America's Blood Centers®
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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2016 #17 **May 20, 2016**

INSIDE:

Please Note: The *Newsletter* will be getting a new look! Please expect to see some layout and formatting changes coming soon.

Study on Platelet Transfusion vs. Standard Care After Spontaneous Intracerebral Hemorrhage (ICH) Associated with Antiplatelet Therapy (PATCH) Shows Significant Increase Rate of Death

ICH causes half of all stroke deaths in the U.S. and leaves 42 percent of survivors with disabilities and dependence upon others for care. Observational studies report variable outcomes from platelet transfusion versus standard care—which was not defined but based upon contemporary national guidelines—without transfusion for patients who bleed while receiving anti-platelet therapy. A multicenter, randomized, open label, masked-endpoint trial with 190 participants compared the mortality and dependency rates after ICH in patients on antiplatelet therapy who received platelet transfusions with those who did not. Mortality at three months was significantly higher, 24 percent versus 17 percent, among patients who received platelets as was the rate of serious adverse reactions, 42 percent versus 29.

Anti-platelet therapy is given to many patients who have undergone heart surgery, had a myocardial infarction, angina, a previous stroke, or peripheral vascular disease. Twenty-five percent of ICH patients in developed countries are estimated to be on anti-platelet therapy (Lovelock CE, *et al*. *Lancet Neurol* 2007; 6: 487–93). Some observational studies suggested these patients have a reduction in the extent of the hemorrhage associated with platelet transfusions.

	Platelet transfusion group (n=97)	Standard care group (n=93)	Odds ratio (95%CI)	p value
Alive at 3 months (survival)	66 (68%)	72 (77%)	0·62 (0·33–1·19)	0·15
mRS score 4–6 at 3 months	70 (72%)	52 (56%)	2·04 (1·12–3·71)	0·0195
mRS score 3–6 at 3 months	86 (89%)	76 (82%)	1·75 (0·77–3·97)	0·18
Median ICH growth at 24 h (mL)*	2·01 (0·32–9·34)	1·16 (0·03–4·42)	..	0·81

Data are n (%) or median (IQR). mRS=modified Rankin Scale. ICH=intracerebral haemorrhage. *n=80 in platelet transfusion group and 73 in standard care group.

Table 2: Secondary outcomes in the intention-to-treat population

Source: The Lancet, May 10, 2016.

(continued on page 3)

OUR SPACE

ABC President Susan Rossmann, MD, PhD

A Day To Remember

Monday, May 23, will be a red letter day for most of us who work in blood centers. After years of effort, revisions to federal regulations for the collection of blood will become effective. The work involved with determining and implementing these changes has been massive, even without the distraction of Zika. A proposed rule was published on November 8, 2007, and the Food and Drug Administration (FDA) just published the final rule on May 22, 2015. The rules modernize the approach to regulation of infectious disease testing and make new provisions for donor selection.

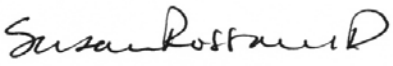
The section on infectious diseases generalizes the approach to donor testing, defining "relevant transfusion-transmitted infection" (RTTI) and providing a framework to add and remove tests via guidance more nimbly as circumstances require. Current testing will remain in place, and a new requirement for control of bacterial contamination of platelets is added. Requirements are further spelled out in a guidance that has been issued on these topics. Platelet contamination was not previously addressed, and this approach, including the use of pathogen reduction, is welcome.

Most of the significant changes come under the selection and care of donors. The donor eligibility must be determined on the day of donation, allowing 24 hours after to clarify donor's history if needed. Most medical history is unchanged, regarding risks of RTTI and risks to the donor. A separate guidance on deferral of MSM for one year past last episode will be implemented by many centers at this time, though it is not part of the CFR changes.

The most significant changes for donor assessment are gender-specific acceptable hemoglobin levels. Males must have a hemoglobin of 13.0 g/dL (or the equivalent 39 percent hematocrit). This raises the current standard of 12.5/38 for both sexes, reflecting a more normal level for males. Female thresholds are unchanged, with an option to go down to 12.0/36 with FDA approved measures to mitigate iron depletion. What are approvable is not yet clear, but will require methods to ensure donor iron stores remain sufficient.

