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# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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**2019 #26** **August 9, 2019**

**INSIDE:**



## CMS Proposes Potential Exemption for Laboratory Date of Service Policy in 2020 Outpatient Hospital Rule

The Centers for Medicare and Medicaid Services (CMS) has published the Hospital Outpatient Prospective Payment System (OPPS) proposed rule for calendar year 2020. It would create a potential exemption for blood centers from the laboratory date of service (DOS) exception policy, or 14-day rule, for Advanced Diagnostic Laboratory Tests performed on patients.

In June, CMS extended the enforcement discretion period for six months until January 2, 2020 for the laboratory date of service policy. Without the extension, the DOS policy would have required a laboratory, including a blood center as an unintended consequence, to bill Medicare directly for advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests under some circumstances. Following advocacy efforts from the blood community, CMS delayed enforcement until a workable solution could be established. The proposed OPPS rule outlines three possible changes, which are not mutually exclusive, to remedy this issue:

- a test would be billable by the hospital if the ordering provider determines the results would impact a current or future hospital outpatient encounter;
- removal of molecular pathology tests from the DOS change;
- exclusion of blood banks/centers from the DOS change.

A blood center/bank is defined for this purpose as "an entity whose primary function is the collection, storage and dissemination of blood products." The aforementioned proposals would permit hospitals to continue billing for these tests instead of requiring blood centers to bill.

Additionally, the OPPS proposed rule could alter hospital payment for specific blood products. The agency would continue the cost-to-charge methodology in use since 2005 for blood and blood products. Proposed changes include eliminating the current crosswalk-based payment rate for pathogen reduced platelets, HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit), from the calendar year 2019 OPPS final rule for Pathogen Reduced Platelets. Instead, it would use claims data as the basis which would decrease the payment rate. Also, the proposed changes would assign a higher level of 1D ($31-40) with a payment rate of $35.50 for two approved bacterial detection tests for 7-day platelets (HCPCS P9100), an increase from the CY 2019 rate of $25.50 based on a new technology level 1C ($21-$30).

(continued on page 2)

CMS OPPS (continued from page 1)

Additional information is available to ABC members in MCN 19-057. ABC will submit comments to CMS and continue to advocate on behalf of members for an exemption to testing performed by blood centers for the purposes of identifying the most appropriate blood products for patients. Comments for the proposed rule are due September 27th. Please contact ABC Senior Director of Federal Government Affairs Diane Calmus with any questions or comments.

(Source: MCN 19-057) ♦

## REGULATORY NEWS

**The Centers for Medicare and Medicaid Services (CMS) announced this week that it had finalized a decision to provide coverage to Medicare beneficiaries for Chimeric Antigen Receptor T-cell (CAR-T) therapies approved by the U.S. Food and Drug Administration (FDA).** "President Trump is committed to strengthening the Medicare program by ensuring that beneficiaries have access to new and potentially lifesaving treatments", said CMS Administrator Seema Verma in an agency news release. "As the first type of FDA-approved gene therapy, CAR T-cell therapies are an important scientific advancement in this promising new area of medicine and provide treatment options for some patients who had nowhere else to turn," said CMS Administrator Seema Verma. "Today's coverage decision provides consistent and predictable patient access nationwide. CMS will work closely with our sister agencies to monitor outcomes for Medicare patients receiving this innovative therapy going forward." CAR-T uses an individual's own genetically modified immune cells to combat disease. "We remain committed to supporting the efficient development of safe and effective CAR T-cell therapies," said Acting FDA Commissioner Ned Sharpless, MD in the release. "We know there are relatively limited data about the use of these life-saving therapies in the Medicare population. Our robust postmarket surveillance programs will continue to monitor for potential risks, as we do for all licensed and approved medical products. We will also continue to carefully assess the benefits and risks when considering whether to approve new CAR T-cell products. We will continue working with our partners at CMS and the National Institutes of Health's National Cancer Institute (NCI) to help advance the development and availability of these therapies to patients in need."

