ABC, AABB, and ARC Submit Joint Comments to FDA Zika Docket

America’s Blood Centers, AABB, and the American Red Cross (ARC) submitted comments to the U.S. Food and Drug Administration (FDA) Zika blood donor screening docket. The comments ask FDA to implement the Blood Products Advisory Committee recommendations for converting to minipool (MP) from routine individual donation (ID) nucleic acid testing (NAT). Further, they propose a triggering process similar to that used for West Nile virus (WNV) for conversion from minipool (MP) back to ID-NAT when local Zika activity is identified. “We respectfully repeat our urgent request that FDA re-evaluate the current policy using a risk-based approach, commit resources to expedite the process, and issue a final guidance permitting use of MP-NAT based on our recommended trigger/detrigger criteria.” The three organizations have asked for immediate direct final guidance permitting MP Zika screening to minimize the need for simultaneous Zika and WNV ID-NAT during the rapidly approaching WNV season. ABC members can view the comments in their entirety within MCN 18-024.

(Source: ABC, AABB, ARC Joint Comments, 6/14/18)

Is There an Association of Perioperative RBC Transfusion and Postoperative Venous Thromboembolism?

Each year, up to 200,000 (10 percent of) hospital deaths can be attributed to hospital-associated venous thromboembolism (VTE). Some researchers believe that up to 70 percent of these deaths can be prevented with appropriate mitigation strategies. Red blood cell (RBC) transfusion can be associated with a proinflammatory state, which may contribute to a prothrombotic state.

The National Surgical Quality Improvement Program database (a prospective registry administered by the American College of Surgeons at more than 500 diverse hospitals in the United States) has been interrogated to explore any association of RBC transfusion with deep vein thrombosis and pulmonary embolism in the 30 days following surgery.

A total of 750,937 patients undergoing surgery during 2014, of whom 47,410 had at least one RBC “transfusion event” (the database does not quantify the number of units received), were included in this retrospective analysis using multivariate techniques to control for confounding demographic and clinical characteristics. The adjusted odds ratios (95 percent confidence intervals) comparing transfused to

(continued on page 2)
Perioperative RBC Transfusion and Postoperative VTE (continued from page 1)

untransfused cohorts for target events were 2.1 (2.0-2.3) for any VTE, and 2.2 (2.1-2.4) and 1.9 (1.7-2.1) for deep vein thrombosis and pulmonary embolism respectively.

A statistically significant dose-response trend was seen comparing patients without transfusion to those with 1, 2, or ≥3 “transfusion events”. Associations held across surgical specialties and after propensity matching designed to further mitigate the impact of unmeasured confounders. The use of effective VTE prophylaxis was not assessable from the database, nor were data to adjust for hemoglobin transfusion triggers. Many of the indices used to control for severity of illness were surrogates that have not been validated for their relationships to risk for VTE.

The authors conservatively conclude “[T]hese results need prospective validation in cohort studies and randomized clinical trials; if proven, they underscore the continued need for more stringent and optimal perioperative blood management practices in addition to rigorous VTE prophylaxis in patients undergoing surgery”.


**Congress Recognizes World Blood Donor Day**

Capitol Hill joined ABC and its member blood centers in celebrating World Blood Donor Day (WBDD) on June 14th and throughout the week. Reps. Kevin Brady (R-Texas), John Shimkus (R-Ill.), and Erik Paulsen (R-Minn.), all prominent healthcare leaders, each delivered floor speeches (which are hyperlinked) recognizing WBDD and the importance of blood donation. A blood drive also took place at the House of Representatives for congressional members and their staffs hosted by U.S. House of Representatives Majority Whip Steve Scalise (R-La.) who donated blood one year after requiring blood donations following a shooting at a congressional baseball practice. Photos from the blood drive in Washington, D.C. and from home district blood centers tours that began this week are on page 4 of this issue. Additional tours will take place in the coming weeks as more than 75 congressional offices contacted ABC interested in a blood center visit. A brief video of the WBDD festivities led by ABC is available. Members of ABC may contact their congressional members individually at any time using the ABC Action Center.
The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

