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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2018 #37 **November 2, 2018**

INSIDE:

CMS 2019 HOPPS Final Rule Revises Payment Rate for Pathogen-reduced Platelets

The Centers for Medicare and Medicaid Services (CMS) released the final rule for the Hospital Outpatient Prospective Payment System (HOPPS).

The final rule includes a recommendation from AABB, America's Blood Centers, and American Red Cross submitted in joint comments asking the agency to forego its proposed payment rate for pathogen-reduced platelets, in favor of continuing to crosswalk that payment rate for pathogen-reduced platelets to the payment rate for leukoreduced and irradiated platelets. The agency will continue to crosswalk for one more year, which sets the reimbursement rate for each unit at $623.47 versus $453.87. The response states:

"We appreciate the concerns of the commenters. Pathogen-reduced platelets (HCPCS code P9073) are a relatively new service. As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37058), there were many changes to the procedure code billed for pathogen-reduced platelets, as well as with the services covered by the procedure codes for pathogen-reduced platelets and the code descriptors. We had concerns that all of these coding changes could lead to billing confusion. The comments we received from providers, stakeholder groups, and the developer of the pathogen-reduced technology support that there indeed may have been confusion about billing that has led to aberrancies in the data we have available for rate-setting.

After consideration of the public comments we received, we are not finalizing our proposal to calculate the payment rate for services described by HCPCS code P9073 in CY 2019 using claims payment history. Instead, for CY 2019 (that is, for one more year), we are establishing the payment rate for services described by HCPCS code P9073 by performing a crosswalk from the payment amount for services described by HCPCS code P9073 to the payment amount for services described by HCPCS P9037. We refer readers to Addendum B to this final rule with comment period for the final payment rate for services described by HCPCS code P9073 reportable under the OPPS. Addendum B is available via the Internet on the CMS website."

Additionally, CMS agreed that the packaged costs for Allogeneic Transplantation of Hematopoietic Progenitor Cells (C-APC 5244) inadvertently omitted the revenue code for costs associated with donor search and cell acquisition costs and therefore have included it in this final rule with comment period for the CY 2019 OPPS rate setting.

(Source: CMS HOPPS Final Rule, 11/2/18)

Blood use after Las Vegas Mass Shooting Incident

An article describing blood and component use in association with the October 1, 2017 event that left 58 dead and more than 600 injured during last year's mass shooting in Las Vegas, Nev. has been published. The authors used deidentified records from the three hospitals that provided the majority of the care, and from blood banks that supplied them to examine transfusion volumes during the first 24 hours after the shootings and donations to local blood collection facilities.

The participating hospitals treated close to 520 patients, of whom 185 (estimated) were admitted, 63 to critical care units. Hospitals serving 71 patients (39 admissions, 5 critical care) did not supply data. The patients were infused with 499 components, including 278 units of red blood cells (1.5 per admission), 151 plasma units (0.82), 45 platelets (0.24), and 25 equivalents of 5-unit cryoprecipitate pools (0.14). These components were rapidly replaced by shipments of more than 700 components from existing Vitalant (formerly United Blood Services) and American Red Cross (ARC) inventories.

At the time of the shootings, the hospital transfusion services were fully stocked, and initial demand was met by that stock and supplements from the local blood centers. Despite an announcement of an adequate blood supply, local law enforcement issued an appeal that "triggered hours-long donation lines, and within 3 days, news reports that people were donating *too much* blood." Local donations in response to the events totaled close to 800 units, of which "over 17 percent of this blood was wasted," 137 units compared to a monthly mean of 26. ARC donation appointments increased 53 percent nationwide between October 2nd-4th, 2017.

The authors conclude "preparation for future mass casualty incidents should include training the community in hemorrhage control, encouraging routine blood donation, and avoiding public calls for blood donation unless approved by local blood suppliers."

According to a CNN report, the study strikes a "delicate balance" and is not meant to dissuade people from donating blood, but it does raise critical questions about how blood donations are used after mass shootings, said James Lozada, MD, lead author of the study. "It's important to convey the message that blood donation is extremely important, but it's important to do it regularly throughout the year," said Lozada, an assistant professor of anesthesiology at Vanderbilt University Medical Center. "The blood that is donated afterwards is very unlikely to be used for these individual tragedies."

