America's Blood Centers®
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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2019 #22 **June 28, 2019**

INSIDE:

Please Note: The *ABC Newsletter* will not be published on July 5th. We will resume regular publication on July 12th. Thank you for your continued interest.

CBER Publishes Updated 2019 Guidance Agenda

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has published an updated guidance calendar for 2019. The agenda outlines the guidance and draft guidance documents under consideration by the agency for development this year. Topics of note that the agency could address include:

- Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Guidance for Industry;
- Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products; Draft Guidance for Industry;
- Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Guidance for Industry;
- Use of Serological Tests to Reduce the Risk of Transfusion Transmitted Human T Lymphotropic Virus Types I and II (HTLV-I/II), Guidance for Industry;
- Considerations for the Development of Dried Plasma Products Intended for Transfusion; Guidance for Industry;
- Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Guidance for Industry; and
- Revised Recommendations for Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry.

A complete listing of the potential guidances for blood and blood components, tissues and advanced therapies, and other categories is available on the FDA's website.

(Source: FDA Announcement, 2/20/19)

Upcoming ABC Webinars – Don't Miss Out!

- **QA Education Webinar – Change Management** – July 16th. Additional details forthcoming!
- **SMT Journal Club Webinar** – August 19. Additional details forthcoming!

PAHPA Signed into Law

President Trump signed the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPA) into law this week following its passage by Congress. The wide-ranging preparedness and response legislation includes specific language providing recognition of the role of blood centers, for the first time-ever, as the law drives the nation's disaster planning and readiness activity. It calls for action in support of a safe and available blood supply through three important provisions for blood centers:

- inclusion of blood centers as stakeholders that the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) must consult in disaster planning;
- recognition of financial implications borne by blood centers for such work; and
- a report to Congress from HHS within one year of the bill's enactment regarding recommendations for supporting an adequate blood supply.

"I applaud President Trump for signing this common sense, sorely needed legislation into law, and my colleagues Reps. Susan Brooks and Anna Eshoo for spearheading this issue through the Energy and Commerce Committee and through the House," said Rep. Greg Walden (R-Ore.) in a news release. "The Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPA) represents a longstanding bipartisan commitment to strengthening our national security. While this is long overdue, I am glad that our nation's public health preparedness and response programs are now reauthorized and extended to give our federal, state, and local officials the tools they need to respond quickly and effectively to ongoing threats of all kinds."

America's Blood Centers (ABC) and its members continuously supported PAHPA by signing onto multiple coalition letters and advocating on Capitol Hill to congressional leadership encouraging its passage during the association's annual Advocacy Day in March. ABC thanks all members that have supported both ABC's and the blood community's advocacy efforts regarding PAHPA.

(Sources: House Energy & Commerce Committee News Release, 6/24/19; Coalition Letter, 3/22/19)

ABC, AABB and the American Red Cross Submit Joint Reimbursement Comments to CMS

America's Blood Centers joined AABB and the American Red Cross (ARC) in the submission of joint comments to the Centers for Medicare and Medicaid Services (CMS) in response to proposed rules for the Medicare program. Links to the joint comments are included below:

- Joint Comments to CMS Regarding Hospice Wage Index and Payment Rate Update FY 2020
- Joint Comments to CMS Regarding Skilled Nursing Facility PPS FY 2020
- Joint Comments to CMS Regarding Inpatient Rehab Facility Prospective Payment System FY 2020
- Joint comments to CMS on Hospital Inpatient PPS for Acute Care Hospitals and Long-Term Care Hospitals FY2020

In the proposed rules, CMS states "[b]lood transfusions are highly protocolized, with multiple safety checks and monitoring required during and after the infusion to avoid adverse events. Coordination with the facility's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require additional nursing staff and care coordination, and impacts planning for transitions of care, as transfusions are not performed in all PAC settings. Receipt of transfusions is also important to

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ABC, AABB, ARC Joint Comments (continued from page 2)

assess for case mix adjustment due to the need for added resources and to the extent that receipt of transfusions indicates a more medically complex patient." The agency also acknowledges the need for blood the availability of blood transfusions for patients in long-term care hospitals, other post-acute care settings, and palliative care in hospice. Additionally, CMS proposes that a transfusion data element be included as standardized patient assessment data for use in quality reporting requirements to help ensure continuity of care and long-term data collection.