**2018 Summer Meeting Registration**

Registration is open for the 2018 Summer Meeting and Medical Directors Workshop in Montreal, Québec hosted by ABC member Héma-Québec July 31st – August 2nd at the Hotel Omni Mont-Royal. Don’t miss an exclusive opportunity for blood community leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Medical Directors Workshop, the Scientific, Medical, and Technical Forum, the Business Forum, and ABC Members Meeting. Additionally, Héma-Québec will host a networking event. Please make your hotel reservations by July 9th to ensure best availability and the group rate. Member and government registration rates are below:

- 3-Day Summer $760: MD Workshop, SMT Forum, Business Forum, Members Meeting
- 2-Day Summer $655: SMT Forum, Business Forum, Members Meeting
- 2-Day Medical $655: MD Workshop, SMT Forum, Business Forum
- 1-Day Medical $435: MD Workshop

You will need a U.S. Passport to enter Canada. Please be sure to check the expiration date.

Hospital, public, and emeritus registration rates are available here. Contact Leslie Maundy for available sponsorship opportunities. Click here for additional meeting information.

**SAVE THE DATE**

**ABC Quality Forum**  
June 21, 2018 at 3 PM EDT

**WEBINAR SAVE THE DATE**

**ABC SMT Journal Club Webinar**  
August 7, 2018 at 3 PM EDT  
Additional details coming soon!

**ABC Has Moved**

ABC moved on April 1st. Our new mailing address is, 1717 K Street NW, Suite 900, Washington, DC 20006. All telephone numbers will remain the same except the fax line which changed to (202) 899-2621. Please update your records accordingly and contact ABC Member Services with any questions.

**We Welcome Your Letters**

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. 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.
WBDD Congressional Outreach in Photos

Rep. Cheri Bustos (D-Ill.) (center)

Rep. Steve Scalise (R-La.)

Rep. Cathy McMorris Rodgers (R-Wash.)

Rep. Will Hurd (R-Texas)

Rep. Dan Newhouse (R-Wash.)
**RESEARCH IN BRIEF**

Revolutionary gene editing technique may have unintended consequences. Transfusion medicine applications of these technologies are many and include e.g. the potential to cure hemoglobinopathies such as sickle cell disease and thalassemia. Efforts have been hampered by the very low efficiency of Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR-Cas9) in human stem cells. Authors from the Karolinska Institute in Sweden, and the Universities of Cambridge (England) and Helsinki (Finland) describe marked improvement of this efficiency after suppressing DNA repair responses by inhibiting the tumor suppressor gene, p53, but note that chromosomal rearrangements and tumorigenic mutations may result and leave edited cells vulnerable to malignant transformation.

A second paper from Novartis, AbbVie, and Blueprint Medicine in Cambridge, Mass. also described marked improvements in editing efficiencies with human pluripotent stem cells after p53 knockout, but caution about a resultant risk from off-target effects that might increase cancer risks. Both sets of investigators call for close attention to these issues during development of human gene editing therapies, but clearly support continued development.


Should we be concerned about Simian Foamy Virus (SFV)? Some within the blood community pondered the threat of SFV several years ago when infections with this retrovirus, distantly related to HIV, were identified in individuals, especially primate workers exposed to monkeys. In the absence of any identified disease associations in those infected, no interventions have been required in the U.S., however there is a donor deferral in effect in Canada for certain non-human primate exposures. French scientists report on the clinical and laboratory signs in 24 gorilla SFV-infected Cameroonian hunters and matched controls. No clinical manifestations were identified. Hemoglobin levels were lower in the infected cohort (12.7 vs. 14.4 g/dL, p=.01). Cases also had higher blood urea nitrogen (BUN), creatinine, protein, creatine kinase and lactate dehydrogenase (LDH) levels than controls. They conclude that further work is needed to “establish the medical relevance of these observations because more than half of cases had mild or moderate anemia.”

