ABC Calls on the FDA to Cease Testing for Zika Virus

In light of ongoing epidemiology data showing no evidence that mosquitoes in the continental U.S. have transmitted Zika virus (ZIKV) since 2017, America’s Blood Centers (ABC) believes the Food and Drug Administration (FDA) should take immediate action to cease testing of blood donations for the Zika virus. Ongoing Zika virus testing imposes significant costs to the healthcare system without materially contributing to transfusion recipient safety. It is essential that we focus our attention and resources on issues that continue to promote a safe and available blood supply and allow for ongoing work to protect against future threats. We applaud the FDA for continuing to evaluate this testing requirement and stand ready as a willing partner to assist in any way needed.

In a one-pager that provides the current realities, risks, and recommendations about ZIKV, ABC states that it is time for a change in the policy around Zika testing, asking regulators to:

- assess and consider the cost and subsequent economic effects of presumed safety measures before executing recommendations, and
- repeal testing requirements that add unnecessary financial burdens without commiserate benefits.

The complete document is available on the ABC website and includes additional information.

(Source: ABC Calls on the FDA to Cease Testing for Zika Virus, 12/9/19) ♦

ABC Urges Changes to CMS Outpatient Reimbursement

In continued advocacy efforts on behalf of member blood centers, America’s Blood Centers (ABC) submitted both individual and joint comments to the Centers for Medicare and Medicaid Services (CMS) in response to the Hospital Outpatient Prospective Payment System (OPPS) Final Rule to prioritize reimbursement for blood products and ensure consideration of the blood industry in rule and policymaking. ABC expressed gratitude to CMS for the blood center exclusion from the laboratory Date of Service (DOS) policy. The DOS policy exception introduced in the 2018 OPPS rule would have required blood centers to bill Medicare directly for advanced diagnostic laboratory tests. As a result of advocacy outreach by ABC and the collective efforts of other industry stakeholders, CMS exercised enforcement discretion to allow hospitals to continue to bill for tests run by blood centers. The

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ABC Responds to OPPS (continued from page 1)

exclusion of blood centers from this policy will allow blood centers to provide testing that ultimately benefits Medicare beneficiaries without needing to bill Medicare directly.

Additionally, ABC also informed CMS that U.S. Food and Drug Administration’s (FDA) guidance impacting the cost of platelets for transfusion has been issued. The October 2nd, 2019 FDA final guidance, “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion” offers options to achieve enhanced safety of platelets for transfusion. The current OPPS payment rates for calendar year 2020 provide reimbursement for some of the options, including pathogen reduction (P9073) and for the pathogen testing of the two approved bacterial detection tests for 7-day platelets (P9100). However, the Large Volume Delayed Sampling (LVDS) options will increase the cost for platelets without a correlated code to appropriately reimburse for this increase. Due to this, ABC has requested to work with CMS directly to ensure prompt inclusion of appropriate reimbursements for this FDA guidance. Additionally, ABC is seeking a meeting with CMS to follow up on the request to include the cost of the FDA guidance in the CMS reimbursement rates.

ABC, AABB, and the American Red Cross (ARC) also sent a joint comment letter to CMS requesting a modification to the status indicator assigned to the new miscellaneous code for blood components and products, code P9099. The new miscellaneous code was a result of joint efforts by the three organizations.

Both the comments and the letter in their entirety are available on the ABC member site. ABC encourages feedback and suggestions from all members blood centers by reaching out to Diane Calmus, deal-mus@americasblood.org or 202-654-2988 with any questions.

(Source: ABC OPPS Comments, 11/30/19; ABC, AABB, ARC, Joint Letter, 12/2/19)
REGULATORY NEWS

Stephan Hahn, MD has been confirmed as the new Commissioner of the U.S. Food and Drug Administration (FDA). “I congratulate Dr. Hahn and thank the Senate for prioritizing his nomination,” said U.S. Department of Health and Human Services (HHS) Secretary Alex Azar in an HHS statement. “President Trump has chosen a superbly qualified leader for FDA, and Dr. Hahn garnered strong bipartisan support. Having a confirmed FDA Commissioner of Dr. Hahn’s caliber will be a major boost to the already rapid pace of the President’s aggressive public health agenda. Dr. Hahn brings an impressive set of scientific and leadership qualifications to the job, and I look forward to seeing the FDA and its people thrive under his leadership. I am also grateful to Admiral Brett Giroir and Dr. Ned Sharpless for their dedicated work as Acting Commissioners and for their enduring commitment to public health.” Dr. Hahn is the full-time replacement for Scott Gottlieb, MD, who resigned earlier this year, and had been replaced by Ned Sharpless, MD, current director of the National Cancer Institute. Dr. Sharpless ran FDA on an interim basis as Acting Commissioner until last month when his term ended. Since that time, Admiral Brett Giroir, had been filling in as the commissioner. Dr. Hahn most recently served as the chief medical executive at MD Anderson.