Citation: Lozada, M.J., Cai, S., Li, M. *et al.* The Las Vegas Mass Shooting: An analysis of blood component administration and blood bank donations. *J. Trauma and Acute Care Surg*. doi: 10.1097/TA.0000000000002089. ♦

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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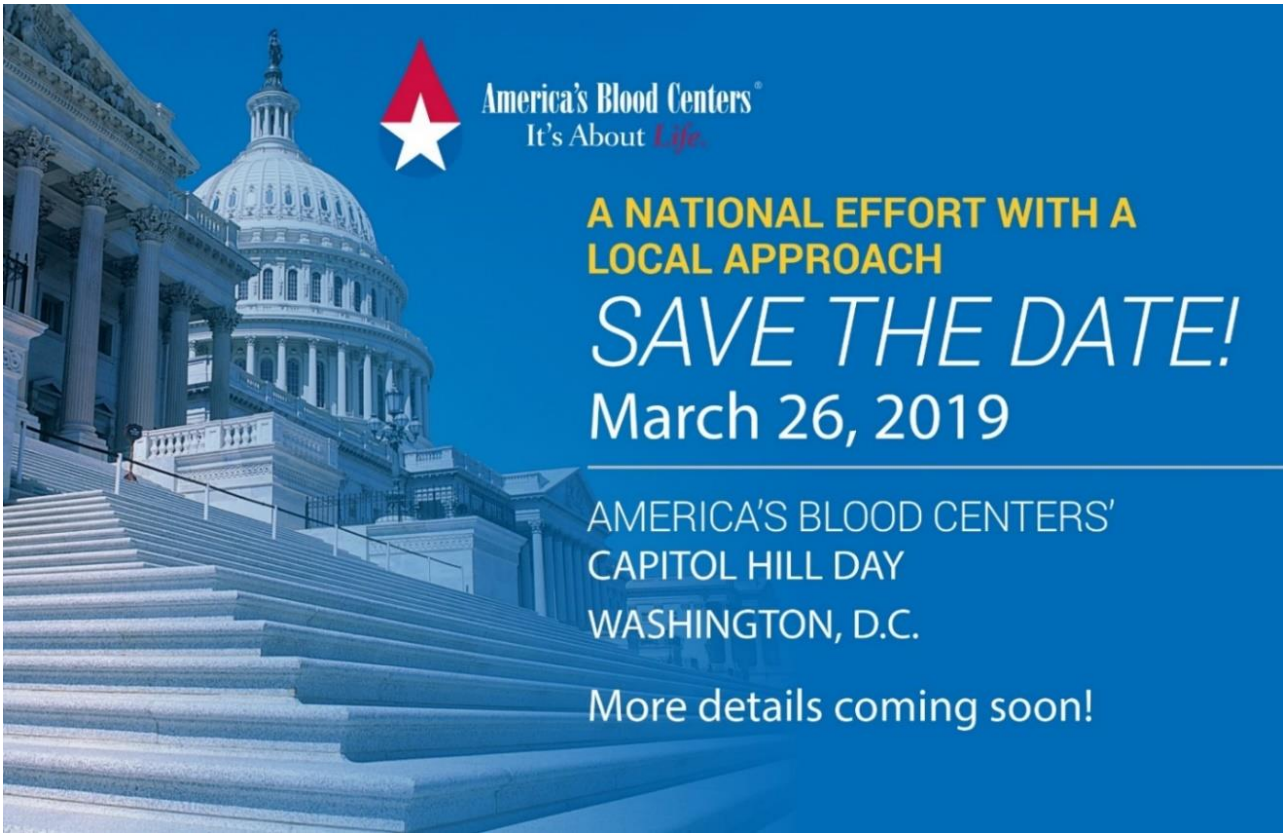
AABB, ABC, ARC Provide Feedback on ASPR National Health Security Pillars

AABB, America's Blood Centers and American Red Cross sent a joint letter to the Assistant Secretary for Preparedness and Response (ASPR) following a listening session on the four pillars for achieving national health security. The letter emphasizes the importance of prioritizing the availability of a safe blood supply to the national public health security capabilities of the U.S., "[b]lood components are an essential treatment in trauma and are also medically necessary treatments for patients with certain chronic health conditions. Yet, our nation's blood supply is often an overlooked and misunderstood aspect of emergency preparedness and response systems."

