America's Blood Centers®
It's About Life.

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

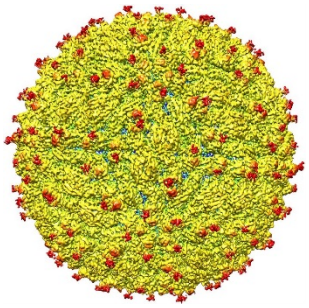
Issue #27
July 29, 2016

Local Zika transmission in Florida provokes FDA response; testing already online in many centers.

Florida has the first vector-borne Zika virus (ZIKV) infection cases in the continental U.S. Since July 15, four cases in Broward and Miami-Dade counties have come under investigation, none of whom appear to have had traveled to affected areas or sexual contact with other people infected with ZIKV.

"The individuals do not have travel history themselves," State Surgeon General Celeste Philip said, as quoted by the *Miami Herald*, at the Broward health department in Fort Lauderdale. And Tom Skinner, a spokesman for the Centers for Disease Control and Prevention, told *Reuters*, "Evidence is mounting to suggest local transmission via mosquitoes is going on in South Florida." The Centers for Disease Control have stated they believe there is a link between local mosquitoes and the four cases. A total of 49 new Zika infections were reported in Florida in the past week, making the state's total number of ZIKV cases 383, according to the Florida Department of Health.

In response, the Food and Drug Administration advised that blood centers in Miami-Dade and Broward County halt collections as of July 27, 2016, ***UNTIL*** the centers are able to test each unit for ZIKV RNA or until they have an approved or investigational pathogen inactivation technology that can inhibit the spread of ZIKV. That testing is live at all OneBlood donation sites as of yesterday and LifeSouth blood center in Gainesville, Fla., both of whom are now screening 100 percent of their Florida blood donations. LifeSouth will be expanding their testing into their Georgia and Alabama locations by next Tuesday as well, said Jill Evans, vice president of Quality at LifeSouth. Other Florida centers are considering and developing their testing options, anticipating that the virus may not remain contained in Miami-Dade and Broward. The FDA has also advised



blood centers in nearby and adjacent counties to implement the same precautions and blood centers around the country will be adding the affected areas to their lists that trigger donor deferral for travel within four weeks.

Blood centers in the area are dealing, as are many centers nationwide, with what has proven to be a fairly tight blood supply this summer. The confluence of constraints on the blood supply, including donor losses from the raised hemoglobin cut-off for men, the Haemonetics filter recall, and the added Zika travel deferrals,

(continued on page 3)

INSIDE:

OUR SPACE

ABC Chief Medical Officer Louis Katz, MD

Oy Vey!

Some blood centers are testing for Zika viral RNA using investigational new drug (IND) protocols cleared by the Food and Drug Administration (FDA) and more will soon or are considering doing so. FDA has ***required*** that ***test-negative*** blood components be labeled "negative for Zika virus by an investigational test". The FDA also ***recommends*** that an appropriate "acknowledgment" or consent be obtained prior to transfusion of high-risk recipients via a labeling supplement or modification of the circular of information. Here is language accepted by FDA for one IND participant. For "areas of active transmission or donations collected from individuals with known risk factors, it is recommended that an appropriate acknowledgment or consent be obtained prior to transfusion of a high risk recipient, e.g., a fetus in utero or pregnant woman." You can imagine that this is causing some consternation at centers and hospitals. Dr. Susan Stramer at the American Red Cross and I are fielding urgent inquiries from our clinical friends asking what they should be doing (and why).

Untested units require no such labeling and there is no recommendation they be infused with recipient consent or acknowledgment regarding Zika. The agency's intent is to ensure that recipients of blood components are aware that because of a potential risk of acquiring Zika virus through transfusion and its consequences, the blood was tested for Zika with an investigational assay. The language about informing and consenting patients and their surrogates is a ***recommendation*** that FDA required in the INDs—FDA has not previously tried to regulate the bedside interactions of clinicians with individual patients when testing INDs were used (e.g. HIV, HCV and WNV).
Some questions come to mind.

1. How was it determined that the risk from Zika-tested components justifies these actions?
2. Who, other than a fetus *in utero* or a pregnant woman, is at high risk—i.e. what patients are subject to the recommendation?
3. If you were a "high risk recipient", would you accept such a unit or prefer an untested unit with no such "warning"? Is the unintended message that the tested unit is somehow "less safe"? Is it possible that necessary transfusion will be delayed or refused?
4. Why are we not recommending the approach for other individual recognized transfusion-transmitted pathogen—especially those for which we expect the risk is higher than for Zika e.g. WNV, babesiosis in highly endemic states, bacteria in platelets? Serious non-infectious hazards that are more common and arguably cause more morbidity?
5. Is it appropriate that the agency inserts itself at the bedside, where its regulatory authority is limited, via the IND process where its authority is unchallenged as opposed to via more transparent routes like the guidance process?

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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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APPARENT LOCAL ZIKA TRANSMISSION (continued from page 1)

caused AABB, ABC, and the American Red Cross to issue a joint appeal since July 11, and a number of ABC members made similar requests to their communities.

ZIKV donor screening assays for use under an Investigational New Drug (IND) application are available from Roche Molecular Systems on the cobas 6800/8800 and from Hologic on the Panther instrument. Under IND, as many as about 1 percent of donors in Puerto Rico, where there is a large vector-borne outbreak, are positive. Testing by a number of centers in the continental United States has not yet identified infected donors after testing of around 70,000 donations.