Finally, the new requirements include a "donor acknowledgement." In this section, the FDA wants to make sure the donor acknowledges salient risks of donation from our educational materials and those of RTTI's. The agency has a touching faith that providing educational materials assures their reading and comprehension. The difficulty of providing such materials, especially to a new donor who is already nervous about phlebotomy, is substantial. Critically, donors, despite what we tell them, make their own judgments about the safety of their blood and relevance of their own history. It is not wrong to suggest otherwise, but it may be futile.

Thank you to all in our centers who have done the hard work of putting compliant processes in place. It has been a long and painful process, and is not done: the taskforce on the donor history questionnaire's standard materials have not yet been accepted by the FDA, leaving centers in an unclear regulatory position. Things could have moved more quickly on all sides, but when we are done, we will have better blood products for our recipients and a safer process for our donors.



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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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Study on Platelet Transfusion vs. Standard Care (continued from page 1)

The authors studied the hypothesis that platelet transfusion would reduce the risk of death and dependence compared with standard care. The results failed to confirm this.

Designed and coordinated by the Department of Neurology of the Academic Medical Center at the University of Amsterdam, the Netherlands, the phase-three trial studied 190 patients over 41 sites in 60 hospitals throughout the Netherlands, the United Kingdom, and France. Ninety-seven patients were randomly assigned platelet transfusion therapy as well as standard care and the other 93 patients were assigned standard care only. Transfusion was initiated within six hours of symptom onset and within 90 minutes of brain imaging. The transfusion was administered to patients who had also received antiplatelet therapy for at least seven days prior with a pre-hemorrhage modified Rankin Scale score of 0 (no symptoms) or 1 (no significant disability despite symptoms).

Platelets were dosed according to the inhibitor the patients were receiving—COX inhibitor patients received one platelet concentrate and ADP inhibitor treated subjects received two. The researchers based the dosage on *in vitro* experiments. Neurologists acting as blind observers or research nurses not affiliated with the patient's care recorded the participants' outcomes at three months with a numerical system ranging from 0 (no symptoms) to 6 (death) via telephone or in-person interviews.

Among patients receiving platelet transfusion, there was a significant increase in death or dependence at three months (crude common OR 1.84, 95% CI 1.10-3.08; p=0.02), (adjusted common OR 2.05, 95% CI 1.18–3.56; p=0.0114). The effect was consistent across all predefined subgroups and remained so after adjusting for potentially modifying and confounding factors.

The authors conclude platelet transfusion is inferior to standard care without transfusion in this patient group. They cited the relatively small sample size, a predominance of aspirin treatment compared to ADP inhibition, and the possibility of selective enrollment as potentially limiting the generalizability of the results, and point to similar trials nearing completion needed to confirm or contradict their findings.

Citations: Baharoglu IM, Cordonnier C., *et al*. Platelet transfusion versus standard care after acute stroke due to spontaneous cerebral haemorrhage associated with antiplatelet therapy (PATCH): a randomised, open-label, phase 3 trial. *The Lancet*, published online May 10, 2016.

Prodan C., Platelets after intracerebral haemorrhage: more is not better. *The Lancet*, published online May 10, 2016.

Comments filed to the Food and Drug Administration (FDA) on Bacterial Risk Control Strategies for Platelet Transfusions

On May 16, ABC, AABB, and the American Red Cross (ARC) submitted joint comments to the Food and Drug Administration (FDA) on the second draft guidance of the "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion." The comments filed highlighted clarification requests, recommendations, and rationales for such recommendations. The FDA was commended for changing the use of secondary bacterial testing on days four and five of platelet shelf-life from a "suggestion" to a "recommendation." The Bacterial Contamination Work Group (BCWG), a subgroup of AABB's Transfusion Transmitted Diseases (TTD) Committee drafted the letter and, in part, included:

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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.

Presentations from ABC Workshop Now Available for Download

Presentations from the ABC Human Resources & Training/Development Workshop in San Antonio, Texas, are now available on ABC's Member Website for download. Members can now download presentations from all three days on any topic covered, including The Performance Management Cycle from day one of the workshop by Laura Eickhoff, director of Learning and Total Compensation at BioBridge Global, and Bo Carrington, principal/president of Bo Carrington & Associates, Inc.; Dr. Susan Rossmann's State of the Blood Industry Update; and Customer Service Training: A Tale of Two Journeys, from Ursula Alvarado from BioBridge; Laurie McGraw, director of education and training at Gulf Coast Regional Blood Center; and Ms. Eickhoff. The presentations are free to download for all members. If you do not currently have an account, you may sign up for one here.

