and Innovation for Cell-Based Regenerative Medicine. *N. Engl. J. Med.* 2018. doi: 10.1056/NEJMsr1715626.

### **RESEARCH IN BRIEF**

How can you best encourage plasma donation from women with anti-RhD? Dutch authors have published an exploration of the factors involved in facilitating the enrollment and maintenance of women alloimmunized to RhD in programs to provide plasma for further manufacture of anti-D, used for immunoprophylaxis of hemolytic disease of the fetus and newborn. The most important barrier identified was lack of knowledge. Facilitators of donorship included lack of children in the home, altruism, and having registered as an organ donor. Active, targeted strategies to identify and enroll appropriate donors is encouraged.

# **SAVE THE DATE**

ABC SMT Journal Club Webinar

March 29<sup>th</sup> at 2 PM EDT

Additional information available to ABC members in <u>MCN 18-012</u>.

**Citation:** Slootweg, Y.M., Koelewijn, J.M., de Kort, W.L. *et al.* Facilitators and barriers for RhD-immunized women to become and remain anti-D donors. *Transfusion*. 2018. <u>doi:10.1111/trf.14490</u>.

What is the status of the association of dura mater implantation with Creutzfeldt-Jakob disease (CJD)? The dura mater grafts that were associated with transmission of CJD, and that resulted in blood donor screening in the U.S. for a history of exposure, were far more commonly used in Japan. Investigators from Japan have published an update on their experience during the interval from 1975–2017. There were 132 cases from 1975–2008, and an additional 22 since that time. More than 60 percent of cases globally have been recognized in Japan (four cases have been identified in the U.S.). The longest incubation period after the dura exposure is at least 30 years, and risk persists even after that long interval.

**Citation:** Ae, R., Hamaguchi, T., Nakamura, Y., *et al.* Update: Dura Mater Graft–Associated Creutzfeldt-Jakob Disease — Japan, 1975–2017. *Morbidity and Mortality Weekly Report*. 2018.

**Guidelines from the United Kingdom (UK) for using plasma and cryoprecipitate.** Using defined and rigorous methods, the British Society of Haematology has provided an extensively referenced description of available products and examined both historic and current use patterns. A review of the literature around



how best to thaw frozen products is provided. Storage and compatibility issues are discussed, and use recommendations provided. The authors emphasize that standard coagulation tests (e.g. the prothrombin time and/or international normalized ratio) have not been shown to predict bleeding risks in patients. Dosing recommendations are provided with appropriate caveats. The safety and adverse effects of preparations available in the UK are enumerated.

**Citation:** Green, L., Bolton-Maggs, P., Beattie, C., *et.al.* British Society of Haematology Guidelines on the spectrum of fresh frozen plasma and cryoprecipitate products: their handling and use in various patient groups in the absence of major bleeding. *Brit. J. Haematology.* 2018. <u>doi: 10.1111/bjh.15167</u>.

**Central nervous system (CNS) morbidity from Zika infection during pregnancy quantified in the French Caribbean.** In a prospective study following 546 pregnant women with Zika infection confirmed by the presence of viral nucleic acid using reverse-transcription polymerase chain reaction on blood and/or urine, the rate of adverse fetal outcomes has been assessed. There were 555 fetuses and 11 miscarriages. Thirty-two cases of microcephaly (head circumference more than 2 standard deviations below the mean for gender and gestational age) were identified or 5.8 percent, while 5.0 percent had other or additional CNS abnormalities. The combined rate of CNS and ocular defects "possibly associated with" Zika infection was 7 percent. Rates during the first, second, and third trimesters were 12.7 percent, 3.6 percent, and 5.3 percent respectively. An editorial notes that these rates are similar to those seen in the U.S. but much lower than rates reported from Brazil (>40 percent). Explanations for these differences are not clear. Further, the full spectrum of CNS injury will not become clear until the surviving infants age and can be assessed over time.

Citations: Hoen, B., Schaub, B., Funk, A., *et al.* Pregnancy outcomes after ZIKV infection in French territories in the Americas. *N. Engl. J. Med.* 2018. <u>doi: 10.1056/NEJMoa1709481</u>.