**Citation:** Buseyne, F., Betsem, E., Montange, T. *et al.* Clinical signs and blood test results among humans infected with zoonotic simian foamy virus: a case-control study. *J. Inf. Dis*. 2018.

More from the United Kingdom using their approach to reduce platelet-associated bacterial sepsis. Investigators from NHS Blood and Transplant report on their experience with the bacterium *Staphylococcus aureus* from more than 1.6 million platelet units from 2011–16. They use primary culture from each platelet product after 36 hours. Eight mLs are inoculated into both aerobic and anaerobic bottles, and units released if negative for 6 hours or more. This is combined with visual inspection at issue and reporting into the Serious Hazards of Transfusion surveillance system. Overall contamination rates were .02 and .07 percent for apheresis and pooled platelets respectively. *S. aureus* accounted for confirmed contamination in eleven apheresis units and 4 pools. Where available, comparison of isolates from the donor platelets with strains isolated from the donors supported the donors as the source of contamination.

The contaminated units included four missed by the primary screening. Three were near miss incidents interdicted by visual inspection of the units before transfusion, and a single sepsis episode from this organism.

(continued on page 6)
RESEARCH IN BRIEF (continued from page 5)


False positive HIV-1 nucleic acid test (NAT) assays after chimeric antigen receptor t-cell (CAR-T) therapy. A letter in Blood reports false positive reactivity in four patients who received CAR-T treatment using U.S. Food and Drug Administration-cleared HIV-1 diagnostic (not donor screening) assays. Lentiviral vectors, highly modified from HIV, are used to transform t-cells to make CAR-T cells for the treatment of several malignancies. The sequences detected by available NAT assays are proprietary, so predicting which assays might detect sequences of the persisting vector by a given assay is problematic. Authors from Dallas, Texas, Philadelphia, Penn., Toronto, Canada, and Novartis describe four patients with prior negative HIV screening, who received tisagenlecleucel or CTL119 and had positive HIV NAT screening 1–5 months after their cell therapy. Discordant results with alternate NAT and/or HIV antigen testing suggested the initial results were false positive. The authors emphasize the need for a high index of suspicion for false reactivity in recipients of lentiviral-based cell therapies and a diagnostic approach to adjudicate suspected false positive results.


Anti-complement therapy reported to be effective for ADAMTS13-deficient thrombotic thrombocytopenic purpura (TTP) resistant to standard treatment. Relapse or failure to respond to plasma exchange for TTP is well recognized by blood center physicians providing therapeutic apheresis services. A case report from Italy describes 2 patients who failed the usual treatments for TTP (plasma exchange, steroids, rituximab). They were subsequently treated with eculizumab, an anti-complement monoclonal antibody, and had rapid clinical and hematologic responses. The drug was stopped, and the response maintained for at least several weeks after discontinuation of therapy.


BRIEFLY NOTED

Health Canada has announced the publication of a report examining the country’s self-sustainability of the immune globulin (Ig) supply. An expert panel commissioned by the regulatory agency applied an “evidence-based assessment” exploring the impact of commercial expansion of the plasma industry on the Canadian blood supply and overall sustainability of the nation’s Ig supply. The findings determined that a crisis doesn’t exist in the “medium term” as supply can meet demand, efficiencies could be improved to collect more plasma and increase utilization, currently commercial plasma collection does not adversely impact Canada’s whole blood supply (though continued monitoring is recommended), and Ig and other plasma products remain “very safe” demonstrating “effective regulation and oversight.” Health Canada will review the panel’s findings and engage industry stakeholders in deciding the next steps necessary to ensure both safety and accessibility regarding these plasma derivatives. An executive summary of the report is available. “As stewards of the national blood system, we are not surprised by the expert panel finding that Canada needs to collect more source plasma,” said Canadian Blood Services CEO Graham Sher, MD, PhD.

(continued on page 7)
BRIEFLY NOTED (continued from page 6)

“Our plan remains to significantly increase plasma collections from Canadian donors for Canadian patients, as per our voluntary, publicly funded collections model.”