The Future Leader Scholarship from America's Blood Centers has been extended to today, May 20. Scholarship recipients will obtain $1,200 in funds to help pay for registration fees and any supplemental travel and hotel costs associated with attending the annual summer conference—this year in Honolulu, Hawaii. ABC is committed to helping its member blood centers and their staff grow and develop the next generation of leaders. Scholarship applicants must be non C-suite level blood center staff members who are nominated by a C-level staff member. Applicants must not have received a previous ABC scholarship for at least three fiscal years prior, April 1 to March 31. Submit an application today!

"In the late 1700s, Polynesian navigators voyaged thousands of miles of open ocean and discovered Hawaii.

Using modern day wayfinding techniques, together we will explore ways to navigate the challenging times ahead facing the blood banking industry. Let the island host culture inspire us with its Aloha Spirit, high energy of world-famous Waikiki, natural beauty, entrancing hula and the thrill of fire knife dancing. Discover our paradise this summer."

– *Kim Anh Nguyen, MD, PhD, president and CEO, Blood Bank of Hawaii*

Blood Bank of Hawaii
Give Blood. It's Safe. It's Simple. It Saves Lives.

Honolulu International Airport (HNL) is served by most major airlines. Visit http://www.honoluluairport.org.

August 1-4, 2016 – Honolulu, HI
Hilton Waikiki Beach on Kuhio
special room rate: $240 + tax

Future Leader Scholarship Program
Supported by the FABC, these scholarships offer non-C-suite blood center executives the opportunity to advance professionally by attending the ABC Summer Meeting. Details available upon registration.

Registration Fees
ABC Summer Meeting: $760
Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation and registration fees and information.

Meeting Schedule
Monday August 1:
Links for Life Golf Tournament
Links for Life Golf Reception
Tuesday, August 2:
Medical Directors Workshop
Hospitality/Networking
Wednesday, August 3:
SMT Forum
Blood Center Leadership Forum
Host Event by Blood Bank of Hawaii
Hospitality/Networking
Thursday, August 4:
ABC Members Meeting

For sponsorship opportunities contact Jodi Zand at jzand@americasblood.org.

Comments Filed to the FDA (continued from page 3)

- Requests for clarifications on the impact of delayed sampling and relative safety of approved culture-based tests.
- A recommendation that approval as a "safety measure" should not be required for culture-based secondary testing, which is known to more sensitive than rapid/point of issue tests, when pursuing extension of dating based secondary testing.
- A request to allow delayed primary testing with large inocula as a route to seven-day dating for primary culture screenings as has been approved in the United Kingdom and Quebec.
- To reword a statement used on labeling bacterially-tested platelet products to also include labeling when pathogen reduction technology has been applied.
- The FDA should recommend a minimum of a 12 hour incubation period for when bacterial detection devices do not specify an incubation period.
- A request to delete the FDA's recommendation that labeling after secondary testing include the type of test and date and time of testing as redundant when the appropriate expiration date and time are on the label; and
- A request to change the requirements relating to the Circular of Information to reduce redundancy and to recognize the use of pathogen reduction methods.

Previous draft guidance was issued on December 2014 from the same group and many of the major requests were changed within this new draft guidance. Some of those changes were that blood centers are not required to use bacterial testing, but may choose between bacterial and pathogen reduction technology now. The comments continue to strongly encourage the FDA to engage with product manufacturers to facilitate the availability of appropriate containers that will allow seven-day dating of platelets.

RESEARCH IN BRIEF

Blood centers might find it operationally possible to lower the deferral rate of frequent donors who are iron deficient by mailing them supplements, reads a recently published report in the journal *Vox Sanguinis*. Iron depletion is frequent in regular whole-blood donors, as measured using plasma ferritin. In this 197-person study, supported by a grant from the Foundation for America's Blood Centers, 170 donors at fixed donation sites were found to have low ferritin levels and were sent a month's worth of iron supplements. Ninety percent of the donors reported they took the supplements for five days or more per week, with a low instance of minor side-effects, and the mean ferritin rose from 8.7 ng/ml to 24.2 ng/ml. Whether the blood centers can recuperate the costs of ferritin testing and of mailing the supplements is left for further economic analysis, note the authors.