(Source: HHS Statement, 12/12/19; The Washington Post, Senate confirms oncologist Stephen Hahn as FDA commissioner, 12/12/19)

The Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response in HHS has issued a request for information (RFI) entitled “Next Generation Blood Products.” The agency is looking for information on blood products which “overcome the current limitations such as limited shelf life and the need for donor/recipient compatibility in the event of a radiological or nuclear event.” BARDA is seeking statements on the capabilities of qualified businesses that can treat symptoms associated with acute radiation syndrome. The statements are limited to 15 pages and are due no later than 5 p.m. Eastern on February, 15th, 2020 to Christopher Scott. The statement:

- should describe the currently available technology for blood products to include the readiness level of the proposed products
- should address the narrative in the following manner:
  - primary & secondary indications for use
  - potential market penetration
  - technology roll out plan (i.e. decentralized and centralized manufacturing, supply through blood centers or directly to hospitals)
  - product development plan
  - regulatory strategy
  - engagements with the FDA
  - pathogen reduction technology status (i.e. log reduction information on bacteria, viruses and fungi (if applicable))
  - in vitro characterization (i.e. comparison to standard blood product equivalent, etc.)
  - non-clinical studies
  - clinical studies
  - manufacturing process & release testing (include time to release of final product)
  - storage conditions & stability testing (i.e. temperature, duration)

(continued on page 4)
REGULATORY NEWS (continued from page 3)

- must contain in the capability statement the following:”
  - company name and address
  - point of contact
  - phone/fax/email
  - NAICS Code(s)
  - business size and status
  - capability information in response

(Source: BARDA Announcement, 12/12/19)

The Food and Drug Administration has published Compliance Policy Guide CPG Sec. 230.150: Blood Donor Classification Statement, Paid or Volunteer Donor, Guidance for FDA Staff dated December 2019. This CPG provides guidance on the appropriate labeling of blood and components with the appropriate donor classification statement relative to the use of incentives. Within the CPG, the agency defines an incentive as anything a donor is given for donating blood or components except those normally associated with the donation process such as refreshments. It also contains both evaluation criteria for incentives and examples that have been reviewed. Key factors to consider in determining whether an incentive other than cash is readily convertible to cash are:

- Is the incentive transferable?
- Is the incentive refundable or redeemable for cash?
- Does a market exist for the incentive?

Additional information is available in MCN 19-083 to ABC members.

(Source: MCN 19-083, 12/9/19)

BRIEFLY NOTED

Joshua Denny, MD, MS has been named chief executive officer of The National Institutes of Health (NIH) All of Us Research Program, a precision medicine initiative, with the goal of enrolling 1 million participants. In this role, Dr. Denny will “oversee NIH’s efforts to build one of the largest and most comprehensive precision medicine research platforms in the world, in partnership with a diverse network of awardees and participants.” Prior to joining NIH, he worked as a professor in the department of Biomedical Informatics and Medicine at Vanderbilt University. Additionally, Dr. Denny has served as a principal investigator for the All of Us Research Program in addition to being a member of the advisory committee to the Director of Precision Medicine. He succeeds Eric Dishman who will transition into the Chief Innovation Officer role.

(Source: NIH Announcement, 12/11/19)

Creative Testing Solutions (CTS) will cease testing in its Portland lab on April 27th, 2020. According to the CTS announcement, most of the donor testing currently performed in Portland will be transitioned to CTS labs in either Dallas or Phoenix. The Portland lab will remain open until June 30th, 2020.

(Source: CTS Announcement, 12/10/19)
Clinical Effects of Childbearing Age Donors on Maternal and Neonatal Outcomes

Iron deficiency is a global problem in women of childbearing age and is associated with adverse maternal and neonatal outcomes. Repeated blood donations deplete iron stores and decrease hemoglobin levels. The clinical impact of iron deficiency on mothers and neonates due to blood donation is uncertain. The objective of this study published in *Transfusion Medicine Reviews* was to assess the association between repeated blood donations in female donors of child-bearing age and the associated risk of adverse maternal and neonatal outcomes.