It outlines a framework for the inclusion of the blood community as stakeholders in disaster preparedness. "Including blood centers in establishing and updating guidelines for regional health care emergency and response systems is paramount and consistent with the HHS recognition of blood as one of the core functional areas in Emergency Support Function #8 of the National Response Framework. Under ESF#8, HHS monitors and coordinates the need for blood components and related medical supplies in coordination with the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (AABB Disaster Task Force)." The complete letter is available here.

(Source: Joint National Health Security Letter, 10/23/18)



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INSIDE ABC

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

ABC *Awards of Excellence* Call for Nominations

ABC members are encouraged to nominate blood donation sponsors, corporations, and advocates for the 22nd Annual *Awards of Excellence*. This year's ceremony will be in Washington, D.C. during ABC's 57th Annual Meeting on Monday, March 25th at the Ritz-Carlton (Pentagon City). Nominations are currently open until Friday, November 30th. Additional details are available in MCN 18-044. The online submission form is available here. ABC members are permitted to submit up to three nominations per category.

The following awards will be presented during the awards ceremony and are currently open for nominations:

- ABC Outstanding Blood Drive of the Year
- Outstanding Public Relations Campaign
- Corporation of the Year Award
- Larry Frederick Award (jointly presented by ABC and ADRP)
- William Coenen President's Award
- Blood Community Advocate of the Year Award
- Thomas F. Zuck Lifetime Achievement Award

A complete description of each award is available. Please direct any questions about nominations or the awards ceremony to Leslie Maundy.

(Source: MCN 18-044)

ADRP Announces Call for Speaker Abstracts

ADRP has opened the call for abstracts for its 2019 Annual Conference in Indianapolis, Ind. Marketing, communications, recruitment, and collections professionals and experts are invited to submit abstracts to share their expertise. The deadline to submit is Friday, November 30th. Speakers that are chosen will receive a 30 percent discount off conference registration. This year's sessions will feature speaker panels, breakout sessions, and roundtable discussions. Interested individuals can submit their abstracts here.

Upcoming ABC Webinars – Don't Miss Out!

- **Quality Integration Part II** – November 27th at 3 pm. EST. Additional details forthcoming!
- **SMT Journal Club** – December 12th at 12 pm. EST. Additional details forthcoming!

(continued on page 5)

INSIDE ABC (continued from page 4)

ADRP Award Nominations Open

Recognize a peer or outstanding donor group by nominating them for an ADRP Award. Submissions are being accepted until Friday, November 30th via the online nomination form. This year's categories include:

- Donor Recruiter of the Year
- Donor Collections Team Member of the Year
- Leader of the Year (Recruitment & Collections)
- Franzmeier Lifetime Achievement Award
- Gilcher MD/CEO Award
- Media Partner Award
- Blood Drive Award (Creative & Most Productive)
- School Blood Drive Award
- Humanitarian Service Award

RESEARCH IN BRIEF

What does sickle cell trait (SCT) mean for donors? Blood collection facilities identify a large number of donors with SCT and are often called upon to counsel them. A systematic review in the *Annals of Internal Medicine* collates data from 41 qualifying studies (mainly population-based cohorts and case-control studies) after a literature search that identified more than 7,000 potential references. High quality evidence supports modest statistical associations between SCT and pulmonary embolism with a hazard ratio (95 percent confidence interval) of 2.24 (1.28-3.95), with albuminuria, 1.86 (1.49-2.31), and with chronic kidney disease, 1.57 (1.34-1.84). A weaker association was estimated for exertional rhabdomyolysis, and no associations were found for deep vein thrombosis, heart failure, stroke, or with pediatric growth metrics.

Citation: Naik, R.P., Smith-Whitley, K., Hassell, K.L. *et al.* Clinical outcomes associated with sickle cell trait: a systematic review. *Ann. Int. Med.* doi:10.7326/M18-1161.