(Source: CMS News Release, 8/7/19)

**CMS has published its fiscal year 2020 "Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Prospective Payment System" final rule.** ABC advocated that that LTCHs will not have the resources needed to provide patients with access to blood

(continued on page 3)

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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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REGULATORY NEWS (continued from page 2)

transfusions and requested that CMS consider whether payments to LTCHs are adequate to cover the cost of this resource intensive, specialized service. The agency responded, "We wish to clarify that the Transfusions SPADE collects information on the complexity of the patient and resources the patient requires. At this time, this item will not be used for any payment purposes, and thus we are not able to comment on the cost of this service. This SPADE is not intended to measure the ability of an LTCH to provide in-house transfusions, only to capture the services a given patient may be receiving. Further, for patients who require services related to blood transfusions, information collected by this data element is a part of common clinical workflow, and thus, we believe that burden on resource intensity would not be affected by the standardization of this data element. After consideration of the public comments we received, we are finalizing our proposal to adopt the Transfusions data element as standardized patient assessment data beginning with the FY 2022 LTCH QRP as proposed."

(Source: CMS IPPS Final Rule, 8/6/19)

**The Food and Drug Administration's Center for Biologics Evaluation and Research (CBER) has published its 2018 annual summary of Biological Product and Human Cells, Tissues, and Cellular Tissue-based Product (HCT/P) Deviation** Report (BPDR). Deviations potentially affecting safety, purity, or potency, as well as unexpected events that occur during the manufacturing of blood and blood products must be reported to CBER in accordance with 21 CFR 606.171. In addition, manufacturers of non-reproductive HCT/Ps regulated by FDA are required to submit deviation reports involving distributed products if the deviation or the unexpected event is related to a core Current Good Tissue Practice Requirement and related to the prevention of communicable disease transmission or HCT/P contamination. The annual summary provides an overview of the reports FDA received during the fiscal year, including detailed information regarding the number and types of deviation reports received. FDA combined data received over the last three fiscal years to compare data and highlight changes. However, it is important to note that CBER's system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends. During fiscal year 2018, Oct. 1, 2017 to Sept. 30, 2018, CBER entered 46,967 deviation reports into its database, a 10.1 percent decrease (5,264) from FY 2017. While the number of reports trended downward, the number of reporting establishments increased from 2,003 in FY 2017 to 2,105 in FY 2018. The largest category of BPDRs from licensed blood and plasma establishments was reports involving post donation information, accounting for about 70 percent of BPDRs submitted by blood and plasma establishments. The number of reports relating to post donation information decreased by 10 percent. During FY 2018, 361 HCT/P manufacturers submitted 22 more reports than in FY 2017.

(Source: CBER Biological Product and HCT/P Deviation Report – Fiscal Year 2018, 8/8/19)

## Transfusion Risks: Perception vs Reality

*Contributed by Richard Gammon, MD, Medical Director at OneBlood*

***Please note: The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers.***

Two recent articles explored transfusion risks, both real and perceived. The first study evaluated the perception of transfusion-transmitted infections (TTIs). As certain tests to detect TTIs in donated blood have cost-effectiveness exceeding $1 million per quality-adjusted life year and while cost-sensitive decision-making approaches have recently been proposed, the paper noted that initiatives to remove inefficient safety measures have not been widespread and blood services continue to introduce safety measures of questionable efficiency (e.g., Zika nucleic acid testing(NAT) in the U.S. and hepatitis E virus NAT elsewhere). Policymakers must often balance risk of TTI and the public's risks perceptions when creating blood safety policies. The authors investigated the views of stakeholders regarding the Dutch blood supply. The research used phenomenological hermeneutics that studied ethical literature, along with in-depth interviews or group discussions with stakeholders and then compiled the consensus views. There were 25 semi-structured interviews and two focus group discussions that included policymakers, hematologists, blood donors, and recipients with respondents encouraged to discuss general concerns about the blood supply, to address the tolerability of TTI risks in comparison to other hazards. They were also able to comment on the costs of blood safety, as an analysis of arguments for tolerance or intolerance towards TTI risks also occurred. Stakeholders' views were clustered into seven categories:

- clinical impact;
- probability of infection;
- avoidability of infection;
- cost and health benefits;
- other consequences of safety measures;
- non-consequentialist ethical arguments; and
- stakeholders' interests.