This was an observational cohort study of all females who delivered a live or stillborn infant in Ontario, Canada between January 1st, 2010 and March 31st, 2012. Included was the woman’s first pregnancy within the study timeframe, excluded were women under 18 or over 50 years of age at delivery and multiple birth pregnancies. Women were considered donors if they gave at least one whole blood donation to Canadian Blood Services (CBS) between January 1, 2007 and pregnancy. Platelet or plasma apheresis donors were excluded, and CBS does not perform double red cell collections. The primary outcome was a diagnosis of small for gestational age defined as less than the 10th percentile for birthweight for any gestational age. Secondary outcomes were preterm birth (gestational age less than 37 weeks), low birthweight less than 2500g, APGAR (appearance, pulse, grimace, activity, and respiration) score of less than four out of 10 at five minutes, cord pH less than seven, microcephaly, hypoglycemia, hyperbilirubinemia, stillbirth (delivery after 20 weeks’ gestation), neonatal death, blood product transfusion, infection, preeclampsia, gestational hypertension, gestational diabetes, placental abruption, and maternal death.

A total of 260,037 women delivered live or stillborn singleton infants during the study period of which 7,919 (three percent) were blood donors, with a mean of 2.4 ± 2.1 lifetime donations. Mean maternal age at the time of delivery for non-donors and donors was 30.3 ± 5.4 years and 29.7 ± 4.9 years, respectively. Blood donors had a lower number of previous pregnancies and diabetes, smoking, and alcohol dependence syndrome. A total of 498 (6.2 percent) of women donated blood in a time period that would have occurred after conception. Small for gestational age occurred in 23,706 (9.4 percent) of neonates born to non-donors, and 526 (6.6 percent) born to donors. There was a reduction in the risk of small for gestational age with increasing number of lifetime donations (adjusted OR 0.89 [0.86, 0.92] per additional donation). For the secondary outcomes, there was a reduction in the risk of low birthweight (adjusted OR 0.95 [0.91, 0.98] per additional donation). There was no association with other secondary neonatal or maternal outcomes except for gestational hypertension (adjusted OR 1.03 [1.001, 1.07] per additional donation, n=206 women). The authors concluded that there was not an increased risk of adverse neonatal or maternal outcomes in women who donated blood before their pregnancy in the study group when compared to non-donors nor was risk increased with more donations prior to pregnancy. They noted a generally protective effect of blood donation prior to pregnancy that may be the result of a healthy donor effect or the fact that one must be in a relatively good state of health to consider donating or to be permitted to donate blood.


*Contributed by Richard Gammon, MD, Medical Director at OneBlood*
RESEARCH IN BRIEF

A research study funded by the National Institutes of Health’s National Heart, Lung, and Blood Institute (NHLBI) examined the efficacy of using fresh red blood cells (stored for seven days or less) versus older red blood cells (those stored more than seven days). The investigators examined the impact of the storage age of blood in reducing morbidity and mortality in critically ill patients. They found that “doctors should not be afraid to use older red cells in critically ill children,” said study co-principal investigator Philip Spinella, MD, a researcher with the Pediatric Critical Care Translational Research Program at Washington University School of Medicine in St. Louis in a news release. “Those who are showing a preference for fresh red cells might consider discontinuing this practice unless there are extenuating circumstances.” Dr. Spinella also suggests that blood centers may feel less “pressure” to accommodate requests for fresher blood. The authors also did acknowledge that study’s weaknesses such as not examining the impact on outcomes of red blood cells 35-42 days old. “The results of this study and other studies suggest that future research should be focused on deeper characterization of red blood cell products. This will help optimize the safety and effectiveness of these products among children, as well as others,” added Traci Mondoro, PhD, the NHLBI project officer for the study. An accompanying editorial was also published in The Journal of the American Medical Association (JAMA). Its authors feel that the trial “provides important data to support the safety of current international transfusion practice in regard to allocation of red blood cells for transfusion in critically ill children. This trial also demonstrates the feasibility of large internationally collaborative randomized trials to address evidence gaps in transfusion medicine involving pediatric patients.


MEMBER NEWS

South Texas Blood and Tissue Center recently celebrated 75-year-old donor Ron White surpassing the 125-gallon milestone. Mr. White has been a regular platelet and blood donor for the past 25 years. “I had a very high platelet count, so every time I’d donate, they’d get a triple from me,” said Mr. White to KENS5-CBS. “So, they said I was saving, or helping, nine people instead of three.” He credits the impact of knowing his donations are making a difference in the lives of patients and their families as the motivating factor that inspires him to encourage others throughout the country to follow his lead. “Why do I donate?” asked White. “Well, I ask them, ‘Why don’t you donate?’”