ZIKV in platelet and plasma units can be inactivated with pathogen reduction technology, like Cerus Corporation's INTERCEPT technology, and are considered safe for transfusion per the FDA's guidance from February 16.

The Food and Drug Administration (FDA) Grants Variances for Zika Area Deferrals

The FDA has granted some blood centers verbal variances to not defer prospective donors based on a history of traveling to or living in areas with active Zika virus transmissions, as long as the centers continue to test 100 percent of the individual donations. Read a full variance request here.

Data Hijackers Could Turn You Non-Compliant

The latest wrench in a digital hacker's toolbox is gaining popularity—ransomware. Ransomware attacks have increased by over 300 percent since 2015, and occur daily at a rate of about 4,000 per day, reads a recent interagency report from the federal government. Ransomware is a type of malware, or malicious software, which essentially hijacks the user's computer—blocking the user from accessing his/her data—until a sum of money is paid. If the demands are not met, files can begin to be deleted forever.

For those organizations that must adhere to HIPAA regulations, ransomware can be especially problematic. Not only are files containing personally identifying information being hijacked (and possibly sold to identity thieves), but non-compliant with HIPAA security regulations can severely harm an organization's ability to stay in operation.

(continued on page 4)

DATA HIJACKERS (continued from page 3)

How do you prevent this?

Some suggestions laid out in a fact sheet from the Department of Health and Human Services (HHS) for those under HIPAA security regulations, include:

- Implementing a security management process, which includes conducting a risk analysis to identify threats and vulnerabilities to electronic protected health information (ePHI) and implementing security measures to mitigate or remediate those identified risks;
- Implementing procedures and applications that can detect and prevent malware;
- Training staff and users on safe internet use and malware protection so they can assist in detecting malware and how to report such detections; and
- Limiting access controls to ePHI to only those persons or software programs requiring access.

The HIPAA Security Rule also requires organizations, like blood centers, to have and follow a data back-up plan. But because some ransomware attacks have been known to block online backups, maintaining an offline backup, unavailable from networks, should also be performed to safeguard against hackers.

Business continuity plans should also be laid out as well as easy to implement in case a ransomware attack ever exists. A business continuity plan helps ensure the victim-organization is able to continue with business as usual while responding to the attack.

How to respond to a ransomware attack?

- Detect and conduct an initial analysis of the ransomware;
- Contain the impact and propagation of the ransomware;
- Eradicate the instances of ransomware and mitigate or remediate vulnerabilities that permitted the ransomware attack and propagation;
- Recover from the ransomware attack by restoring data lost during the attack and returning to "business as usual" operations; and
- Conduct post-incident activities, which could include a deeper analysis of the evidence to determine if the entity has any regulatory, contractual or other obligations as a result of the incident (such as providing notification of a breach of protected health information), and incorporating any lessons learned into the overall security management process of the entity to improve incident response effectiveness for future security incidents.

If you believe a ransomware incident has occurred at your organization, you are required to report the incident and respond to it, more information can be found here. To find out more about ransomware and how to respond to an attack, visit HHS' Fact Sheet on Ransomware and HIPAA.

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter.* Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Lisa Spinelli at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

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INSIDE ABC

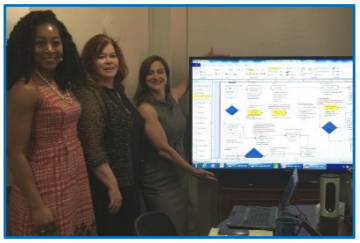
The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

Dr. Anthony S. Fauci Speaks to the Press About Zika

ABC members were represented when Dr. Fauci, director of the National Institute of Allergy and Infectious Diseases, spoke on Zika's emergence as a "pandemic in progress" at the Bipartisan Policy Center in Washington, D.C., on July 29. CEO Dr. Christine Zambricki had the opportunity to speak to the press regarding the critical role that ABC member centers play in providing a safe blood supply, including donor deferrals for travel to Zika areas and testing per the Food and Drug Administration guidelines.

Dr. Fauci warned that what we are seeing in the Americas has not been seen before with Zika, which has historically been an inconsequential virus until linked to microcephaly. Although the numbers are changing rapidly, at present, there are 1,658 Zika cases in the continental U.S. and 4,750 in the U.S. territories, with 433 pregnant woman who have been infected with travel related Zika. Dr. Fauci stated in no uncertain terms that women who are pregnant or anticipate getting pregnant should refrain from traveling to areas with local transmissions of Zika. When asked about funding for Zika research and abatement, Dr. Fauci expressed frustration at the politicization of the issue and he expressed hope that Congress will be effective in passing a funding bill when they return from recess.

Help Us Give the Newsletter a Facelift



After spending a day in Lean Six Sigma training a week ago, we here at ABC are working to make the newsletter process more efficient and ensure we are meeting the needs of our readers. We examined the weekly process of creating and developing the newsletter and asked a lot of poignant questions about this decades-old mainstay of America's Blood Centers. What we have determined is that we want your feedback to ensure we are delivering the product you crave.

Please find five minutes to take this extremely brief survey so we can ensure we are delivering the best possible product to you. Thank you in advance!

Register for the IT Workshop

Join the ABC IT Workshop on September 13 and 14 at The Depot Renaissance Minneapolis Hotel in Minneapolis, Minnesota. Member center experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more about this workshop, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.