This study indicated that stakeholder's views may be less entrenched than previously thought as not all blood product recipients may demand zero risk whatever the cost. Some participants felt that resources spent on inefficient blood safety measures could be applied more beneficially elsewhere. The authors concluded that a better understanding of stakeholder concerns may help shape broadly supported rational policy decisions.

The second paper focused on postpartum hemorrhages in developed countries as 3 percent of all women receive blood transfusions. The authors' aimed to investigate whether blood transfusions postpartum were accompanied by an increased risk for transfusion reactions (TRs) when compared to transfusions given to nonpregnant women. The study featured 517,854 women who gave birth in one county in Sweden between 1990 and 2011 of which 12,183 (2.4 percent) received a blood transfusion. There were 96 TR postpartum, a prevalence of 79 per 10,000 compared with 40 per 10,000 among nonpregnant women (odds ratio, 2.0; 95 percent confidence interval, 1.6-2.5). The postpartum risk of a TR after transfusions of red blood cells

(continued on page 6)

### 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.

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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.*

## Updated Disaster Response Plan

ABC and Blood Centers of America, Inc. (BCA) have reviewed and updated disaster plans and documents. Version 2.0 of the ABC/BCA Disaster Plan is available and has been amended to reflect industry changes over the past decade. The previous Disaster Plan depended on the use of the ABC Hub and Spoke system which no longer fit the current need due to mergers and consolidations within the industry. In lieu of the Hub and Spoke system, operational responses to disasters will continue to be coordinated by BCA with regulatory and communication support provided by ABC. The ABC/BCA Disaster Plan Version 2.0 reflects these changes. We strongly encourage members to review the plan with your internal teams to acquaint yourself to the process and incorporate into your own disaster plans. The disaster page on the ABC Member site contains links to various documents that have been updated as appropriate to assist members in disaster planning and response.

(Source: MCN 19-052, 7/19/19)

## August SMT Journal Club Webinar Articles Announced

The ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar on August 19th at noon EDT will feature the articles below:

- Financial impact of alternative approaches to reduce bacterial contamination of platelet transfusions (*Transfusion*);
- Response to random apheresis platelets versus HLA-selected platelets versus pooled platelets in HLA-sensitized patients (*Transfusion*); and
- Platelets stored in whole blood at 4 C: in vivo posttransfusion platelet recoveries and survivals and in vitro hemostatic function (*Transfusion*).

Additional details are available to ABC members in MCN 19-054.

(Source: MCN 19-054, 7/25/19)

## July *Blood Bulletin* Available

ABC's Scientific, Medical, and Technical (SMT) Publications Committee has published the July 2019 Issue **(PDF or MS Word versions)** of the *Blood Bulletin*, titled "Using Group A Plasma to Support Emergently Bleeding Patients."

The article was written by Jonathan Hughes, MD, Medical Director at Vitalant and Chris Gresens, MD, Senior Chief Medical Officer, North & West Divisions at Vitalant. *Blood Bulletin* is reviewed and edited by ABC's SMT Publications Committee.

ABC publishes the *Blood Bulletin* for you to use in your educational programs as a value-added service for hospital customers.

(Source: MCN 19-055, 7/26/19)

Transfusion Risks (continued from page 4)

(RBCs) only was increased by 80 percent (OR, 1.8). Compared with the background pregnant population, women with preeclampsia (OR, 2.0), induced labor (OR, 1.7), or premature delivery (OR, 1.7) were at increased risk for a TR.

A significant increase in risk occurred when a combination of all three types of blood components were given, which may be attributed in part, by the higher risk of a TR from plasma and platelet units when compared with RBC transfusions exclusively. Also, an indication bias may exist due to sicker patients, with an increased risk for TRs, needing broader transfusion support. A limitation of the study included the researchers lacking access to the type of TR or transfusion history. The authors concluded that special care should be taken when women with preeclampsia were considered for blood transfusion postpartum, as the study's findings suggest that pregnancy was associated with an increased risk for TRs.