(Sources: Health Canada Statement, 5/23/18; Canadian Blood Services News Release, 5/23/18)

Coinciding with World Blood Donor Day (WBDD) efforts to encourage blood donation and calling attention to the ongoing need for blood donors, an article appeared in U.S. News & World Report stressing the importance of building the next generation of young adults and teens to make a blood donation a habit. Contributed by Abbott’s John Hackett, PhD, he shares his personal connection to blood donation after needing blood transfusions for him and his daughter following an automobile accident. Dr. Hackett explains the importance of maintaining a safe and adequate blood supply to ensure blood is available when needed and the role that young adults must play moving forward complementing this year’s WBDD tagline of “Be there for someone else. Give blood. Share life.”

(Source: U.S. News & World Report, A plea to young Americans: donate blood, 6/14/18)
WORD IN WASHINGTON

The House Appropriations Committee has proposed draft legislation that would provide $89.2 billion to the U.S. Department of Health and Human Services in funding. This would be more than $1 billion more than last year’s funds and $2.4 billion more than the amount requested by President Trump. The bill allocates increased funds specifically to the National Institutes of Health ($1.25 billion) and the Public Health and Social Services Emergency Fund ($860 million). The bill proposes cuts for funding to the Centers for Disease Control and Prevention ($663 million), Health Resources and Services Administration ($196 million), and Centers for Medicare & Medicaid Services ($168 million).

The House voted late last week to approve $15 billion as part of a White House-backed rescission plan, which includes cuts to the Children’s Health Insurance Program (CHIP) and the Center for Medicare and Medicaid Innovation (CMMI). Earlier this year, the White House Office of Budget Management recommended that Congress cut $7 billion in funding for CHIP following congressional passage of CHIP legislation as part of a continuing resolution that would fund the program for 10 more years. Recommended cuts to CMMI total $800 million. “President Trump’s spending cut request is a straightforward and smart way to trim a bloated federal budget,” said House of Representatives Majority Leader Rep. Kevin McCarthy (R-Calif) to the New York Times. The Senate now has until June 22nd to approve legislation.

(New York Times, House votes to trim unused funding, a gesture of fiscal restraint, 6/7/18) ◆

MEMBER NEWS

BloodCenter of Wisconsin (BCW) honored Floreine Kurtweil for her 41st donation on her 97th birthday. “I’m grateful to God and to everybody who’s helped to make my life what it is,” said Ms. Kurtweil. “It feels good to be able to help and to donate at my age.” She donated for the first time when she was 21 years old and has continued to donate at BCW for years resulting in more than five gallons. “I don’t make an appointment, I just put it on my calendar and come in. And they accept me,” joked Ms. Kurtweil in a BCW news release. She is a type O negative donor and celebrated the milestone with friends and staff. “Community is very important to me,” added Ms. Kurtweil.

(Source: BloodCenter of Wisconsin News Release, 6/11/18) ◆
**STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply**

**Total ABC Red Cell Inventory**

<table>
<thead>
<tr>
<th>Date</th>
<th>East</th>
<th>Midwest</th>
<th>South</th>
<th>West</th>
</tr>
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<tbody>
<tr>
<td>10-May</td>
<td>28%</td>
<td>54%</td>
<td>48%</td>
<td>47%</td>
</tr>
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<td>51%</td>
<td>46%</td>
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</tr>
<tr>
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<td>30%</td>
<td>48%</td>
<td>43%</td>
<td>47%</td>
</tr>
<tr>
<td>31-May</td>
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<td>46%</td>
<td>47%</td>
</tr>
<tr>
<td>6-Jun</td>
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<td>43%</td>
<td>47%</td>
<td>30%</td>
</tr>
<tr>
<td>13-Jun</td>
<td>26%</td>
<td>47%</td>
<td>30%</td>
<td>9%</td>
</tr>
</tbody>
</table>

- No Report
- Green (3 days or more)
- Yellow (2 days)
- Red (1 day or less)