(Source: MCN 19-046) ♦

Formation of Testing Laboratories United, LLC Announced

Central California Blood Center (Fresno, Calif.), Community Blood Center (Appleton, Wis.), Oklahoma Blood Institute (Oklahoma City, Okla.), and QualTex Laboratories (San Antonio, Texas and Norcross, Ga.) have formed Testing Laboratories United, LLC. According to the announcement, the newly-formed company will promote innovation by "[assisting] with clinical trials and help bring cutting edge equipment and advanced donor screening assays to market." Additionally, it will be "dedicated to keeping blood centers nimble in adapting to the explosion of new cell therapy, personalized medicine, and community health screening opportunities arising for blood centers." Kim van Antwerpen, MBA has been elected to serve as the president and Ward Carter as secretary by the organizations that manage Testing Laboratories United, LLC. "It is our mission to continue local, optimal service to our hospital partners, their patients and our communities," said Ms. van Antwerpen," in the news release. "We are excited to partner with three other institutional leaders in our industry to achieve the highest levels of value from our joint testing operations."

(Source: Testing Laboratories United, LLC Announcement, 6/25/19) ♦

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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

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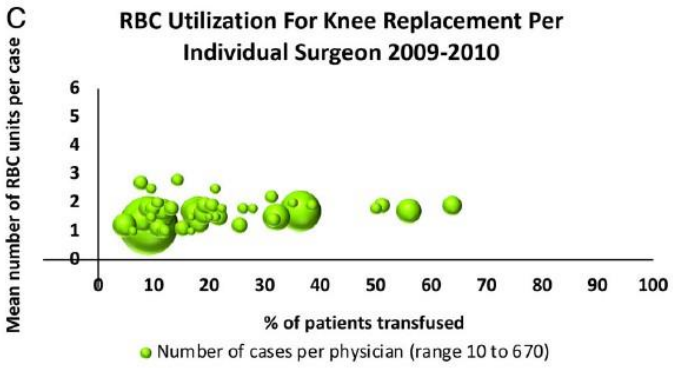
Bubble Graphs Effectively Monitor Tranexamic Acid's Effectiveness with Orthopedics

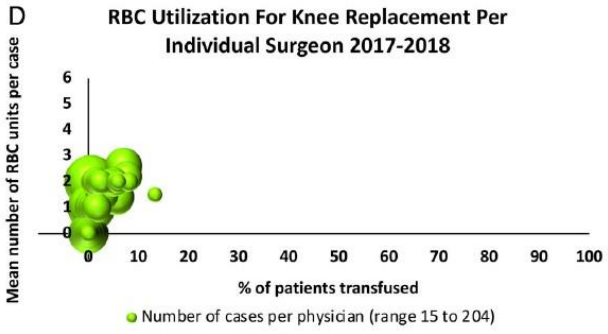


In 2010, University of Pittsburgh Medical Center set a goal of universal use of the antifibrinolytic medication tranexamic acid (TXA) in orthopedic surgeries to reduce allogeneic red blood cell (RBC) transfusions. Also, a patient blood management (PBM) program launched and included evidence-based transfusion triggers, computerized physician order entry, preoperative anemia optimization, point-of-care laboratory testing, and an intraoperative autotransfusion program.