**Citations**: Kramer, K., Verweij, M., Zaaijer, H.L. When are infection risks of blood transfusion tolerable? Towards understanding the ethical views of stakeholders in the blood supply. *Vox Sanguinis*. 2019. DOI: 10.1111/vox.12821.

Thurn, L., Wikman, A.,Westgren, M., Lindqvist, P.G. Incidence and risk factors of transfusion reactions in postpartum blood transfusions. *Blood Advances*.2019. DOI 10.1182/bloodadvances.2019000074.

## MEMBER NEWS

**Community Blood Center (Appleton, Wis.)** has partnered with Gift of Hope Organ & Tissue Donor Network (Chicago, Ill.). The partnership allows Community Blood Center to expand its operations to the South Side of Chicago with a blood donation center located within a Gift of Hope community training center. "Both Gift of Hope and [Community Blood Center] are focused on the gift of life and how the selfless act of blood, platelet, bone marrow, organ, and tissue donations can save the lives of those in our communities," said Community Blood Center CEO and President John Hagins in a news release. "The potential impact of this partnership for the Chicagoland area is exciting." Community Blood Center will begin collecting blood in Chicago in 2020.

(Source: Community Blood Center Announcement, 8/2/19)


*Photo courtesy of The Blood Connection*

**The Blood Connection (Greeneville, S.C.)** recently dedicated its newest blood donation bus to Trooper Eric Nicholson, who lost his life in the line of duty in 2000. The bus was officially named "Eric" during a ceremony that featured more than 70 individuals. On the day of his death, Trooper Nicholson donated at a blood drive hosted by his wife Misty, who has been passionate about spreading the message of blood donation throughout the community. She views her commitment to blood donation as her way of keeping his legacy alive. A blood drive followed the dedication on July 26th. Misty Nicholson and Eric's sister, Amy Dedea, both donated blood after the ceremony. A plaque will be placed on the bus to serve as a constant reminder to blood donors that they are a part of keeping Trooper Nicholson's memory alive.

(Source: The Blood Connection Announcement, 7/29/19)