Citation: Gorlin J., Katz L., *et al*. Prevalence of blood donor iron deficiency and feasibility ferritin-based iron replacement: a blood collection agency based study. *Vox Sanguinis*. March 2016. DOI: 10.1111/vox.12408.

BRIEFLY NOTED

Administering transfusions of plasma and platelet (PLT) concentrates treated with pathogen reduction (PR) technology might result in a net loss of life in patients resuscitated after a massive hemorrhage(s), according to a commentary in *Transfusion*. The PR process inescapably involves the loss and alterations of platelets and clotting factors, which in the case of the potency of plasma and PLTs

(continued on page 6)

BRIEFLY NOTED (continued from page 5)

have generally been viewed as minor problems. The authors of this commentary reviewed published data describing physical and functional losses in treated platelets and plasma, summed them, and projected their effects on plasma and platelet doses during trauma resuscitation. They compared the benefits of reducing infectious disease morbidity to that of uncontrolled hemorrhages. The authors assert that trauma patients given PR platelets with a 30 percent lower potency due to PR and plasma potency loss of 20 percent might be associated with 400 deaths each annually. The authors note PR technology has appropriate uses, but suggest there may also be risks of harm and cautioned this should be carefully considered when decisions are made about its use.

Citation: Hess J., Pagano M., *et al*. Will pathogen reduction of blood components harm more people than it helps in developed countries? *Transfusion*. May 2016. DOI:10.1111/trf.13512.

An updated guide on tickborne rickettsial diseases (TRD) was published on the Center for Disease Control and Prevention (CDC) website. The updated guide, published on May 13, provides practical information to help healthcare providers and public health officials to recognize, determine, test, treat, and report TRD-positive patients. The authors heavily stress the use of doxycycline treatment as the treatment of choice and highlight early antibacterial treatment therapy to prevent severe illness or death from TRD. The updated guide replaces the 2006 CDC recommendations. Several such infections are of recent interest to the blood community, especially babesiosis and anaplasmosis.

Citation: Biggs H., Barton Behravesh C., *et al*. Diagnosis and Management of Tickborne Rickettsial Diseases: Rocky Mountain Spotted Fever and Other Spotted Fever Group Rickettsioses, Ehrlichioses, and Anaplasmosis. CDC website, Recommendations and Reports, May 13, 2016. 65(2);1–44.

Testosterone replacement therapy (TRT) has no link to increased rates of prostate cancer, said Stacy Loeb, MD, at New York University's Urology and Population Health Department, at the 2016 American Urological Association annual meeting. In an examination of 38,570 prostate cancer cases logged in a Swedish database from 2009 to 2012, checked against the Prescribed Drug Register of Sweden, Loeb's team found no association between those given TRT and controls. In fact, they found a 50 percent reduction in risk of aggressive prostate cancer in men treated with TRT for over a year. Two other studies from Ahmad Haider, MD, in Germany and Thomas J. Walsh, MD, at the University of Washington in Seattle found no association with TRT and prostate cancer rates as well. ABC centers have been interested in the effects of testosterone supplementation since many who receive it are being referred for therapeutic phlebotomy related to excessive dosing.

Citation: Loeb S., *et al*. Men with Low-Risk Prostate Cancer: Nationwide, Population-based Study in Sweden. Abstract, AUA2016.org. May 6, 2016. PD08-05.

Researchers at Tufts University and pharmaceutical company Vaxess Technologies devised an innovative way to store blood samples without immediate refrigeration. Most blood samples drawn for analysis need to be refrigerated or examined immediately or the biomarkers crucial for identifying diseases in the sample could deteriorate. However, researchers at Vaxess found that if silk fibroin, a protein extracted from silkworm cocoons, was mixed with the blood samples and air-dried, the samples could be stored at temperatures between 71.6 and 113 degrees Fahrenheit (22 to 45 degrees Celsius). Stability was demonstrated for up to 84 days at 45 degrees Celsius.