AABB Annual Meeting: Bloodworks Northwest reports that providing information on iron is associated with better attraction of teens and improved qualification of teenage female donors. ABC member Bloodworks Northwest has produced age appropriate information on iron physiology (iron requirements, the impacts of donation on iron stores, and suggestions for their maintenance) asking whether iron information will encourage or discourage blood donation and if it can influence the proportion of donors with acceptable hematocrits. The information is mailed to the homes of parents of potential 16- and 17-year-old blood donors with parental permission forms and shown to 18-year-old donors (who do not require parental permission) on the day of donation. The authors compared the numbers of teen donors registered and the proportion with acceptable hematocrits before and after the intervention documenting a 6.6 percent increase in the number of teen donors (11 percent among 16-17-year-old females) and higher rates of acceptable hematocrits among the females (males already qualified at a 99 percent rate).

Citation: Haley, R., Lantz, J., Cotton, K. *et al.* The effect of special iron information for teen age donors on deferral rates and recruitment success Abstract BBC51. *Transfusion*. 2018

Do we need to control the temperature of red blood cell (RBC) storage more tightly? Investigators at the National Institutes of Health (NIH) investigated the differential effects of human and canine RBC storage at 2, 4, and 6 degrees Celsius on measures of hemolysis and RBC recovery after transfusion using

(continued on page 6)

RESEARCH IN BRIEF (continued from page 5)

chromium-51 labeling. Cell-free hemoglobin and non-transferrin bound iron were comparable at all three temperatures after seven days of storage but were elevated after 35 days at 4 and 6 degrees compared to 2 degrees Celsius. RBC survival studies were confounded by the observation that a cohort of cells that likely survive poorly are removed by the chromium labeling process. The authors conclude that the "higher refrigeration temperatures are not optimal during extended RBC storage" and call for more work to "determine the reproducibility of our findings in human volunteers and the magnitude of their clinical importance."

Citation: Blaine, K.P., Cortes-Puch, I., Sun, J. *et al.* Impact of different standard red blood cell storage temperatures on human and canine RBC hemolysis and chromium survival. *Transfusion.* 2018. doi:10.1111/trf.14997.

Nucleic acid donor testing for malaria? Thousands of low risk blood donors are lost to malaria deferrals annually, while transfusion-transmitted malaria continues to occur rarely in the U.S., but with substantial frequency in endemic countries. Parasite detection *in vitro* might offer an approach to both transfusion safety and donor salvage. Many mitochondria, each containing DNA, are present in every cell, including malaria parasites, so their DNA molecules are present at much higher copy number than is genomic DNA. The analytical sensitivity of mitochondrial DNA testing for *Plasmodium vivax* was determined to be 0.000006 parasites/µL in a study from Brazil. This extrapolates to as few as 1.2 red blood cell parasites/500 mL whole blood collection at a hematocrit of 40 percent. With a sample size of only 150 µL per assay, it is unclear if that will be sensitive enough to identify asymptomatic infectious donors with very low levels of parasitemia who might transmit to recipients. Studies are planned by other investigators using ribosomal RNA, also present at high multiplicity.

Citation: Batista-dos-Santos, S.A., Freitas, D.R.C., Raiol, M. et al. Strategy to improve malaria surveillance system preventing transfusion-transmitted malaria in blood banks using molecular diagnostic. *Malaria J.* 2018.

RECENT REVIEWS

Aplastic Anemia. The pathophysiology, diagnosis, and treatment of aplastic anemia are reviewed in the *New England Journal of Medicine*. Transplantation and immunosuppression have changed a formerly bleak prognosis over recent decades, while "gene editing with restoration of function offer hope" for further improvements.

Citation: Young, N.S. Aplastic anemia. *N. Engl. J. Med.* 2018. 379: doi: 10.1056/NEJMra1413485.