In 2009 and 2010, TXA was administered in the minority of orthopedic surgeries. At its introduction, because of fear of thrombotic complications associated with intravenous use, a 3 g dose of TXA was used topically during these surgeries. A meta-analysis published in 2018 reviewed 67 studies involving 6,034 patients. The majority of trials evaluated orthopedic procedures. The review found no difference in the odds of developing a venous thromboembolic complication between the topical TXA and control groups (pooled OR=0.78, 95 percent CI 0.47 to 1.29; P=0.33) or the topical and intravenous groups (pooled OR=0.75, 95 percent CI 0.39 to 1.46; P=0.40).

This supported the practice that over time, TXA use evolved into 1 g IV at the beginning of the surgery and 1 g IV of TXA at the time of closure. In addition to the two IV doses, the current TXA regimen included an oral 1,950-mg dose on postoperative day (POD) 0 at 18:00 hours with an additional oral dose of 1,950 mg if drain output exceeded 100 mL on POD 1 at 06:00 hours at physician's discretion.

A bubble graph or chart can be defined as a visual tool to display three dimensions of data in a two-dimensional space. It is a variation of a scatterplot, which uses bubbles (circles) instead of data points at the intersections of the x-axis data and y-axis data. Unlike the scatterplot, in the bubble graph, the x-axis and the y-axis represent values rather than categories. In a bubble graph, the relative size of the bubbles shows the third dimension. Such graphs can be constructed using widely available business software. They can also be effective in presenting transfusion metrics.



In the included graphs, a bubble represents an individual surgeon and the graph show knee replacement RBC utilization before (2009-2010) and after (2017-2018) universal TXA use and implementation of a PBM program. The size of the bubble represents the number of cases performed by each individual surgeon. The x-axis indicates the frequency with which a particular surgeon's patients received at least one RBC

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Bubble Graphs Monitor TXA Effectiveness (continued from page 4)

unit. The y-axis indicates the mean number of RBCs transfused per patient. A dramatic decrease in perioperative RBC transfusion that included both number of units and percent of patients transfused was achieved in knee and hip arthroplasties after implementing a universal TXA use policy for these procedures.

Citations: Kaplan, A., Wisniewski, M., Waters, J.H., Yazer, M.H. Implementation of tranexamic acid reduces red blood cell utilization in orthopedic surgeries. *Transfusion*. 2019. Doi: 10.1111/trf.15403.

Montroy, J., Hutton, B., Moodley, P., *et al*. The efficacy and safety of topical tranexamic acid: a systematic review and meta-analysis. *Transfusion Medicine Reviews* 2018.

Gammon, R.R., Use of Bubble Graphs. In: Fredrich, N., Gammon, R.R., Richards, C.A., Tauer, R. PBM Metrics. AABB Press. 2019.

Note: Figures used with permission of Dr. Mark Yazer.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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 and published after editorial review. 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.

America's Blood Centers®
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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.

2019 Summer Summit & MD Workshop Agenda Available

The agenda for the 2019 America's Blood Centers Summer Summit and Medical Directors Workshop has been released. Registration is open for this year's meeting in Denver, Colo. July 30th – August 1st at the Grand Hyatt Denver (reserve rooms by July 5th). Don't miss an exclusive opportunity to take part in this year's newly designed meeting format that brings together thought leaders throughout the blood community to focus on the future of blood centers and the larger transfusion community. The theme of the Summer Summit is "Defining and Promoting Innovation in the Blood Sector." It will feature leaders from both within and outside the industry, case studies from your blood center peers, and engaging roundtable discussions to promote peer-to-peer collaboration in discussing the latest trends and issues impacting community blood centers. The meeting will also include the Medical Directors Workshop, the Summit Reception, and the Women-Inspiring-Leading-Learning High Tea Luncheon sponsored by Terumo BCT. Member, government, hospital non-member, public, and emeritus registration rates are available here. Contact Leslie Maundy for available sponsorship opportunities. Click here for additional meeting information.

Advocacy Update Regarding 14-day Rule for Advanced Laboratory Tests: CMS to Exercise Enforcement Discretion until January 2020

America's Blood Centers (ABC), together with AABB and American Red Cross, continue to advocate for blood centers to be exempt from a Medicare outpatient payment rule published in December 2017 that requires testing laboratories bill Medicare directly for certain Advanced Diagnostic Laboratory Tests (ADLTs) and molecular pathology tests performed on patient samples.