Citation: Kluge J., Li A., *et al*. Silk-based blood stabilization for diagnostics**.** *Proceedings of the National Academy of Sciences*. May 9, 2016. DOI: 10.1073/pnas.1602493113.

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BRIEFLY NOTED (continued from page 6)

In the updated guidelines from the International Society for Stem Cell Research (ISSCR) for research and the development of new clinical therapies, the authors call for an end to "stem cell hype." Studies on stem cells are arguably hyped by researchers in the field with hyperbolic language, developing unrealistic expectations amongst the public and media, and driving premature or unwarranted clinical use, the authors claimed. The ISSCR, representing 4100 researchers, published their newest guidelines calling for an end to the hype and urged researchers to promote accurate, balanced, and responsive public representations of stem cell research. (Source: ISSCR.org, ISSCR Releases Updated Guidelines for Stem Cell Research and Clinical Translation, May 12, 2016.)

After considerable discussion between representatives from ABC, AABB, the American Red Cross, the Center for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), the Council of State and Territorial Epidemiologists (CSTE) has released recommendations for how state and local health department heads should notify local blood collection organizations and blood banks on Zika infections. In this proposal, CSTE defines Zika infections as two or more residents being infected with the virus due to separate, local, active vector-borne transmissions occurring within two weeks of each other. The proposal also calls on blood collection organizations to follow current FDA guidance to keep the blood supply safe once notified about the active virus infection(s). Read the proposal. (Source: CTSE, May 5, 2016.)

REGULATORY NEWS

The International Council for Commonality in Blood Banking Automation (ICCBBA) announced updates to ISBT 128, the international identification, labeling, and information processing system for products of human origin. Version 6.16.0 of the ISBT 128 Product Description Code Database is now available to licensed facilities. All database updates are listed in the version control sheet. The new database can be downloaded as a Microsoft Access database. The **Standard Terminology for Medical Products of Human Origin v6.16 has also been** released. It provides definitions to all ISBT 128 terminology and should be used in conjunction with the ISBT 128 Product Description Code Database and has removed the "non-mobilized" attribute from existing product descriptions and product formulas within these latest updates. (Source: ICCBBA, May 12, 2016.)

The Occupational Safety and Health Administration (OSHA) has issued a final rule revising its Recording and Reporting Occupational Injuries and Illnesses regulation to make workplace injuries more transparent. OSHA is now requiring employers in certain industries, including blood centers and hospitals, to electronically submit all employee workplace injury and illness data that employers are already required to keep under OSHA regulations. OSHA intends to post this data on a public website. The OSHA final rule reads that regulators do not intend to post any information on the website that could be used to identify individual employees. The changes also address how employers inform employees to report work-related injuries and illnesses to their employer. Read the full final rule. (Source: OSHA, Docket No. OSHA-2013-0023, May 11, 2016).

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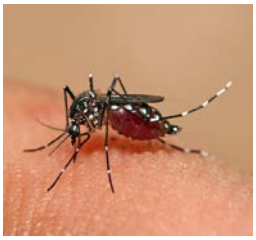
We Welcome Your Letters

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 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.

REGULATORY NEWS (continued from page 7)

The Food and Drug Administration (FDA) issued a final guidance on how manufacturers report and conduct postmarket surveillance of class II and class III medical devices. The guidance, released May 13, provides manufacturers with recommendations on making surveillance study submissions. Device manufacturers subject to 522 orders, an order requiring companies to submit a surveillance study within 15 months of receiving the order, will now have more guidance on what information to include and how to format the studies. (Source: RAPS.org, FDA Finalizes Guidance on Postmarket Device Surveillance.)

THE WORD IN WASHINGTON



A bill providing $1.1 billion in emergency Zika response financing passed the U.S. Senate on May 17. The bill still has to pass the U.S. House of Representatives, and is substantially lower than the $1.9 billion the White House requested. Republicans in the House have put forward a plan with $622 million in reallocated funds from other health programs—some of them for fighting Ebola, and are being sharply criticized by the Center for Disease Control and Prevention Director Dr. Thomas Frieden, "This is no way to fight an epidemic," he said in a telephone interview with the *New York Times*. Dr. Anthony S. Fauci, the director of the National Institute of Allergy and Infectious Diseases, told the paper that even with the lowered amount, he was confident his organization could get a vaccine produced. (Source: *New York Times*, Senate Votes to Advance Emergency Funding to Fight Zika Virus**,** May 17, 2016.)