BRIEFLY NOTED

First responders in San Antonio, Texas are the first in the country to carry whole blood for medics to perform transfusions in the case of severe traumas. According to *Becker's Healthcare*, "[t]he San Antonio Fire Department modified seven ambulances to include high-tech coolers and warmers to store the blood between 1 to 9 degrees Celsius. Paramedics can also remove the coolers and warmers to perform blood transfusions in a different location, if necessary. The ambulances share a blood supply with local medical helicopters, which received the transfusion equipment before the ambulances. Whatever blood is not used is given to local hospitals." San Antonio Fire Department Deputy Medical Director C.J. Winckler, MD told *Becker's Healthcare* that he expects ambulances to see better outcomes as result, similar to the uptick in better outcomes in trauma survival rates that was seen in patients treated aboard medical helicopters equipped with blood products.

(Source: *Becker's Healthcare*, San Antonio hospitals report better trauma outcomes after ambulances stock blood for transfusions, 10/18/18) ♦

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) issued a draft guidance on October 29th entitled "Considerations for the Development of Dried Plasma Products Intended for Transfusion." The guidance outlines recommendations on the "optimal sources of input plasma, manufacturing and product quality, including product characterization; packaging and reconstitution; clinical studies; and device submissions," including for the successful development and licensing of freeze-dried plasma products. The complete guidance is available on the agency's website and comments are due on January 28, 2019. ABC members with comments on the guidance are encouraged to send them to Ruth Sylvester for consideration for inclusion in ABC comments to the docket.

(Source: FDA Draft Guidance, 10/29/18)

Ribbon-cutting ceremony for the opening of the Health Sector Cybersecurity Coordination Center

The U.S. Department of Health and Human Services (HHS) held a dedication for the opening of the Health Sector Cybersecurity Coordination Center (HC3) on October 29th. "HHS is proud to work with the health community to better protect Americans' health data and confidential information," said Deputy Secretary Eric Hargan, JD in an agency news release. "Today's announcement is a recognition of the importance we place on stakeholder engagement as part of our cybersecurity work." The ceremony took place as National Cybersecurity Awareness Month wound down and was the latest in a series of cybersecurity updates from the federal government, which included the cybersecurity partnership between the U.S. Food and Drug Administration (FDA) and U.S. Department of Homeland Security (DHS) and draft guidance from the FDA on the cybersecurity of medical devices. "We believe that when a risk is shared across sectors, the only way to manage that risk successfully is to manage it collectively," said Assistant Secretary for Cybersecurity and Communications in DHS Jeanette Manfra in the release "We know that the majority of the cybersecurity attacks that occurred over the past year could have been prevented with quality and timely information - and the heightened importance of sharing information cannot be stressed enough. The HC3 is a vital capability for the early detection and coordination of information between the private sector and the federal government, and with cyber professionals across the federal government."

(Source: HHS News Release, 10/30/18)

The Joint Commission released its 2019 National Patient Safety Goals. The first goal aims to make patient identification more accurate by using "at least two patient identifiers when providing care, treatment or services" and specifically references eliminating transfusion errors due to patient misidentification through three recommended steps depending on the setting:

1. Before initiating a blood or blood component transfusion:
   - Match the blood or blood component to the order.
   - Match the patient to the blood or blood component.

(continued on page 8)

REGULATORY NEWS (continued from page 7)

- Use a two-person verification process or a one-person verification process accompanied by automated identification technology, such as bar coding. (See also NPSG.01.01.01, EPs 1 and 2)

2. When using a two-person verification process, one individual conducting the identification verification is the qualified transfusionist who will administer the blood or blood component to the patient.

3. When using a two-person verification process, the second individual conducting the identification verification is qualified to participate in the process, as determined by the organization.

Additional information is available on the Joint Commission website including the complete chapters for lab, hospital, critical access hospital, ambulatory, nursing care center, and office-based surgery settings.

(Source: Joint Commission Website, 10/16/18)

WORD IN WASHINGTON

The Sickle Cell Disease Research, Surveillance, Prevention and Treatment Act introduced in the Senate earlier this year by Sens. Tim Scott (R-S.C.) and Cory Booker (D-N.J.) has passed with unanimous approval. ABC joined 66 other organizations in signing a letter thanking Sens. Scott and Booker for their efforts in introducing the bill in the Senate and promoting the importance of sickle disease awareness nationally. ABC members can view the letter on the ABC member website. "One of the pillars I base my public service on is giving a voice to the voiceless, and that is exactly what my Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act does," said Sen. Scott following the bill's passage according to the *Times and Democrat*. "I am thrilled that the Senate unanimously passed my bill to ensure that we work to improve our medical understanding of this disease through enhanced data collection and public health initiatives." The legislation aims to "increase efforts to collect data" on sickle cell disease and "reauthorize" the Sickle Disease Treatment Demonstration Program.