RESEARCH IN BRIEF

In a follow-up of two cohorts of blood donors and their recipients in the United Kingdom, deemed to be at high-risk for variant Creutzfeldt–Jakob disease (vCJD), both the donors and their recipients remained disease-free and asymptomatic after 10 years. Four transmissions (three associated with illness) of the vCJD prion by transfusion have been reported in the U.K. Two U.K. cohorts were assembled to better characterize their risk. The first was donors (n=112) whose recipients later died from vCJD, and the second was other recipients of blood from those donors (n=33). After 2,397 and 492 person-years of follow-up respectively, there were no deaths from vCJD in either group.

Citation: Checchi M., Hewitt P. E., Bennett P., *et al.* Ten-year follow-up of two cohorts with an increased risk of variant CJD: donors to individuals who later developed variant CJD and other recipients of these at-risk donors. *Vox Sanguinis*. July 19, 2016 Early View. DOI: 10.1111/vox.12426.

Drinking 500mL of (hypotonic) water or an isotonic solution just before giving blood helps prevent donors from feeling faint and/or fainting. A prospective cluster-randomized trial compared 4,576 whole blood donors for reactions after drinking 500 mL of water or 500 mL of an isotonic fluid, or being given advice to drink (control group) before donating blood—coupled with or without muscle tensing exercises. At two regional blood centers in France and one mobile unit, those who hydrated just before donating blood had a lower instance—5.5 percent—of presyncope and syncope reactions at the donation site or within 48 hours after donating. Drinking 500 mL (isotonic solution or water) significantly reduced the rate of events (odds ratio [OR], 0.74; 95 percent confidence interval [CI], 0.55-0.99) independently of muscle tensing exercise. Muscle tensing exercises also reduced the risk of on-site reactions during donation (OR, 0.64; 95 percent, CI, 0.42-0.98), and an isotonic drink significantly reduced delayed off-site syncopal-type reactions (OR, 0.62; 95 percent CI, 0.40-0.98) along with a lower chance of tiredness after donation (OR, 0.75; 95 percent CI, 0.59-0.94).

Citation: Morand C., Coudurier N., Rolland C., *et al.* Prevention of syncopal-type reactions after whole blood donation: a cluster-randomized trial assessing hydration and muscle tension exercise. *Transfusion*. July 24, 2016 Early View. DOI:10.1111/trf.13716.

Treating plasma with the THERAFLEX MB-Plasma system can reduce infectivity of all four serotypes of dengue virus (DENV) and chikungunya virus (CHIKV) of donated units, concluded a new study. DENV and CHIKV remain risks to the safety of transfusion in endemic countries. THERAFLEX MB-Plasma system treats plasma with methylene blue and light and has been shown active against West Nile virus, hepatitis C, and HIV-1, among others. In this study, pooled plasma units were inoculated with dengue virus serotype DENV-1, DENV-2, DENV-3, or DENV-4, or CHIKV and treated with the THERAFLEX MB-Plasma system at four ultraviolet light illumination doses: 20, 40, 60, and 120 (standard dose) J/cm^2. Viral titers (infectivity in culture) and RNA loads were measured before and after each illumination dose. DENV and CHIKV were reduced to the limit of detection at 40 J/cm^2 with a reduction for DENV-1, 2 and 3 of ≥5.17 log and ≥6.58 log for CHIKV. Denv-4 virus reduction reached the limit of detection at 60 J/cm^2, with a log reduction level of ≥4.46.

Citation: Fryk J., Marks D., Hobson-Peters J., *et al*. Dengue and chikungunya viruses in plasma are effectively inactivated after treatment with methylene blue and visible light. *Transfusion*. July 25, 2016 Early View. DOI: 10.1111/trf.13729.

Cardiopulmonary transfusion reactions are severely underreported according to REDS III investigators. This record review of randomly selected transfusion recipients included 17 percent of inpatient transfusion episodes over more than six months at four academic tertiary care hospitals. In total, 4,857 transfusion episodes (for all blood products) were abstracted and 1.1 percent of episodes were associated