Honein, M.A. Recognizing the global impact of zika virus infection during pregnancy. *N. Engl. J. Med.* 2018. doi: 10.1056/NEJMe1801398. ♦





### **RECENT REVIEWS**

**Benefits and harms of 4-factor prothrombin complex concentrates (PCCs).** 4-factor PCCs (e.g. Kcentra® in the U.S.) have replaced plasma for the urgent and emergent reversal of vitamin K antagonist anticoagulants (e.g. coumadin), largely based on evidence that mortality and reversal of coagulopathy are similar between the treatments, but that the former acts more rapidly, with a lower volume of infusion. This paper includes a wealth of information about these products in a single resource. Costs and cost-benefit are not addressed.

**Citation:** Brekelmans, M.P.A., van Ginkel, K., Daams, J.G., *et al.* Benefits and harms of 4-factor prothrombin complex concentrate for reversal of vitamin K antagonist associated bleeding: a systematic review and meta-analysis. *Journal of Thrombosis and Thrombolysis.* 2017. <u>doi: 10.1007/s11239-017-1506-0</u>.

**Transfusion-transmitted hepatitis E virus (TT-HEV).** German authors have provided a well-documented review of TT-HEV with an emphasis on estimating the infectious dose of the virus, and its distribution in various components. The latter is seen to be proportional to the plasma content of the blood product. A comparison of HEV nucleic acid tests (NATs) is provided, including assays from Roche and Grifols, whose platforms for other analytes are in wide use in U.S. donor screening laboratories.

**Citation:** Dreier, J., Knabbe, C., and Vollmer, T. Transfusion-transmitted Hepatitis E: NAT screening of blood donations and infectious dose. *Frontiers in Medicine*. 2018. <u>doi: 10.3389/fmed.2018.00005</u>.



# **BRIEFLY NOTED**

The cost of information technology (IT) for healthcare organizations continues to rise, though only 15 percent of IT budgets are allocated to data security according to results from the "2018 Impact of



### BRIEFLY NOTED (continued from page 6)

**Cyber Insecurity on Healthcare Organizations**" <u>study</u>. The results of the study released this week by the Ponemon Institute, a public policy think tank devoted to data protection and information security, in partnership with Merlin International discovered that "each cyberattack costs nearly \$4 million to recover from, while each healthcare organization spent an average of \$30 million on IT in 2017," according to <u>Modern Healthcare</u>. Cybersecurity vulnerabilities will continue to threaten patient records and data, "[h]ealthcare organizations must get even more serious about cybersecurity to protect themselves and their patients from losing access to or control of the proprietary and personal information and systems the industry depends on to provide essential care," said Brian Wells, chief technology officer for Merlin International in a news <u>release</u>. *Modern Healthcare* also reported that more than 50 percent of those surveyed identified a lack of budgetary resources among the IT security challenges faced by their organization with 74 percent indicating insufficient staffing as an additional barrier.

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(Sources: *Modern Healthcare*, <u>Most healthcare organizations have suffered data breaches</u>, <u>survey shows</u>, 3/12/18; Ponemon Institute and Merlin International, News <u>Release</u>, 3/12/18)

Larry Frederick recently had the opportunity to reunite with two of the individuals who helped save his life almost 36 years ago. Jim Fazackerley and Steve Stuart, who were emergency medical technicians for Allied Ambulance at the time, met Mr. Frederick and his wife Gail for lunch. "I won't ever forget that call or the remarkable recovery you made," said Mr. Fazackerley to The Press Democrat (Santa Rosa, Calif.). Mr. Frederick was injured on duty as a police officer in Oakland, Calif. during a traffic stop when another vehicle struck him. He required 54 pints of blood during his first day in the hospital. "A series of small miracles saved his life," said Ms. Frederick. Since that time, Mr. Frederick has become a blood donation advocate and namesake of America's Blood Centers' Larry Frederick Award, given annually to an in-



Larry Frederick (*left*) catching up with two of the first responders that helped save his life.