(Source: *Times and Democrat*, A victory vs. sickle cell disease, 10/23/18)

MEMBER NEWS

Coffee Memorial Blood Center (Amarillo, Texas) announced that it is finalizing a partnership with air ambulance companies to provide blood products to them for transfusing during transport in hopes of improving patient outcomes. "We've seen it first hand, our crews at LifeStar have seen it first-hand, as far as being able to give blood and give plasma immediately to these patients means in their outcome," said Steve Marshall, a flight nurse and critical care educator at LifeStar at Northwest Texas Hospital to KFDA NewsChannel 10. LifeStar has provided air medical transport services for 25 years to the Texas Panhandle.

Photo courtesy of KFDA NewsChannel 10

(Source: KFDA NewsChannel 10, Coffee Memorial Blood Center partners with air ambulance companies, 10/25/18)

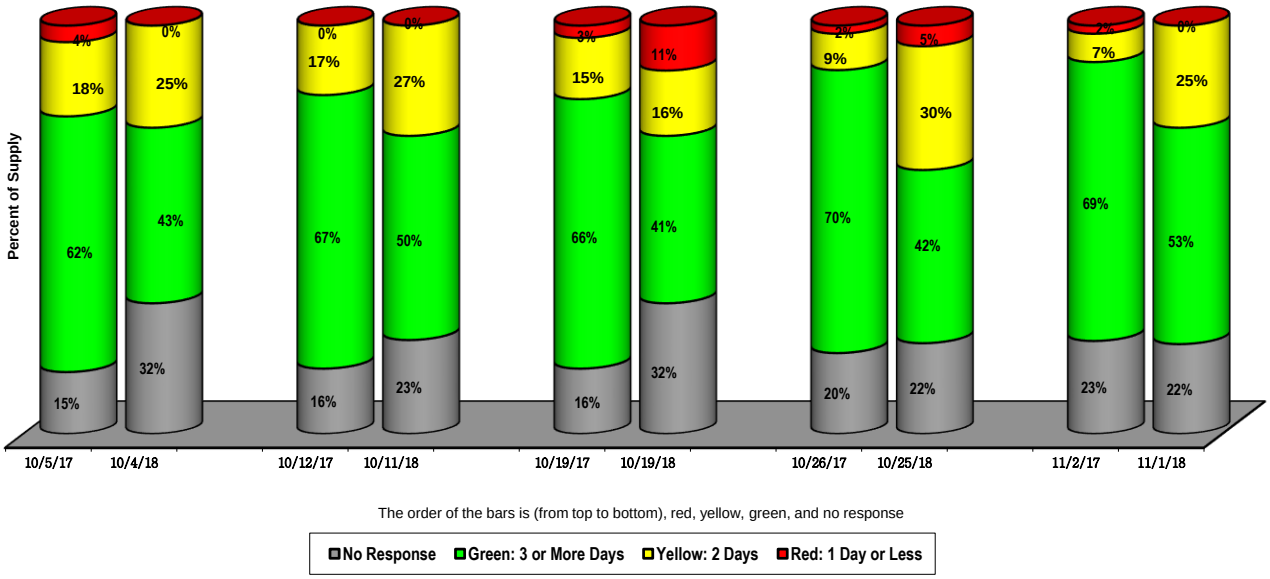
(continued on page 9)

MEMBER NEWS (continued from page 8)

Vitalant recently celebrated the 500th donation by Richard Packman in Chicago, Ill. Mr. Packman began donating in the 1990s and enjoys making a difference through platelet donation, "[i]t takes longer than a blood donation, but it's well worth it," said Mr. Packman to the *Chicago Tribune*. "I really enjoy being a platelet donor because you really know you're saving lives." He first began donating through a church-sponsored drive and has continued for more than two decades. His wife Diana joined Vitalant staff in celebrating the achievement. "That's hundreds of hours he spent doing that just for the satisfaction of saving people's lives because there is absolutely no replacement for platelets from a person," said Vitalant's Stephanie Boulware to the *Chicago Tribune*.