The Centers for Medicare and Medicaid Services (CMS) has recognized the complexity of the rule and announced on Friday, June 28th that the agency will exercise enforcement discretion until January 2, 2020 (previously July 1, 2019) "for the laboratory date of service exception policy for advanced diagnostic laboratory tests and molecular pathology tests subject to the laboratory date of service exception policy."

We have asked for an exemption or flexibility in the application of the new rule for tests not used for diagnostic purposes and will continue to advocate on behalf of the blood community. Thank you to all that have supported this effort over the past several months by sharing data and experience. Please contact Ruth Sylvester with any questions.

(Source: CMS Announcement, 6/28/19)

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!

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INSIDE ABC (continued from page 6)

ABC Stoplight Reporting Update

America's Blood Centers (ABC) has transitioned the Stoplight blood supply reporting system to a newer version. Going forward, ABC member blood centers will receive a single inventory request each weekday. During the transition, there may appear to be some short-term fluctuations in the stoplight data that will settle out over time. This is due to differences in how the two systems perform calculations.

It is important that the report be completed daily. This report is used by ABC and reported to AABB for aggregation with American Red Cross data in a report to the U.S. Department of Health and Human Services (HHS) on behalf of the AABB Disaster Task Force. It is the one conduit to keep HHS appraised of the blood inventory status. The national inventory has been tracking lower than normal going into the summer which can potentially have significant implications during the typical summer lull in donations. We urge all members to report their daily inventories so that we have an accurate snapshot.

Thank you for continued support of this important task. Please direct questions or comments to Ruth Sylvester.

(Source: MCN 19-044)

CALL FOR GRANT PROPOSALS

Commonwealth Transfusion Foundation (CTF) is a private foundation that inspires and champions research and education that optimizes clinical outcomes in transfusion medicine and assures a safe and sustainable blood supply for the U.S. **Our current funding priorities are:** Patient Centric approach to transfusion medicine decision making. Responsible, evidence-based regulatory constructs. Timely, safe, and reliable access to blood products for all patients. Appropriate attention to donor safety measures. Better understanding of the supply chain and economics underpinning the blood industry. Interested parties should visit CTF's website (www.CTF.life) to learn more about our grants process and/or to begin the application process. Please pay special attention to what CTF does not fund. Prior to submitting an application, applicants must submit a Letter of Inquiry (LOI) that briefly describes the proposal. If approved, applicants may proceed to the application form. The deadline for applications for the current grant cycle is (**July 26, 2019**). With this in mind, we encourage applicants to begin the process as soon as possible so that applications may be received by the deadline. For more information, feel free to contact us at info@CTF.life.

CTF COMMONWEALTH TRANSFUSION FOUNDATION

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!

BRIEFLY NOTED

The International Society of Blood Transfusion (ISBT), in collaboration with the International Haemovigilance Network and AABB developed a working group to revise the international definition for transfusion-associated circulatory overload (TACO). The latest revision of the international definition is available as well as results from a validation exercise that have been published in *Lancet Haematology* (early-view).

(Source: Alliance of Blood Operators Announcement, 6/20/19)

The BEST Collaborative has issued the call for Scott Murphy Memorial Award Lecture Applications according to a recent announcement. The Scott Murphy Memorial Lecture was established in 2007 in recognition of the tremendous contribution of the late Dr. Scott Murphy, a past chair of the BEST Collaborative, made to the field of transfusion medicine and to the science of platelet storage. The BEST Collaborative is encouraging junior faculty involved in the broadly understood field of transfusion medicine to apply for this unique award. The recipient of the next award will be invited to San Antonio, Texas to present during the BEST Meeting and to network with BEST members. A list of prior award recipients and their presentation titles can be found here. Online applications for the San Antonio Meeting to be held October 16-17, 2019 must be submitted by July 15, 2019, with the recipient announced by August 15, 2019. The award recipient will also be able to attend the entire BEST 2-day meeting, as BEST will provide up to $1,000 USD toward travel expenses plus a $500 honorarium.