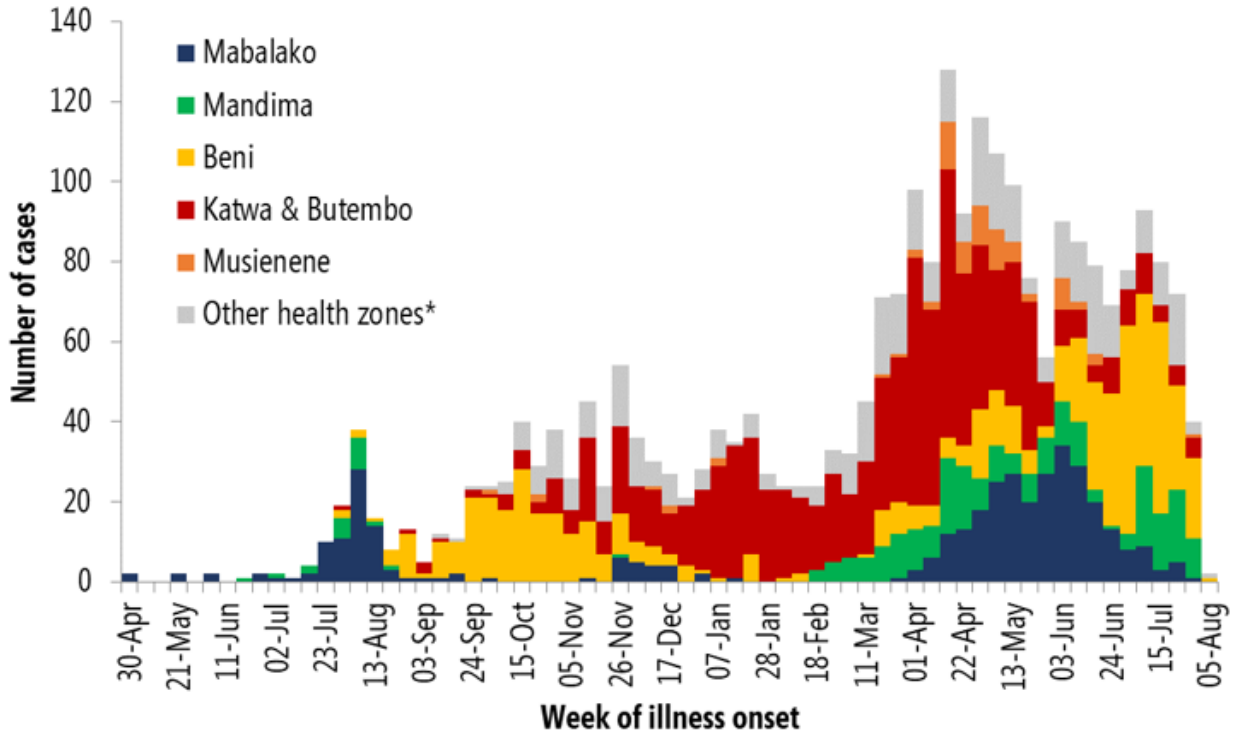
## INFECTIOUS DISEASE UPDATES

### EBOLA

The Ebola outbreak in the Democratic Republic of the Congo (DRC) continues to spread roughly a year after it began in spite of ongoing containment efforts. A third death has occurred in Goma, a city near the border of Rwanda. The World Health Organization (WHO) declared the Ebola outbreak in the Democratic Republic of the Congo (DRC) a Public Health Emergency of International Concern (PHEIC) in July. The Centers for Disease Control and Prevention (CDC) stated this week that, "[a]s the WHO PHEIC declaration makes clear, this Ebola outbreak continues to be a complex and serious public health threat," said CDC Director Robert R. Redfield, MD in a news release. "CDC remains prepared for the prolonged journey ahead and remains committed to working with our U.S. government and international partners to support the response and end this outbreak."

The WHO and CDC have not classified the affected areas as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that "in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2). As of August 6th, there were 2,687 confirmed cases with 1,866 confirmed deaths in the DRC.

**Confirmed and probable Ebola virus disease cases by week of illness onset, data as of August 6th***




**Data in recent weeks are subject to delays in case confirmation and reporting, as well as ongoing data cleaning. Trends during this period should be interpreted cautiously.*

(Source: Ebola virus disease – Democratic Republic of the Congo, 8/8/19; CDC News Release, 8/1/19)

## PEOPLE

**Brian Forbis** has been named CEO of Blood Bank Computer Systems, Inc (BBCS). He previously served as vice president. Mr. Forbis has been with the organization since 2007. His tenure began in a business development role before promotions to manager of Sales and Implementation and director of products and business development. "I am grateful for the opportunity to lead this organization during such an exciting time," said Mr. Forbis in a news release. "BBCS is continually evolving to meet the needs of our blood centers and I'm looking forward to making a difference in this ever-changing industry. I am blessed to have had my amazing mother and mentor, Beth, to look up to all these years and to help guide me on this journey that we have shared together. Her leadership and passion for this industry has not only impacted us at BBCS, but each and every one of our clients." Mr. Forbis succeeds Beth McGee who held the position for 24 years. She will continue to serve as board chair and president of BBCS. "It is with great pride that I am turning over the reins of BBCS to my very capable son, Brian," said Ms. McGee in the BBCS news release. "He shares my passion for our clients, their communities and the industry we serve. Over the years, Brian has been diligent about learning every facet of the organization in preparation for his transition to CEO. We are confident that Brian will lead BBCS to new heights." Before joining BBCS, Mr. Forbis managed online projects and online marketing campaigns at Keystone Resorts. He holds a B.S. degree in Information Technology, Administrative Management and Network Administration from Central Washington University. He became a certified ScrumMaster in 2011 and is also a certified Scrum Product Owner through the Scrum Alliance.