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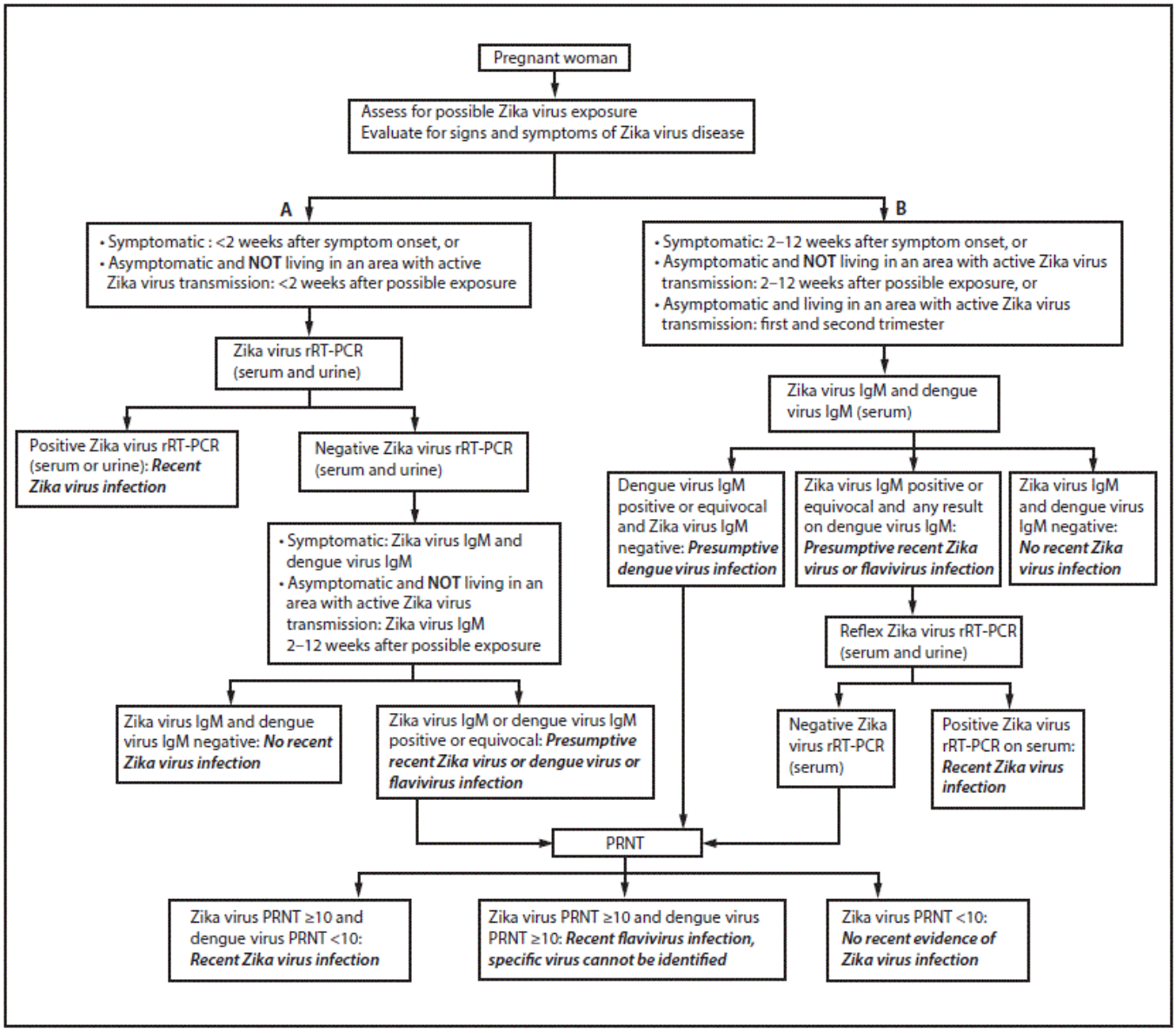
RESEARCH IN BRIEF (continued from page 6)

with a serious transfusion-associated reaction, with circulatory overload being the most frequent serious reaction (1 percent). Trained clinical research nurses recorded relevant information and a panel of transfusion medicine experts adjudicated the reactions. Clinical documentation identified 59 percent of the cases, but only 5.1 percent were reported to the transfusion service. This discrepancy highlights the failure of passive reporting systems, noted the researchers.

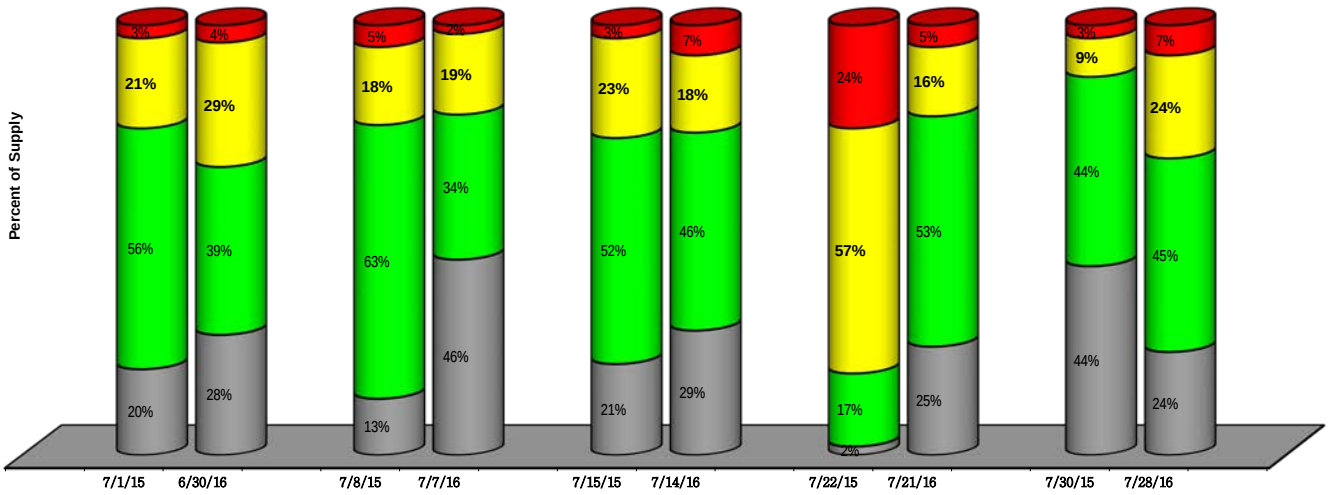
Citation: Hendrickson J.E., Roubinian N.H., Chowdhury D., *et al*. Incidence of transfusion reactions: a multicenter study utilizing systematic active surveillance and expert adjudication. *Transfusion*. July 26, 2016 Early View. DOI:10.1111/trf.13730.