(Source: BEST Collaborative Announcement, 6/21/19)

REGULATORY NEWS

AABB published Association Bulletin #19-02 this week entitled "Recommendation on Use of Group O Red Blood Cells" (RBCs). It contains recommended practices to reduce the reliance on group O RBCs for transfusion services and blood centers. Blood center recommendations are:

- Collection facilities should work with hospital clients to develop reasonable targets for group O blood usage;
- collection facilities can work with hospital clients to develop ways to encourage optimal use of group O Rh(D)- RBCs.

The complete bulletin and recommendations are available on the AABB website.

(Source: AABB Association Bulletin #19-02, 6/26/19)

The Food and Drug Administration approved the biologics license application (BLA) of Abbott for the Alinity Human T-Lymphotropic Virus (HTLV) I/II assay. With this license, FDA authorizes the company to manufacture the Alinity HTLV I/II assay which screens for HTLV I/II antibodies in blood and plasma donors on the Alinity s System. More information can be found in the FDA approval letter.

(Source: FDA BLA approval Letter, 6/26/19)

The agenda for the public workshop entitled "Perspectives on In Vitro Diagnostic Devices Regulated by the Office of Blood Research and Review" being held by FDA July 15th and 16th at the agency's White Oak Campus in Silver Spring, Md. has been published. The workshop aims to explore the important elements of regulatory submissions of such devices and facilitate communication and education

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REGULATORY NEWS (continued from page 8)

between manufacturers and regulators. Sessions include:

- Elements of Submission Review
- Devices Used for Screening for Infectious Disease in Blood and Plasma Donations
- In Vitro Diagnostic Devices Regulated by Division of Blood and Component Devices

Registration is free and currently open for both in-person and webcast attendance.

(Source: FDA Announcement, 6/27/19)

FDA released a joint statement this week from Norman Sharpless, MD, acting commissioner, and Peter Marks, MD, PhD, director of FDA's Center for Biologics Evaluation and Research (CBER), in response to a permanent injunction from a federal judge over controversial unlicensed stem cell treatments performed U.S. Stem Cell Clinic LLC in Weston and Sunrise, Fla. The ruling follows an injunction issued by a U.S. district court earlier this month in favor of the FDA in their bid to bring regulation to the growing industry, while prioritizing patient safety. "Today's action by Judge Ungaro is significant and sends a strong message to others manufacturing violative stem cell products," said the FDA statement from Drs. Sharpless and Marks. "Court decisions like this reaffirm the FDA's compliance and enforcement efforts in the ongoing fight to protect the public from individuals and clinics who mislead patients with unapproved and potentially harmful medical products. The agency will continue to take steps—such as issuing warning letters or initiating court cases—against those who endanger patients' health with inadequate manufacturing conditions or by manufacturing and marketing products without the submission of appropriate applications containing safety and efficacy information to the FDA. Patient safety is the foundation of our mission. We're now nearly halfway through the period during which the agency intends to exercise enforcement discretion for certain regenerative medicine products with respect to the FDA's investigational new drug application (IND) and premarket approval requirements – but only for those where the use of the product does not raise reported safety concerns or potentially significant safety concerns." Some hematopoietic stem cell therapies have been approved by the agency to treat diseases of the blood and immune system, but stem cell clinics such as U.S. Stem Cell Clinic LLC that sell unapproved treatments can potentially be viewed as capitalizing on the public's confusion regarding stem cell therapies and can lead to serious adverse outcomes.