(Source: KENS5-CBS, Man helps save over 3,000 lives by donating 125 gallons of blood and platelets, 12/5/19)

Miller-Keystone Blood Center has received a $100,000 grant from the Air Products Foundation. The grant will assist the blood center in purchasing a new bloodmobile that is scheduled to be operational by the spring 2020.

(Source: The Morning Call, Miller-Keystone Blood Center receives grant and other company news, 12/8/19)
Registration Opens for 58th ABC Annual Meeting

Registration is open for America’s Blood Centers’ (ABC) 58th Annual Meeting in Washington, D.C. March 8th – 11th, 2020 at the Ritz-Carlton (Pentagon City). Don’t miss an exclusive opportunity for blood center leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Celso Bianco, MD Lectureship, the Scientific, Medical, and Technical Forum, Capitol Hill Visits, General Sessions, Public Awareness Forum, and the 23rd Annual Awards of Excellence. Please make your hotel reservations by February 1st to ensure best availability and the group rate. Contact Jeanette Brown for available sponsorship opportunities.

ADRP Provides National Blood Donor Month Resources

With National Blood Donor Month quickly approaching in January, ADRP has created several resources to create a complete toolkit for blood centers to use throughout the planning and implementation of their National Blood Donor Month strategies. These resources include:

- Social media graphics, sized for Twitter, Instagram, and Facebook
- Sample social media posts
- Blood donor facts infographic
- Press release template
- Op-Ed article to be used with your local media and partners

Please review the available resources and start incorporating them into your plans today!

(Source: ADRP Announcement, 11/22/19)

Upcoming ABC Webinars – Don’t Miss Out!

- ADRP Webinar: Community Outreach and Engagement – December 19th from 1 p.m. – 2(ET). Additional details available here.

2020 ADRP Award Nominations Available

Each year, ADRP honors individuals and organizations that have demonstrated outstanding service, accomplishments, or leadership in blood banking. Blood centers are encouraged to nominate individuals and organizations. In addition to a complimentary conference registration, winners receive a commemorative award and recognition in the ADRP newsletter and website. The nomination deadline is December 31, 2019. This year’s award categories are:

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INSIDE ABC (continued from page 7)

Individual Awards
- Donor Recruiter of the Year
- Collections Team Member (Recruitment and Collections)
- Rolf Kovenetsky Leader of the Year
- Ron Franzmeier Lifetime Achievement
- Ronald O. Gilcher, MD

Organization Awards
- Media Partner
- Humanitarian Service
- Blood Drive (Most Creative and Most Productive)
- School Blood Drive (HS or College)

Additional information on the ADRP awards is available on the ADRP website.

(Source: ADRP Awards Announcement, 10/29/19)

2020 ADRP Annual Conference Now Accepting Abstracts

ADRP, an international division of America’s Blood Centers, is encouraging donor collections, donor recruitment, marketing, and communications professionals to consider sharing their knowledge at the 2020 ADRP Annual Conference by being a presenter. The call for speaker abstracts is open until December 31st. Topics that have been the most requested by attendees include:

- **Leadership and team development:**
  - Critical thinking
  - Time management
  - Staff adequacy and talent level
  - Managing change

- **Blood Type Management:**
  - Collecting correct units based on blood type
  - Maintaining inventory during time of need
  - Rebooking donors and drives with emphasis on time of need

- **Donor and sponsor communication strategies:**
  - Diversification of the donor base
  - Addressing donor apathy
  - Communications strategies

As the industry’s leading conference for donor facing professionals in the areas of collections, communications, marketing, and recruitment, this year’s focus, “Charting the Course to Excellence,” will delve into each step of the donor journey and provide proven solutions for how staff from all aspects of the blood center can work together to achieve the best possible outcomes. Additional information about the conference is available on ADRP’s website.

(Source: ADRP Abstract Submission Form, 10/10/19)
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 newsletter@americasblood.org or by fax to (202) 393-1282. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

2020


July 21-23. 2020 ABC Medical Directors Workshop and Summer Summit, Cleveland, Ohio. More details coming soon.

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ABC 2020 Meetings & Workshops

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<td>More details coming soon!</td>
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Notes:

For the most up-to-date information on all events, members of ABC may check the calendar on ABC’s Member Site. Non-members may attend all events; information will be updated on ABC’s Public Site.