GLOBAL NEWS

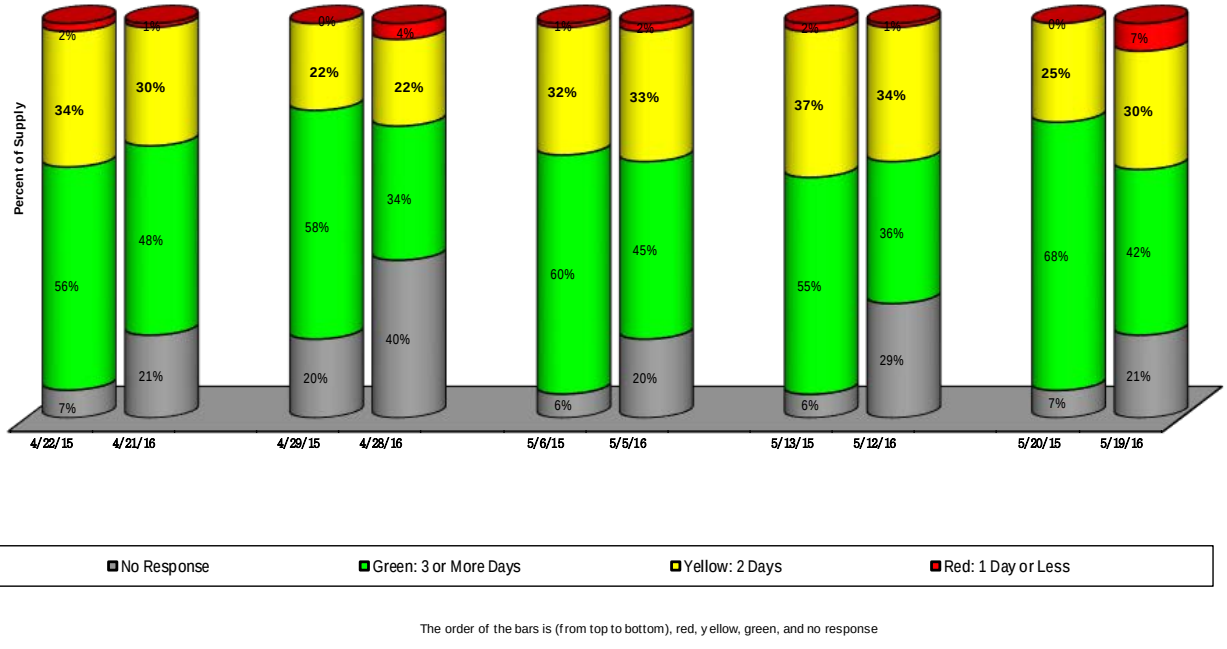
A yellow fever outbreak in sub-Saharan Africa coupled with a possible vaccine shortage could become a global emergency, wrote Daniel Lucey, MD, and Lawrence Gostin., JD, in *JAMA*. Yellow fever causes a hemorrhagic fever and hepatitis syndrome with a high mortality rate. The current epidemic started in Angola in December 2015 and the World Health Organization (WHO) now reports 661 confirmed cases with 277 associated deaths as of May 4. Infected travelers have taken it as far as China. With more than 7 million Angolans already vaccinated and the Democratic Republic of Congo planning to vaccinate another 2 million, the plans could be a "tipping point" for the vaccine supply. The authors ask the WHO to "urgently convene" an emergency committee to discuss mobilizing funds, coordinating an international response, and spearheading a surge in vaccine production.

Citation: Lucey D., Gostin L., A Yellow Fever Epidemic, A New Global Health Emergency?, *JAMA*. Published online May 09, 2016. DOI:10.1001/jama.2016.6606.

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!