(Source: *Chicago Tribune*, Chicago man makes 500th blood donation: 'You actually get an opportunity to save someone', 10/12/18)

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



Daily updates are available at:
www.AmericasBlood.org

COMPANY NEWS

Cerus announced that its pathogen-reduced cryoprecipitate has received "Breakthrough Device" designation from the U.S. Food and Drug Administration (FDA). "This designation reaffirms and validates our belief that pathogen-reduced cryoprecipitate addresses a clear, unmet clinical need," said Cerus President and CEO William 'Obi' Greenman in a Cerus news release. "Control of massive bleeding is a significant challenge in U.S. hospitals today, especially for patients with traumatic injury or maternal hemorrhage, which are among the leading causes of death in the U.S. for patients under the age of 45. Pathogen-reduced cryoprecipitate is being developed to potentially confer important features, such as an extended thawed shelf-life and improved product standardization, which could markedly improve the time it takes physicians to control bleeding in these patients." The designation from the FDA helps expedite product availability and patient access to more effective treatment options for life-threatening or irreversibly debilitating diseases or conditions.

(Source: Cerus News Release, 10/31/18)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2018

Nov. 14. **2018 Cybersecurity Summit, Washington, D.C.** More details available here.

Nov. 29-30. **FDA Pathogen Reduction Technologies for Blood Safety Public Workshop, Silver Spring, Md.** More details available here.

2019

Feb. 4-5. **15th Annual FDA and the Changing Paradigm for HCT/P Regulation, Washington, D.C.** More details available here.

March 6-7. **IPFA 4th Asia Workshop on Plasma Quality and Supply, Hanoi, Vietnam.** More details available here.

March 23-26. **2019 ABC Annual Meeting, Washington, D.C.** More details coming soon.

May 14-16. **ADRP Annual Conference, Indianapolis, Ind.** More details available here.

May 22-23. **IPFA/PEI 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens", Krakow, Poland.** More details available here.

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Clinical Laboratory Scientist. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a nonprofit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Clinical Laboratory Scientist (CLS). This is a full-time, fully benefitted position. The Northern California Community Blood Bank offers a low-stress environment, excellent work-life balance, and the opportunity to advance your professional development while working for an employer with a vibrant community relationship. The Clinical Laboratory Scientist is responsible for activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Clinical Laboratory Scientist performs reference immunohematological testing and participates in training, validation, implementation of new procedures, and compliance with regulatory and standard-setting agencies. Experience, Education and Licensure: Four-year degree from an accredited college or university in science, medical technology or a related field. Valid current CA license as a Clinical Laboratory Scientist. Experience preferred but will train a motivated new CLS. To apply, contact: Jo Anna Ow, Administrative Services, Northern California Community Blood Bank, 2524 Harrison Avenue, Eureka, CA 95501; (707) 443-8004.

Medical Director. The European Blood Alliance (EBA) is looking for an expert with medical and blood service background to serve as a part-time Medical Director of EBA. The Medical Director will bring her/his expertise to support the secretariat and will report to the Executive Director (ED). She/he will work preferably in Belgium or virtual if the person is not based in Belgium. **Key goals** are to support the EBA membership by sharing technical/medical information in relation to blood services, contribute to EBA strategy and policies, represent EBA when medical expertise is sought and act as a facilitator of knowledge exchange on technical/medical matters among EBA members and in working groups/projects. The successful candidate must be able to demonstrate achievements in the field of blood services, have a thorough knowledge in transfusion medicine in Europe, donor management and health, as well as be able to work with a diversity of profiles, nationalities and cultures. A track record of networking and interacting with blood services from various countries would be a bonus. This post would ideally suit a person who has a well-established career, willing to work part time, and involves frequent travels mainly in Europe. More information on: https://wp.me/p4l3nF-2cC.