(Sources: FDA Statement, 6/25/19; *New York Times*, Judge halts treatments at Florida stem cell clinic, 6/25/19; *Washington Post*, FDA wins groundbreaking case against for-profit stem cell company, 6/4/19)

WORD IN WASHINGTON

Sen. Richard Blumenthal (D-Conn.) and Rep. Doris Matsui (D-Calif) introduced bicameral legislation that would authorize and appropriate $2 billion in funding in FY20 and subsequent years for the Prevention and Public Health Fund (PPHF). ABC joined a coalition of more than 180 public health groups in a sign-on letter of support for PPHF, which was previously established under the Affordable Care Act (ACA) to aid vaccination, chronic disease prevention, and health education programs. "This bill marks a historic investment in lifesaving public health programs, which have been neglected for far too long," said Sen. Blumenthal in a news release. "A robust Public Health and Prevention Fund will support vital federal and local efforts to combat existing public health crises, like the measles outbreak, teen e-cigarette epidemic, and high rates of chronic illness. Restoring this fund will also ensure our nation is ready for any public health threats that may emerge in the future." PPHF has suffered from cuts and a lack of appropriated funding due to other legislative priorities since being established. "When we passed the Affordable Care

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WORD IN WASHINGTON (continued from page 9)

Act, we made a strong commitment to public health programs by creating the Prevention and Public Health Fund," said Rep. Matsui in the news release. "Unfortunately, this program has been regularly underfunded or raided to pay for other priorities – to the detriment of communities across the country. With increasing rates of suicide, substance use disorder, and contraction of preventable diseases like measles, we need robust public health funding now more than ever. By fully funding the Prevention and Public Health Fund at the originally intended $2 billion funding level, we can better support public health departments in their efforts to improve patient outcomes and create communities where everyone has the opportunity to live healthy and fulfilling lives."

(Source: Sen. Richard Blumenthal and Rep. Doris Matsui News Release, 6/25/19)

The Administration has awarded close to $1 million in Ryan White HIV/AIDS Program grants to 10 Part A jurisdictions in metropolitan areas to bolster interventions in the HIV epidemic. President Trump previously expressed in February his commitment to end the HIV/AIDS epidemic by 2030 and asked Congress to make a similar commitment. "Today, on National HIV Testing Day, we are proud to be taking initial steps to support the implementation of President Trump's strategy to end the HIV epidemic in America by 2030," said HHS Secretary Alex Azar in a news release issued this week. "The Ryan White HIV/AIDS Program has a long track record of success in providing HIV treatment, and the President's plan to end the HIV epidemic involves building on that success." HRSA Administrator George Sigounas, MS, PhD added, "HRSA's Ryan White HIV/AIDS Program Part A plays a critical role in the United States' public heath response to ending the HIV epidemic. These grants will help ensure proactive programming so the most vulnerable people living with HIV/AIDS in the United States have access to life-saving care and treatment to improve health outcomes and reduce HIV transmission."

(Source: HHS News Release, 6/27/19)

MEMBER NEWS

Versiti recently announced that the Versiti Blood Research Institute has received a $13.2 million grant from the National Institutes of Health (NIH). The five-year grant award will contribute to ongoing research efforts for von Willebrand disease (VWD) as part of The Zimmerman Program on the Biology of VWD. "By tracking the amount of bleeding in patients over time, and looking at variables such age, stress, surgery and genetic factors, this grant will not only help us pinpoint why factor levels and the effects of the disease can change throughout a patient's life, but also provide more accurate diagnoses for VWD," said Versiti Blood Research Institute Senior Investigator Robert Montgomery, MD in the news release. Other participants in the program include Children's Hospital of Wisconsin, the Medical College of Wisconsin, Royal College of Surgeons in Ireland, Queens University in Kingston, Ontario, Canada, the University of Colorado, Washington University in St. Louis, and 10 clinical hemostasis centers across North America. "Our investigators strive to make discoveries that contribute to better patient care. As we continue our search to find better treatments for children and adults battling bleeding disorders, we are honored to participate in this prestigious program which will help make a life-changing impact on people with von Willebrand disease in our community and around the world," added Versiti Executive Vice President of Research and Chief Scientific Officer Gilbert White, MD.