STOPLIGHT®: Status of the ABC Blood Supply, 2015 vs. 2016



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

MEMBER NEWS

Courtesy of GCRBC

Commit for Life is a motto Gulf Coast Regional Blood Center (GCRBC) does not limit to our own species. Last week, the blood center donated use of a centrifuge dedicated to the Houston Zoo in an effort to help save elephant lives. Elephants afflicted with Elephant Endotheliotropic Herpesvirus (EENV) have a morbidity rate of 70 percent. Zoo personnel draw the blood from the elephants, spin the sample in the donated centrifuge, located at GCRBC headquarters, and separate plasma from the rest of the blood products. The plasma is then used for EENV treatments. The plasma separation process now takes 10 minutes, down from around 12 hours. (Source: CW39.com, The Houston Zoo teams with Gulf Coast Regional Blood Center to bank elephant blood, May 10.)

The Community Blood Center of the Carolinas (CBCC) **has announced its 8th annual "Students Saving Summer" scholarship program that will give away thousands in scholarship money.** High school and college students applying for the scholarships organize and host their own blood drives between June 1 and September 30, 2016, and must collect a minimum 25 units of blood. Winners of the top five blood drives will be awarded $1,000 in scholarship funds each. This scholarship program represents a unique way to drive awareness for its center, recruit young-donors as well as save local lives in the process.

PEOPLE

Kathy Waldman, senior vice president of Quality and Regulatory Affairs at the American Red Cross (ARC), is retiring after 32 years with the organization. In the last three-plus decades, Ms. Waldman has performed a number of roles and been a part of numerous significant achievements for the ARC. Working with functional area executives to establish quality, compliance, and regulatory strategies, Ms. Waldman also served as liaison between the ARC and the FDA on all consent decree issues. Ms. Waldman began her career at the ARC in the Information Technology department in 1985, moved into the Biomedical Services department, and was key in helping to establish national testing laboratories between 1992 and 1995. She has also served as the senior project director in establishing the first ARC nucleic acid testing laboratory for the human immunodeficiency and hepatitis C viruses. She was recognized by ABC as a 2000 Laboratory Public Service National Leadership Award recipient. Ms. Waldman assumed her last role with the organization in 2010 and was instrumental in the FDA-Red Cross Working Group.

MEETINGS

June 9 - 11 **14th International Cord Blood Symposium, San Francisco, Calif.**

AABB, with support from the Cord Blood Association, will host the 14th International Cord Blood Symposium from June 9 to 11 in San Francisco, Calif. The scientific program brings all of the umbilical cord blood related fields of hematopoietic stem cell transplantation, banking, and potential in regenerative medicine together in one interactive three-day conference. The program, registration details, and other information can be found here.

August 1 - 4 **ABC 55th Summer Meeting Honolulu, Hawaii**

Registration has begun for the ABC 55th Summer Meeting in Honolulu, Hawaii, hosted by Blood Bank of Hawaii, will take place August 1 to 4, 2016 at the Hilton Waikiki Beach. It will feature the ABC Medical Directors Workshop and the Foundation for America's Blood Centers Golf Tournament. Click to register.

September 8 **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.**

This free, first-come-first serve, public workshop titled the Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products (HCT/Ps) subject to premarket approval, including stem cell-based products. The workshop will take place at White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room in Silver Spring, Md.

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MEETINGS (continued from page 10)

September 12 - 13 **FDA Public Hearing on HCT/Ps, Bethesda, Md.**

Early registration for this public hearing to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products will last until June 1. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found 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 6 percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS AVAILABLE:

Manager, Donor Services – Mobiles. The Donor Services Manager, Mobiles is fully trained as a Donor Services Technician (Phlebotomist); this includes the collection of whole blood on mobiles, as well as center environments, autologous and therapeutic collections and technologies of automated equipment. Carries out supervisory/managerial responsibilities either directly or indirectly in accordance with the organization's policies and applicable laws. Ability to delegate and ensure accountability of job performance; provides documentation of performance/disciplinary issues as needed and/or positive reinforcement. Ensures training courses are developed and executed in a timely manner. Analyzes departmental measurements/metrics such as deferral rates, QNS rates, split rates, errors, staff turnover, etc. Develops and executes process improvement plans to meet and maintain compliance and quality standards. Implements direct process improvement plans to meet annual collection goals, to enhance quality, to enhance the donor experience and encourages donors to support their community blood program. Oversees mobile collections problem trends and supports corrective actions required to sustain continuous improvement across the organization. Assures effective internal and external communication between all department levels and functions to foster teamwork and enhances operational success. Continually develops, mentors and supports staff to reach their full potential; in achieving independent and efficient work status. Assists in mobile collections as needed. Apply online at www.cbcc.us/careers.