BRIEFLY NOTED

The Centers for Disease Control and Prevention (CDC) released updated recommendations regarding how pregnant women with possible Zika virus exposure should be evaluated and cared for. This chart demonstrates the complexity of the interim guidance. (Source: CDC MMWR, July 25, 2016.)



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



No Response	Green: 3 or More Days	Yellow: 2 Days	Red: 1 Day or Less

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

INFECTIOUS DISEASE UPDATES

***Aedes aegypti* and *Aedes albopictus* mosquitoes remain the most likely candidates for spreading Zika virus (ZIKV) in the U.S., reports the Centers for Disease Control and Prevention.** In a controlled laboratory study at the University of Wisconsin–Madison, the *Culex (Cx.) pipiens* and *Aedes triseriatus* mosquito species were tested for their ability to become infected and transmit ZIKV. *Aedes aegypti* and *Aedes albopictus* were used as controls. Researchers found *Cx. pipiens* mosquitoes were negative for ZIKV by plaque assay in their ability to be infected and transmit the virus. And even though *Ae. triseriatus* mosquitoes were able to become infected with Zika, they were unable to transmit the virus.

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Citation: Brooks J., Friedman A., Kachur R., *et al.* Update: Interim Guidance for Prevention of Sexual Transmission of Zika Virus — United States, July 2016. *MMWR Morb Mortal Wkly Rep*. ePub: July 25, 2016. DOI: http://dx.doi.org/10.15585/mmwr.mm6529e2.

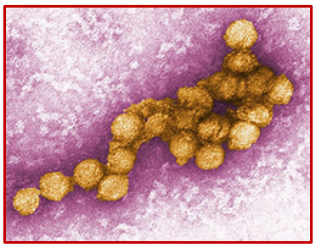
A Canadian site will join the two U.S. sites conducting human clinical trials for a DNA-based Zika vaccine. The Food and Drug Administration approved the phase one study last month from GeneOne Life Science Inc., a Seoul, Korea-based company, and Inovio Pharmaceuticals in Philadelphia. Health Canada has now approved the Universite Laval to join Miami Research Associates and the University of Pennsylvania in testing the vaccine. The trial is still recruiting participants for all three sites with a total of 40 participants expected to join. Testing is expected to begin in the next few weeks, but a vaccine won't be available for years to come. (Source: *Toronto Sun*, Quebec researchers get approval to begin testing Zika vaccine on humans. July 20, 2016; ClinicalTrials.gov, July 22, 2016.)

WORD IN WASHINGTON

The Food and Drug Administration (FDA) is establishing a public docket for comment on the blood donor deferral recommendations for reducing the risk of human immunodeficiency virus (HIV) transmission.

Comments to the document are invited, based on and with scientific evidence attached. One possible policy change the FDA listed in their document was to alter the men who have sex with men (MSM) 12-month deferral policy to an individual risk assessment. U.S. Representative Mike Quigley (D-Ill.) released a statement last week praising the FDA for the docket and its reexamination of the MSM blood donor policy after the Orlando Pulse nightclub shooting when many gay men were deferred from blood donation centers.

(Source: FDA, July 26, 2016.)



A new strain of West Nile virus (WNV) may be surfacing in the U.S. Investigators from the Food and Drug Administration (FDA) published insights into genetic changes of the WNV since its U.S. emergence in 1999. Samples from the 2012 U.S. outbreak from 19 WNV-infected donors were sequenced and compared to samples obtained from 1999 to 2012. Several mutations were identified. The study found that genetic variants could have been spread over the nation by migratory birds. Such data can yield insights important for vaccine-development and to maintain the performance of donor screening tests.

Citation: Grinev A., Chancey C., Volkova E., *et al.* Genetic Variability of West Nile Virus in U.S. Blood Donors from the 2012 Epidemic Season. *PLOS Neglected Tropical Diseases*, May 16, 2016. DOI: http://dx.doi.org/10.1371/journal.pntd.0004717.

REGULATORY NEWS

The Food and Drug Administration (FDA) updated a guidance "Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma" last week. This final guidance recognizes version 2.0 of the Plasma Protein Therapeutics Association's (PPTA) standardized Source Plasma full-length and abbreviated donor history questionnaires. The guidance can be implemented immediately. Version 2.0 reflects changes necessitated by recent changes in FDA regulations and the guidance reflecting changes to the men who have sex with other men (MSM) policy. While PPTA's questionnaires are designed to meet U.S. FDA requirements, version 2.0 also includes alternate and optional questions that allow plasma sourcing companies to meet European requirements as well, said Vice President of Global Medical and Regulatory Policy at PPTA Mary Gustafson. (Source: FDA, July 22, 2016.)

The proposed 8th edition of Standards for Cellular Therapy Services draft from AABB is open for public comment until August 24. Changes include donor eligibility modifications for emerging viruses, processing test requirements for non-HPC products as well as full ISBT 128 implementation. Comments may be submitted online. The 8th edition will go into effect on July 1, 2017. (Source: AABB Weekly Report, July 22, 2016.)

MEMBER NEWS

New York Blood Center announced it will be combining operations with Innovative Blood Resources. Their new partnership comes on the heels of NYBC's highly successful 2014 alliance with Community Blood Center of Greater Kansas City (CBC). New York Blood Center Chairman Howard P. Milstein said in a statement, "IBR is an ideal partner for our center, and we welcome them to the NYBC family. As the market for blood services and products evolves, we believe this combination will be of great benefit to both organizations as we continue to provide the highest quality blood products, services and cutting-edge research and development." More news on how any structural or operational changes will take place were not immediately divulged. (Source: New York Blood Center, July 28, 2016.)