(Source: Versiti News Release, 6/20/19)

GLOBAL NEWS

***France 24* is reporting that gay rights activists have filed a discrimination complaint with the European Commission concerning France's current 12-month deferral policy for men who have sex with other men.** "[It] creates legal uncertainty for LGBT individuals because it makes possible discrimination on the basis of sexual behavior," said Etienne Deshoulieres, a lawyer representing gay rights groups in the complaint. An individual identified as Maxime who was deferred due to the MSM policy added "I felt humiliated…We are categorised as both 'gay and banned." France moved to a 12-month MSM deferral in 2016, which removed the previous lifetime deferral that had been in place since 1983. "This rule, which is still in place, effectively excludes 93.8 percent of gay men from donating blood," said a joint statement by Stop Homophobie, Mousse, ELCS (Local officials against AIDS), SOS Homophobie and Familles LGBT.

(Source: France 24, Gay rights activists complain to EU over French blood donor sex ban, 6/20/19)

ABC 2019 Meetings & Workshops				
Meeting/Workshop	**Dates**	**Location**	**Hotel/Hotel Rate**	**Registration Dates & Fees**
Medical Directors Workshop	July 30 (precedes Summer Mtg)	Denver, CO	Grand Hyatt, $239/night	Register by July 5!
Summer Summit	July 31-August 1	Denver, CO	Grand Hyatt, $239/night	Register by July 5!
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.				

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) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2019

July 15-16. **FDA Perspectives on In Vitro Diagnostic Devices Regulated by the Office of Blood Research and Review Workshop, Silver Spring, Md.** More details available here.

July 30-Aug. 1. **2019 ABC Summer Summit & Medical Directors Workshop, Denver, Colo.** More details available here.

Sept. 23-25. **The MedTech Conference, powered by AdvaMed, Boston, Mass.** More details available here.

2020

Mar. 9-11. **2020 ABC Annual Meeting, Washington, DC.** More details coming soon.

May 13-14. **IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available here.

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details coming soon.

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

Registered Nurse (*3000 SIGN-ON BONUS*). Essential Functions: Ensures compliance with relevant CBC, FDA, AABB and OSHA regulations. Performs therapeutic Apheresis procedures on patients at CBC and area hospitals. Performs quality control on apheresis instruments and related equipment. Assists with training and competency assessment, as needed. Communicates with staff, CBC Medical Director and outside facilities/physicians to ensure optimal patient care and efficient use of resources. Communicates confidently and interprets intermediate information in English to all members of the public and CBC staff. Ensures billing for department services are current. Meets all credentialing requirements of any hospital CBC serves. Administers injectable vaccines, ex: Hepatitis B and Filgrastim. Reports all traffic tickets or license suspension to the Manager. Education: Minimum of ADN or BSN – must provide copy of transcript. Current RN license in Missouri & Kansas – must provide copy of license. Experience: Minimum of two (2) years' experience in critical care, therapeutic apheresis or dialysis. Must maintain a valid KS or MO driver's license and clean driving record. To apply: Please visit www.savealifenow.org.

Senior Director of Donor Recruitment and Marketing. The Community Blood Center of the Ozarks (CBCO) is seeking a Senior Director who will be responsible for the effective and efficient management of Donor Recruitment and Marketing departments in our area. This position coordinates recruitment and collection activities to produce balanced collections. Creates a positive working relationship with all customers. Ensures that a high standard of customer service is maintained at all times. Production planning through coordination with other departments is essential. Qualified candidates with a Bachelor of Science/Arts degree in communications, marketing, business, or closely related field are preferred. Managerial, marketing/sales, analytics, blood recruitment, and communication experience preferred. CBCO offers a comprehensive benefit package and pay commensurate with experience. Qualified candidates should send a cover letter and resume to Stacey Connell, Senior Director of Human Resources at connells@cbco.org. CBCO is an Equal Opportunity Employer and a Tobacco Free Workplace.