Photo courtesy of The Press Democrat (Santa, Rosa Calif.)

dividual for his or her community leadership in raising awareness of the need for blood donations. He has organized several bike rides throughout California and two across the U.S. to assist community blood centers in creating awareness for blood donation.

(Source: *The Press Democrat*, Smith: Years after the crash, a grateful ex-cop thanks his heroes, 3/12/18)

### **MEMBER NEWS**

**Community Blood Center** (Appleton, Wis.) has received approval by the U.S. Food and Drug Administration (FDA) to distribute Intercept pathogen reduced platelets. "Our [biologics license application] approval will enable us to supply Intercept-treated platelets for patient care within Wisconsin and throughout the United States," said John Hagins, president and CEO of Community Blood Center in a news <u>release</u>. "Through increased availability of pathogen reduced products, we can help our hospitals protect patients from transfusion-transmitted infections, including from bacteria and newly emerging pathogens." Community Blood Center becomes the fourth blood center to receive FDA approval. "With the [biologics license application] approval, [Community Blood Center] can now ship Intercept-treated platelets across



MEMBER NEWS (continued from page 7)

state lines thereby increasing patient access to safe and effective blood products," added Cerus President and CEO William "Obi" Greenman.

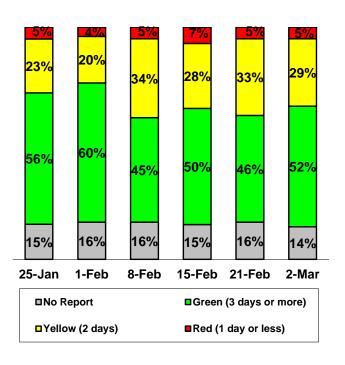
(Source: Cerus News Release, 3/13/18)

Blood recipient Mia McPoland recently met and thanked 34 blood donors from **United Blood Services**. Their blood donations are part of the more than 200 transfusions that she has received during her treatment for Diamond Blackfan Anemia, a condition which prevents her body from producing enough red blood cells. "What went through me was such joy and such pleasure knowing that these are the people who saved my life," said Ms. McPoland to 12 News (KPNX-TV, Phoenix, Ariz.). The event also provided United Blood Services with the opportunity to thank Ms. McPoland for helping raise awareness of the need for blood.



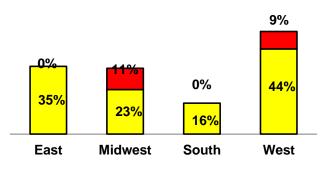
(Source: 12 News, <u>Phoenix girl who receives blood transfusions every month meets 34 of her donors</u>, 3/3/18) ♦

# STOPLIGHT<sup>®</sup>: Status of America's Blood Centers' Blood Supply



**Total ABC Red Cell Inventory** 

Percent of Regional Inventory at 2 Days Supply or Less, March 2, 2018



Percent of Total ABC Blood Supply Contributed by Each Region

East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at: www.AmericasBlood.org



# IN MEMORIAM

**ABC** Newsletter

Mississippi Blood Services and the blood community were saddened by the loss of **Pamela Jett, MD**, who passed away on March 9<sup>th</sup> following a brief battle with cancer. Dr. Jett held the position of vice president of Medical Affairs for Mississippi Blood Services November 1993 until her retirement in December 2017. She received her Doctor of Medicine degree from the University of Louisville and completed her residency in pathology at the University of Florida. Dr. Jett was passionate about medicine and loved to take care of people. Prior to joining Mississippi Blood Services, she practiced as a clinical pathologist at Mercy and Parkview hospitals in Vicksburg, Miss. for 10 years. Memorial donations in memory of Dr. Jett may be made to St. Jude Children's Research Hospital or a charity of your choice.

Contributed by David Allen, President and CEO, Mississippi Blood Services

### **COMPANY NEWS**

The Advanced Medical Technology Association (AdvaMed) has acquired the MedTech Conference. The acquisition allows AdvaMed to assume full ownership and operation of the conference. "This is an important milestone in AdvaMed's growth as an association," said Scott Whitaker, president and CEO of AdvaMed according to an AdvaMed news release. "Fully integrating the conference into AdvaMed's day-to-day operations will provide us with increased creative and operational control as our annual event continues to expand and flourish. I am very excited for what this means for the future of The MedTech Conference and for AdvaMed." This year's conference will take place in Philadelphia, Penn. September  $24^{th} - 26^{th}$ .