Apheresis Registered Nurse. The Apheresis Registered Nurse is responsible for supporting and monitoring standard operating and special blood banking procedures to ensure safety of blood products and alignment with organization goals and compliance with regulatory guidelines. This position will be responsible for assisting with donor counseling function for reactive testing markers and to serve as a resource RN for blood bank personnel, donors and the public. Must be able to create and maintain accurate, detailed reports and records. Must be able to work independently and have critical thinking skills. This position is full-time non-exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, a health and wellness program, and a 401 (k) program are also available. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply online at www.bloodbankofalaska.org.

Performance Improvement Specialist. The Stanford Blood Center is seeking a Performance Improvement Specialist. Under the direction of the Process Improvement Director, the Performance Improvement Specialist will develop, implement and manage approaches leadi

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ng to continuous improvement of processes for the testing laboratories, blood manufacturing and operational departments. This includes driving change on process innovation projects across multiple departments, vendors or clients. Use business intelligence to help end-users analyze current and alternative processes that could lead to improved performance and goal-reaching. Work with key leaders to develop metrics to ensure operations are meeting outcomes, service and quality objectives. Qualifications: Four (4) year college degree in medical technology, biology, life science or work-related field/discipline required. Three (3) years of relevant experience in a blood center, clinical laboratory, process/quality improvement, project management or relevant work-related field/discipline required. Certifications & Licenses: None required, however the following licenses or certifications are preferred: MT, CLS, or SBB; Lean Six Sigma certification; Project Management certification; Business Intelligence software certification (i.e., Tableau, SQL, Crystal). We are not able to provide relocation or sponsorship for this position. For a complete job description & to apply online go to: http://www.stanfordhealthcarecareers.com/ Job#36590. Thank you for your interest!

Quality & Regulatory Affairs Specialist. Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the supervision of the director of Quality and Regulatory Affairs, this position will perform the quality and regulatory affairs duties and responsibilities with special emphasis on safety by reviewing department procedures, training documents, product and equipment quality control (QC), change control processes and validations, and assist with development. 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, and process improvement; maintains compliance by enforcing applicable regulations and standards set by regulatory agencies and reporting. Qualifications include: Four year college degree and at least three years of blood banking and/or product/device manufacturing experience with solid familiarity of GMP, safety in a manufacturing setup, CAL-OSHA regulations. Exceptional attention to detail, organization skills, flexibility, prioritize tasks; effective communication skills verbal and written, collaborative interpersonal skills, problem solving, analyze/evaluate complex situations; work independently, initiate improvement ideas to enhance quality and safety programs; develop and train staff. Safety Management, Environmental Health & Safety Training, and/or Disaster Management Certification are highly desirable. For a complete job description & to apply online go to: http://www.stanfordhealthcarecareers.com/ Job# 36898.

Medical Director (16000321). Blood Systems is seeking a full-time, clinically-focused Transfusion Medicine physician to join its Medical Affairs team. The Medical Director is responsible for coordinating communications between the blood center leadership in Denver, the local medical community, and Corporate Medical Affairs in Scottsdale, AZ. Responsibilities include consultation and visits with hospital staff and clinicians, patient blood management oversight, CLIA laboratory directorship, and medical direction to collections, manufacturing, research/specialized donations, NMDP and reference laboratory functions. Qualifications include an MD or DO, board certification in CP with board eligibility / certification in Transfusion Medicine (within two years of hire) or certification in IM or Pediatrics with Hematology certification. Fellowship training in Blood Banking / Transfusion Medicine or Hematology, or three years' experience at a blood center or hospital blood bank is required. Previous research experience is preferred. Current or prompt licensure will be required within Colorado and neighboring states. Relocation assistance will be considered. For immediate consideration, please apply on our website www.bloodsystems.org **no later Tuesday, May 31, 2016** – req. # 16000321. Blood Systems Inc. is an equal opportunity employer.
EEO/Minorities/Females/Disabled/Veterans