Medical Technologist I. Essential Functions: Prepares laboratory reagents and chemicals; performs laboratory quality control tasks; performs equipment maintenance and quality control; performs tasks associated with red cell and platelet antibody detection and identification; antigen typing of red cells and platelets; antibody ID, ABO/Rh, DAT testing; platelet antibody testing; problem solving; identifies, tests, and provides specialty typed red cell components based on client requests; provides consultation and reference services to clients; performs patient antibody identification/problem solving; provides communication with hospitals transfusion service staff; reports and bills for patient test results; and provides excellent customer service and communication to internal and external clients. Requirements: B.S. Degree in Clinical Laboratory Science or other applicable science required. MLS (ASCP), MT (ASCP) or equivalent certification required. One to three years blood bank laboratory experience preferred. Skills and Knowledge: Must be able to effectively communicate using verbal and written skills; confidently read, write, speak, and understand English; knowledge of Immunohematology/Transfusion Medicine; attention to detail; stress management skills; ability to solve problems and work independently within the scope of the tasks; ability to work with others in a team environment and individually; and excellent organizational and time management skills. To apply please visit www.savealifenow.org.

Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a **Medical Director**. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of free medical coverage with a competitive benefit package, 403(b) retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Jacksonville, Florida area, with some of the most gorgeous beaches in the nation! If you want to

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join our life saving mission and team of dedicated employees, visit our *Careers* page at www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.

Laboratory Services Manager. LifeSouth Community Blood Centers is currently seeking a skilled individual for a Laboratory Services Manager position in our Immunohematology Reference Laboratory in Gainesville, FL. This position is responsible for overseeing all laboratory testing activities performed in the LifeSouth facility. This includes meeting the needs of customers for accurate, timely and high-quality immunohematology reference laboratory testing and services. This position is also responsible for compliance with established laboratory policy and with applicable governmental regulatory requirements from CLIA, FDA, AABB, HIPAA and state licensing regulations. Bachelor's degree in clinical laboratory, chemical or biological science required. SBB Certification required. Five years of clinical laboratory experience at a licensed, certified or accredited facility required. Previous management experience required. Master's degree may compensate for less experience. Relocation expenses negotiable. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. VEVRAA Federal Contractor. Follow this link to apply: https://lifesouth.careerplug.com/jobs/901033/apps/new.

Medical Director. Provide transfusion medicine (TM) clinical care at Heartland Blood Center (HBC) and its associated hospitals in the scope noted below, as well as effort in leadership of the Immunohematology Reference Laboratory (IRL) as Medical Director at HBC/Versiti. Key components of this position would comprise TM consultation and oversight of blood management at HBC and Versiti partner hospitals, as well as participation in educational initiatives and clinical/applied research within both Versiti blood centers and their affiliated health systems. Primary Responsibilities: Oversees blood donor center collections in the Chicagoland and various areas of Indiana. Provides medical direction, including compliance with local, state, and federal regulations and accreditation agencies, for blood center and transfusion services at Versiti affiliated hospitals in Illinois and Indiana. IRL Medical Director for HBC, providing oversight of IRL laboratory staff technical duties and working with Versiti and HBC laboratory management to provide education and skill advancement. Education and Licenses: M.D. or D.O. Degree. Board certified in pathology (AP/CP or CP only), internal medicine, or pediatrics (with subspecialty boards in hematology). Board certified/board eligible in Blood Banking/Transfusion Medicine (American Board of Pathology—ABP). Current or eligible for medical licenses in Illinois, Wisconsin, Indiana, Michigan and Ohio. Experience/Certifications: Demonstrated experience in both 1) pathology/laboratory medicine or hematology and 2) transfusion medicine. Ability to write lectures and articles using original or innovative techniques or styles; excellent presentation skills with capacity to present to varied audiences. Click here to view the full job description and to apply.