Last week, Indiana Blood Center sent out a statewide letter thanking donors and organizations who answered their pleas for help during a time of critically low supply of blood products (one day supply of blood left). But the letter called on organizations and the people of Indiana to not just respond in a time of crisis, but to think about donating on an ongoing basis. On the next page is an excerpt of the letter from IBC's president and CEO, Charlie Miraglia, that was published by the *Indiana Business Journal* along with other local news sources.

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Save-the-Date

ABC Quality Education Webinar
"ZIKA and ABC Blood Centers Update"
on August 16, 3:00-4:30 p.m. EDT.
Registration details to follow.

MEMBER NEWS (continued from page 10)

"We put out the call and saw nearly 2,000 donors over the three days that followed. Thanks to those organizations that hosted blood drives with us during that time and the individual donors who visited our donor centers, the inventory of transfusion-ready units is again stable.

Our community was at risk on July 14.

The blood supply is the people's asset. We are vulnerable—the blood supply is vulnerable—if it is top-of-mind only in a crisis. What's more, we fail on our responsibility to our hospitals—and on our responsibility to each other—when the greatest turnout of blood donors occurs when we are in such a dire position that patients are at risk.

Success is convincing 500 Hoosiers, one donor at a time, today is a good day to step up and donate blood. Each night, that measure of success resets…

I appeal to you as business and community leaders. Please, engage in our cause. You are the gateway to your organization's greatest asset—your people. Likely, you already host blood drives. Are you personally involved? Your organization likely contributes thousands of dollars to community causes. How many units of blood do you donate?"

Save-the-Date

ABC Government Affairs Committee Webinar
"Advocacy Update"
on August 15, 4:00-5:00 p.m. EDT.
Registration details to follow

COMPANY NEWS

Blood Bank Computer Systems, Inc. (BBCS) announced the Food and Drug Administration (FDA) has cleared for ABO Express™, Version 2.0.0, for general distribution. ABO Express, an application aimed at reducing blood centers' costs and improving processing, marks the last product in a series of FDA clearances for ABO Suite™.

The key features of ABO Express include a Web-accessible graphical user interface and seamless communication with ABO Wheels and paperless donation records. ABO Express also allows for third-party plug-ins that can be directly connected to the system. In its announcement, BBCS thanked ABC member center Blood Bank of Delmarva and the Blood Center of Central Texas for being their two pilot program participants and who "have paved the way for ABO Suite."

MEETINGS

August 1 **6th Annual Links for Life Golf Tournament, Honolulu, Hawaii**

Held in conjunction with the Summer Meeting, the Links for Life golf tournament has developed into a successful and fun annual fundraiser for the Foundation for America's Blood Centers. This year's tournament will take place at the beautiful Kaneohe Klipper Golf Course in Honolulu, Hawaii. Ranked as one of the world's best military courses, your golf score will be second to the breathtaking ocean and mountain views you will enjoy while playing.

August 1 - 4 **ABC 54th Summer Meeting, Honolulu, Hawaii**

ABC 54th Summer Meeting in Honolulu, Hawaii, hosted by Blood Bank of Hawaii, is on August 1 to 4 at the Hilton Waikiki Beach on Kuhio Ave. It will feature the ABC Medical Directors Workshop and the Foundation for America's Blood Centers Links for Life Golf Tournament. Contact Lori Beaston for more information.

Sept. 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 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.

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

This public hearing was created to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found here.

Sept. 13 – 14 **ABC IT/Workshop, Minneapolis, Minn.**

Experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.

Sept. 21 **Red Cell Genotyping 2016: Clinical Steps, Bethesda. Md.**

The BloodCenter of Wisconsin (BCW) and the Department of Transfusion Medicine at the National Institutes of Health (NIH) Clinical Center, are co-hosting the 6th Annual Red Cell Genotyping Symposium at Lister Center Auditorium, National Library of Medicine, NIH Building 38A, 8600 Rockville Pike, Bethesda, Md., from 8:25 a.m. to 4:15 p.m. This symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. For information,

(continued on page 13)

MEETINGS (continued from page 12)

program fee and advance registration visit BCW's website or contact Phyllis Kirchner phyllis.kirchner@bcw.edu.

Oct. 31 – Nov. 1 **FDA 510(k) Submissions Workshop, Washington, D.C.**
AdvaMed hosts FDA and industry experts to teach the basics of 510(k) submissions. Learn about the FDA's updates to the 510(k) process, considerations for determining a product's regulatory route to market, factors to consider when planning and assembling a 510(k) submission. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register here.

Nov. 2 **FDA IDE Submissions Workshop, Washington, D.C.**

Learn the regulatory and practical guidelines governing when an investigational device exemption is required during this interactive AdvaMed workshop. The workshop will take place at Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register here.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: lmaundy@americasblood.org.