(Source: AdvaMed News <u>Release</u>, 3/16/18) •

### **GLOBAL NEWS**

Facebook has expanded its blood donation feature to Pakistan. The program is designed to assist with combating blood shortages by allowing Facebook users in Pakistan to register to become blood donors via the social media platform. Facebook previously released this feature in India and Bangladesh. Additionally, the tool will allow users to receive alerts directly in their newsfeed when shortages arise. Blood organizations and hospitals in Pakistan will be able to generate special posts or requests that Facebook will connect to individual donors nearby who will have the opportunity to respond directly. "We hope that by increasing awareness and providing tools for people and organizations in need to connect with those who are willing to help, we can make it easier for people to donate blood," said Hema Budaraju, product manager of health at Facebook, according to *MIT Technology Review Pakistan*.

(Source: *MIT Technology Review Pakistan*, <u>Facebook's blood donation feature launched in Pakistan</u>, 2/28/18) ●

#### **We Welcome Your Letters**

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to the Editor at <u>newsletter@americasblood.org</u> 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.

### CALENDAR



*Note to subscribers:* Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (<u>lmaundy@americasblood.org</u>) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

#### 2018

Mar. 17-19. ABC Annual Meeting, America's Blood Centers, Scottsdale, Ariz. More details available here.

Mar. 20. National Blood Foundation Leadership Forum, Scottsdale, Ariz. More details available here.

Mar. 21-22. IPFA 3rd Asia Workshop on Plasma Quality and Supply, Kuala Lumpur, Malaysia. More details available <u>here</u>.

Apr. 16. FDA Public Meeting "Evaluating Inclusion and Exclusion Criteria in Clinical Trials," Washington, DC. More details available <u>here</u>.

Apr. 17-18. **51st Annual Meeting, Heart of America Association of Blood Banks, North Kansas City, MO**. More details available <u>here</u>.

Apr. 24-25. International Consensus Conference "Patient Blood Management," Frankfurt, Germany. More details available here.

May 8-10. ABC Human Resources & Training/Development Workshop, America's Blood Centers, Dallas, Texas. More details available <u>here</u>.

May 9-11. ADRP Conference & Expo., Dallas, Texas. More details available here.

May 15. **2018 NJABBP Spring Seminar & Annual Conference, Woodbridge, NJ.** Join NJABBP by March 15<sup>th</sup> to be eligible to receive benefits. More details available <u>here</u>.

May 16-17. **IPFA/PEI 25th Workshop on "Surveillance and Screening of Blood-borne Pathogens," Athens, Greece.** More details available <u>here</u>.

Sept. 5-7. 3rd European Conference on Donor Health and Management, Copenhagen, Denmark. More details available <u>here</u>.

Sept. 12. 8th Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD. More details available here.

Sept. 28. **36**<sup>th</sup> **Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available <u>here</u>.

#### **CLASSIFIED ADVERTISING**

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: <u>lmaundy@americasblood.org</u>.

#### POSITIONS

**Division Director.** Hoxworth Blood Center seeks a Division Director to direct operations of the Components & Distribution, Immunohematology Reference, and Donor Testing laboratories. This individual will streamline

workflow, increase efficiency while increasing Hoxworth's ability to deliver existing and new products and services. Primary responsibilities: Eliminate inefficient

### POSITIONS (continued from page 10)

processes; Provide weekly order fulfillment, TAT data; Reduce products lost (waste) in manufacturing; Ensure test results are uploaded and product labeling is completed by 8 a.m.; Resource share \$650,000 in products end of first year; Increase recovered plasma sold; Support Donor Recruitment, Donor Operations to implement Source Plasma; and Resource share \$650,000 in products first year. Requirements: MT (ASCP) SBB Certified or master's degree in Immunohematology; or bachelor's degree with seven (7) years of experience; or associates degree with nine (9) years of experience. Degree must be in science. Experience requires at least five years supervision. Apply here.