**Percent of Regional Inventory at 2 Days Supply or Less, June 13, 2018**

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
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<tbody>
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<tr>
<td>South</td>
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</tr>
<tr>
<td>West</td>
<td>30%</td>
</tr>
</tbody>
</table>

**Percent of Total ABC Blood Supply Contributed by Each Region**
- East: 20%; Midwest: 25%; South: 24%; West: 31%;

**GLOBAL NEWS**

Facebook has officially rolled out new blood donation tools in India, Pakistan, Bangladesh, and Brazil that allow individuals to register as blood donors on the social media platform and be notified immediately when a need exists. A campaign to encourage blood donation for these areas will be implemented throughout the month of June. “Our blood banks thus face an urgent need to collect blood through repeat donations from our regular donors and also by recruiting (and retaining) more new donors to ensure replenishment of blood stocks from a low-risk population,” said Professor Hasan Abbas Zaheer, the National Coordinator of the Safe Blood Transfusion Program. To date, more than 10 million individuals have signed-up to be blood donors.

(Source: *The Daily Times*, Facebook helps increase blood donations in Pakistan, 6/13/18)

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**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!
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

June 22. FDA Blood Products Advisory Committee Meeting, Silver Spring, MD. More details available here.


July 18-19. FDA Blood Products Advisory Committee Meeting, Silver Spring, MD. More details available here.

July 31-Aug. 2. Summer Meeting & MD Workshop, Montreal, Québec. Contact: ABC Meetings Dept. Phone: (202) 654-2917; e-mail: meetings@americasblood.org.

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

Sept. 11. 37th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD. More details available 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) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Director of Marketing and Recruitment. The Director of Marketing and Recruitment is responsible for developing and directing the blood center’s strategic marketing and recruitment plan. Achieving annual collection goals. Responsible for management oversight of the department including budget, staffing administration, effectiveness assessment, and internal/external communication in alignment with Blood Bank of Hawaii’s mission. Job Duties and Responsibilities: Strategic and Operational Planning - Develops strategic marketing and recruitment plan for donor recruitment, ensuring that the goals are congruent with the overall mission and vision of the organization. Oversees execution of the overall marketing and recruitment strategies, activities and services to the public in accordance with established policies, and plans. Leadership and Management: Provides leadership, motivation and accountability through key performance indicators. Effectively and collaboratively works with executive and senior management to improve the efficiency of operations, both within the department and on an organization-wide basis. Operational Efficiency and Effectiveness: Develops markets and business through effective implementation of strategies, programs and public outreach/education which measurably increase pint collections and donor base to attain established goals. Experience: Ten plus years of experience in sales and marketing strategic planning with demonstrated success of strategic plans. Five years supervisory experience managing multi-level staff. Other duties. Apply online at http://bbh.org/about-bbh/careers.html.

Director, Marketing and Public Relations. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Marketing and Public Relations. This position is responsible for business strategies and organizational needs and translates them into actionable marketing and public relations initiatives. Builds the long-term success of the Blood Bank “brand” through marketing and advertising. Determines and formulates overall marketing and public relations policies, objectives, and initiatives. Identifies opportunities and (continued on page 11)
POSITIONS (continued from page 10)

develops integrated marketing and public relations campaigns. Coordinates with outsourced creative services and advertising agencies in the production of advertising, promotions and public relations materials. Manages all the elements of the Blood Bank brand, advertising, media, publications, presentations, donor programs and events. Responsible for directing the tactical aspects of telephone recruitment, including the utilization strategy and selection process of new Tele-recruitment staff. Four-year bachelor’s degree (BA/BS) in Marketing, Advertising, Business, Communications, Public Affairs, or a related field. Three to five years’ work experience in marketing and public relations. Valid California Driver’s license. This position reports to the Vice President/Operations. LifeStream is an Equal Opportunity Employer, M/F/D/V. LifeStream participates in the Federal government E-verify program to determine employment eligibility. Apply online at https://www.lstream.org/open-positions.