POSITIONS

Clinical Care/Specialty Services Supervisor (Patient Services Supervisor; DeGowin Blood Center). Required Qualifications: Baccalaureate Degree in Nursing, Professional Masters of Nursing and Healthcare Practice (MNHP), MSN/Clinical Nurse Leader or a Master's Degree in Nursing (MSN, MA). Current license to practice nursing in Iowa. Three to five years nursing experience. Must be proficient in computer software applications. Demonstrates excellent interpersonal skills. Demonstrated leadership abilities and skills. Highly Desired Qualifications: Experience working in an academic health care center. One to three years clinical apheresis experience. Knowledge of FDA, AABB, College of American Pathologists (CAP), Foundation for the Accreditation of Cellular Therapy (FACT) and National Marrow Donor Program (NMDP). Experience using highly specialized medical equipment. For a complete listing of job qualifications and **to apply for this position, please visit our website at** http//jobs.uiowa.edu**, reference requisition #69438.** Applicable background checks will apply. The University of Iowa is an equal opportunity I affirmative action employer. All qualified applicants are encouraged to apply and will receive consideration for employment free from discrimination on the basis of race, creed, color, national origin, age, sex, pregnancy, sexual orientation, gender identity, genetic information, religion, associational preference, status as a qualified individual with a disability, or status as a protected veteran.

Assistant Director, Planning Operations. Under the direction of the Executive Director, Blood Operations you will be responsible for developing and implementing logistical support for the optimal blood donor group schedule, assuring consistent achievement of annual, monthly and daily collection goals. The Assistant Director will assure the department directs customer-driven decisions, focused on an even input of blood, while emphasizing cost controls. This position is responsible for facilitating cross-functional communication as it relates to the production plan to assure strategic initiatives are consistently achieved (cost/revenue, customer, and people). Requirements: Bachelor's degree required, preferably in Business, Finance, or Logistics; Two year supervisory experience; Experience with computer appli

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POSITIONS (continued from page 13)

cations and data base management required; One-year of metrics-based decision-making preferred; Hemasphere, e-Donor, and Crystal Reports desirable; and Texas Operators driver's license. South Texas Blood & Tissue Center, a subsidiary of BioBridge Global, is proud to be an Equal Opportunity Employer committed to providing employment opportunities to minorities, females, veterans, and disabled individuals. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, protected veteran status, genetic data, sexual orientation, gender identity, or any other legally protected characteristics. For more information please apply at: http://bit.ly/2aPA9FW.

Mobile Supervisor, RN (Location: San Bernardino, CA; Schedule: Full-time, 4/10 and Part-time, 3/8 schedules available). Position Summary: Functions as a leader, decision-maker, and member of the LifeStream Management Team. Supervises the operation of different Mobiles, monitors Mobile staff performance, as well as performing duties of Staff Nurse. Performs donor/patient phlebotomy and sample collections including automated procedures if trained. Conducts medical history interviewing and physical assessment. Oversees the safe, procedurally correct, and customer-oriented collection, storage, and transport of blood. Organizes mobile departures, set-up, operations, and return to LifeStream. Serves as a liaison between Mobile Chair people and LifeStream. Completes documentation on Mobile Summaries, Injury and exposure documentation as needed, etc. Conducts deferrals/eligibility overrides per procedure as required. Provides feedback to Management regarding staff performance and assists in presenting employee performance reviews. Education and Experience: Associate's degree (AS) in Nursing. Minimum one year of generalized nursing and/or Clinical and Supervisory experience. Current California Registered Nurse (RN) License and current CPR Certification. Current valid California Driver's License. For further information and to apply online please visit: www.LStream.org. Must pass pre-employment background check, and drug screen. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal governments Everify program to determine employment eligibility.

Registered Nurse II (Location: San Bernardino, CA; Schedule: Monday, Thursday, Friday, and Saturday OR Monday, Tuesday, Friday, and Saturday). Position Summary: Conducts donor and patient interviews, physical assessments, and phlebotomies. Oversees donation process and recovery. Depending on location, work includes performing Whole Blood, special services, and multiple Component Collections in order to provide excellent customer service and to produce safe quality blood products for patients. May be required to learn and maintain skills on multiple Apheresis Technologies based on organizational need. Gives attention to detail and conducts work according to Policy, Procedure, and Regulatory Guidelines. Works as a positive team player to provide effective donor/patient processing. Assumes charge RN responsibilities as assigned. Works at other draw locations as needed. Education and Experience: AS Degree in Nursing. Minimum three months to one year of generalized Nursing and/or Clinical experience. Current California Registered Nurse (RN) License and current CPR Certification. Current valid California Driver's License. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the federal governments E-Verify program to determine employment eligibility. For further information and to apply online please visit: www.LStream.org.

Supervisor, Telerecruitment (Location: San Bernardino, CA; Schedule: Monday through Friday; 8:00 am to 4:30 pm). Summary: This position supervises the daily operation of the Telerecruitment department ensuring assigned staff are providing an adequate community blood supply by contacting donors for blood donations. This position is responsible for evaluating employees' efficiency and productivity through direct observation and production records, conducting training and coaching to staff as needed on a daily basis. This position is also responsible for meeting monthly individual goals established by the manager of Telerecruitment and the director in charge of Telerecruitment. The Telerecruitment Supervisor is also responsible for the daily operations of the dialer, recruitment campaigns, call performance and departmental performance metrics. The ideal candidate will have a high school diploma or GED. Bachelor's degree preferred. Minimum three years' Telerecruiter experience or comparable field. Supervisory experience especially in a customer service environment is highly preferred. For further information and to apply online please visit: www.LStream.org. Must pass pre-employment background check, and drug screen. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal government E-verify program to determine employment eligibility. Job Number: IN-4255164474