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, e-mail: newsletter@americasblood.org

POSITIONS

Hematologist/Medical Director. Our growing clinical practice in the area of outpatient therapeutic apheresis and therapeutic phlebotomy is seeking a board-certified hematologist to broaden our clinical services to include pre-op anemia management, cell therapy and treatment of blood disorders. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of outpatient clinical transfusion medicine, blood banking, immunohematology reference laboratories, (continued from page 10)
**Technical Director.** This position’s responsibilities include coordination/management of the departments of Distribution, Component Production, Testing and Labeling (North Texas) and Hematology (North Texas and East Texas). He/she will manage departmental operations with strong planning and developmental skills. This individual will also be responsible for advising and informing all senior management regarding departmental activities, requirements, and the requirements of the region’s hospitals and transfusion services. Also, the position will maintain effective and regular communication with hospital representatives, both in the laboratory and at the administrative level. Other requirements include: Bachelor’s degree required, MBA preferred, MT degree or equivalent, 10 years’ experience in blood bank administration/management; and five years’ experience in blood banking with experience in inventory management and a working knowledge of component production issues; and five years’ experience in blood bank laboratory operations including product quality control and quality assurance activities. Knowledge of hematology instrumentation, bacterial detection testing and environmental monitoring a plus. Equivalent combination of education and experience, working knowledge of all applicable AABB standards and FDA regulations associated with production, distribution, storage, and transportation of blood products, understanding of employment law, OSHA requirements, departmental planning, cost accounting, and budgeting. Carter BloodCare is an EEO/Affirmative Action employer. For full posting, visit [www.carterbloodcare.org](http://www.carterbloodcare.org).

**Reference Lab Manager.** OneBlood is currently recruiting for a Lab Manager in our AABB-Accredited Immunohematology Reference Laboratory. This position provides leadership and technical expertise, manages staff, and performs training and quality activities for the staff responsible for performing basic through advanced testing procedures on patient and/or donor samples. Applicants must have a bachelor’s degree in medical technology, biological science or related scientific field from an accredited college or university. Five or more years in a clinical laboratory, preferably blood banking environment, or an equivalent combination of education, certification, training and/or experience. Applicants must have SBB certification, as well as a valid and current Florida Clinical Laboratory Supervisor license, or eligible, in Immunohematology or Blood Banking. To apply and view a complete Job Description of this position, go to [www.oneblood.org](http://www.oneblood.org) and click on the Careers tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

**Laboratory Manager (Appleton, Wisc.)** The Community Blood Center is seeking a Manager for our Laboratory Operations. This individual will have a passion for leading others, and experience leading laboratory testing, component, and hospital service activities. The Community Blood Center currently provides 20+ Wisconsin and Michigan hospitals with a full range of blood components. Responsibilities for this individual will include planning, managing and supervising all laboratory testing, component, and hospital service activities. Responsible for oversight of the activities of Laboratory staff and ensuring all processes are compliant and safe. Oversight consists of allocation of resources, monitoring, correcting, improving and updating all technical, regulatory, administrative, and personnel functions. This individual will be responsible for accomplishment of key department and organizational objectives including assigned goals, operational productivity targets, compliance measures and staff engagement metrics; ensuring compliance with quality control functions, documents and industry regulations; budget preparation and plan development to maintain or adjust operations as needed. The position requires a MT(ASCP) or equivalent and minimum two years lab experience, ideally with increasing levels of responsibility. Medical background or blood center experience with strong working knowledge of laboratory practices, equipment and regulations; excellent leadership, staff development and team building skills, in addition to budget preparation and monitoring skills, with a high level of data analysis skills. Apply at: [https://www.communityblood.org/careers](http://https://www.communityblood.org/careers).

**Laboratory Manager (East Texas).** This position’s responsibilities include coordination/management of the departments of Distribution, Component Production, Testing and Labeling (North Texas) and Hematology (North Texas and East Texas). He/she will manage departmental operations with strong planning and developmental skills. This individual will also be responsible for advising and informing all senior management regarding departmental activities, requirements, and the requirements of the region’s hospitals and transfusion services. Also, the position will maintain effective and regular communication with hospital representatives, both in the laboratory and at the administrative level. Other requirements include: Bachelor’s degree required, MBA preferred, MT degree or equivalent, 10 years’ experience in blood bank administration/management; and five years’ experience in blood banking with experience in inventory management and a working knowledge of component production issues; and five years’ experience in blood bank laboratory operations including product quality control and quality assurance activities. Knowledge of hematology instrumentation, bacterial detection testing and environmental monitoring a plus. Equivalent combination of education and experience, working knowledge of all applicable AABB standards and FDA regulations associated with production, distribution, storage, and transportation of blood products, understanding of employment law, OSHA requirements, departmental planning, cost accounting, and budgeting. Carter BloodCare is an EEO/Affirmative Action employer. For full posting, visit [www.carterbloodcare.org](http://www.carterbloodcare.org).

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