Advanced Clinical Lab Specialist - IRL. Blood Systems is one of the nation's oldest and largest comprehensive transfusion medicine organizations. We serve blood centers, hospitals and health systems, offering shared management and support services, quality excellence and effective contracting. Strong. Diversified. Vertically integrated. A modern transfusion medicine organization, Blood Systems brings together the benefits of a lean and effective centralized support structure, a national scope and close-to-the-customer decision-making authority. Openings: 2nd shift, full-time, and part-time available. Qualifications: Bachelor's degree required; must satisfy CLIA requirements for High Complexity Testing required; California testing requirements must be met within one year required. Certification as a Medical Technologist or Blood Banking Technologist (BB) by a recognized certifying agency required. Blood Systems,

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POSITIONS (continued from page 14)

Inc. is an Equal Opportunity Employer. Apply at: http://www.bloodsystems.org/careers.html/. EOE/Minority/Female/Disability/Vets

Donor Services Specialist. Fresenius Kabi is a global health care company that specializes in lifesaving medicines and medical technologies for infusion, transfusion and clinical nutrition. Our employees – more than 30,000 worldwide – develop and deliver injectable pharmaceuticals and infusion systems; blood collection, transfusion and cell technologies; and essential nutrients for parenteral nutrition. We have an opportunity for a Donor Services Specialist who will work in our donor room in Lake Zurich, IL. Responsibilities include: Assist with subject recruitment and enrollment through database review; Assess eligibility, enroll and schedule subjects based on study protocol requirements; Perform whole blood collections and apheresis procedures as defined in the study protocol to support new products, product improvements, and product maintenance activities; Conduct review of laboratory test results and communicate status. Requirements: Clinical experience as either a Medical Assistant (MA), Licensed Practical Nurse (LPN), EMT or Registered Nurse (RN) (preferred) with current Illinois license; one to three years' experience in blood banking industry preferred; proficiency in phlebotomy skills; experience in whole blood collections and aphaeresis procedures preferred. To apply visit our website at: http://www.fresenius-kabi.us/career.html and search Keyword: LZD00070. Fresenius Kabi is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disabilities, or protected veteran status.

IRL Medical Technologist. The San Diego Blood Bank (SDBB) is a progressive and forward thinking company with a respected history of outstanding service and leadership in the blood banking industry. Synergies between SDBB, the community, the biotechnology industry and academic institutions allow us to save lives with quality blood services, innovative clinical research, new technologies, and health & wellness. With proactive and aggressive new approaches to core business, research, and sophisticated technology, SDBB is where you want to be! Openings: Night and Evening shifts available. Qualifications: Bachelor's degree in a biological science; MT(ASCP) / equivalent certification; SBB (ASCP) preferred; California State CLS or CIS License (or eligible); and a minimum of three years direct IRL experience preferred. The San Diego Blood Bank is an Equal Opportunity Employer. Apply at: https://sandiegobloodbank.applicantpro.com/jobs/. EOE/Minority/Female/Disability/Vets

Medical Laboratory Scientist. The Immunohematology Reference Laboratory at ARUP Laboratories is looking for a Medical Laboratory Scientist to join a team of experienced immunohematology reference laboratory technologists. The primary duty of IRL staff members is performing complex serologic testing. IRL technologists also participate in development and revision of procedures, consultation with medical directors, pathology residents and healthcare providers, mentoring and training new MLS and MLS students, and identification of rare donors. There is a career ladder available for promotion to Medical Technologist, Specialist position after one year experience at ARUP. ARUP Laboratories is a national clinical and anatomic pathology reference laboratory and a nonprofit enterprise of the University of Utah and its Department of Pathology. The ARUP IRL supports the complex transfusion service at the University of Utah Health Center, Huntsman Cancer Hospital and Primary Children's Hospital in addition to providing reference laboratory support for clients in Salt Lake City and surrounding area(s) as well as clients located throughout the U.S. This position requires a current MLS(ASCP) or MT(ASCP) and approximately five years' experience in a transfusion service, SBB is preferred but not required. This position requires participation in rotating technical on-call duties. Please apply online to posting #16-0733 at www.aruplab.com/careers.

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer's name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Publications Editor Lisa Spinelli at newsletter@americasblood.org. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

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) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)*

2016

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

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

Sept. 8. **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.** More information available here.

Sept. 12. **Red Cell Genotyping 2016: Clinical Steps, Bethesda. Md.** For information, program fee and advance registration visit our website or contact Phyllis Kirchner phyllis.kirchner@bcw.edu.

Sept. 12-13. **FDA Public Hearing on HCT/Ps, Bethesda, Md.** More information can be found here.

Sept. 13-14. **IT Workshop, America's Blood Centers, Minneapolis, Minn.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 21. **6th Annual Symposium Red Cell Genotyping 2016: Clinical Steps, Bethesda, Md.** Registration can be found here: www.bcw.edu/rcg2016. Contact: Phyllis Kirchner, Phyllis.kirchner@bcw.edu.

Sept. 22. **35th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** Registration can be completed here. Contact: Karen Byrne, kbyrne@cc.nih.gov.

Oct. 22-25. **AABB Annual Meeting, Orlando, Fla.** More information available here.

Oct. 31 – Nov. 1. **FDA 510(k) Submissions Workshop, Washington, D.C.** Find out more information and register here.

Nov. 2. **FDA IDE Submissions Workshop, Washington, D.C.** Find out more information and register here.

2017

Mar. 24-28. **Annual Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Mar. 25. **Board Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

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

Aug. 3. **Board Meeting, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Department. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.