(Source: BBCS News Release, 7/29/19)

## GLOBAL NEWS

**Canadian Blood Services (CBS) recently announced that it will open three dedicated, government-funded source plasma collection facilities.** The sites will be located in Sudbury, Lethbridge and Kelowna as CBS strives to improve source plasma sufficiency amid increased demand for source plasma-derived products. "Canadian Blood Services is responsible for ensuring a safe and secure supply of plasma, and for mitigating the risks and impacts of the growing global demand for plasma protein products such as Ig, within Canada's national healthcare system," said CBS CEO Graham Sher, MBBCh, PhD, FRCPC in a news release. "Opening these stand-alone sites will allow us to increase plasma collection and halt the current downward trend in Canada's source plasma sufficiency levels. By increasing the domestic plasma supply we can continue to be responsive to the needs of Canadian patients, today and into the future." Two of the three sites are scheduled to open in 2020 with the third opening in 2021. The three locations will be proof-of-concept sites that are designed to "to further test and perfect a new collections model that is separate and distinct from the one currently used to collect whole blood." All donations will be both voluntary and unpaid. Last year, Canadian Sen. Pamela Wallin (I-Saskatchewan) introduced legislation that would prohibit the collection of plasma from remunerated donors in Canada. Bill S-252, entitled the Voluntary Blood Donations Act, would cease the operations of organizations such as Canadian Plasma Resources, which has two collection facilities in Canada that incentivize donors with prepaid gift cards that escalate in value based on the frequency of plasma donation to encourage repeat donors.

(Source: Canadian Blood Services News Release, 8/6/19)

(continued on page 9)

GLOBAL NEWS (continued from page 8)

**NHS Blood and Transplant (NHSBT) reported an increase in the total number of organ donations in the annual Organ Donation and Transplant Activity Report.** A record number of organ donations took place despite a decrease in the number of eligible donors. The uptick is attributed to:

- an increased number of families agreeing to support donation;
- a smaller amount of families failing to honor their relative's decision to donate; and
- a higher referral rate of potential donors by medical staff to organ donation teams.

"It is testament to the courage of these donors and their families, as well as the dedication of all the clinical staff involved, that we have been able to save and transform as many lives as we have this year," said NHSBT's Anthony Clarkson, director of Organ Donation and Transplantation in a statement published by the organization. "The reduction in the number of people dying in circumstances where they are able to donate, means that we need to continue to explore ways to improve the donation and transplant process. We are utili[z]ing new techniques and technologies to ensure that donated organs are in the very best possible condition for transplant and are working to increase awareness and understanding of organ donation and the law change across society with the aim that no opportunity for donation is missed." In 2020, England and Scotland will begin an "opt-out" system for organ donation, which stipulates that all adults will be deemed to have given consent to donate their organs upon their death unless they "opt-out" or fall into one of the excluded groups. A similar system has been in existence in Wales since 2015.

(Source: NHSBT Report, 7/18/19)

## WORD IN WASHINGTON

**In the wake of last week's deadly mass shootings, Senators John Cornyn (R-Texas), Rob Portman (R-Ohio), and Presidential hopefuls Rep. Tim Ryan (D-Ohio), and former Rep. Beto O'Rourke (D-Texas) honored the victims of the tragedies and encouraged individuals to remember the importance of the ongoing need for blood donors.** Each shared their individual blood donation experience on their official social media channels to inspire their followers to give blood. Sen. Cornyn and former Rep. O'Rourke donated in El Paso, Texas at ABC member Vitalant, while Sen. Portman and Rep. Ryan donated at ABC member Community Blood Center (Dayton, Ohio).



**Upcoming ABC Webinars – Don't Miss Out!**

- **SMT Journal Club Webinar** – August 19. Additional details available to ABC members in MCN 19-054!

## ABC 2020 Meetings & Workshops

| Meeting/Workshop | Dates | Location | Hotel | Registration Dates & Fees |
|---|---|---|---|---|
| 2020 ABC Annual Meeting | March 9th-11th | Washington, DC | Ritz-Carlton (Pentagon City) | More details coming soon! |
| ADRP 2020 Conference | May 19th-21st | Phoenix, AZ | Hyatt Regency | More details coming soon! |

**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**

Aug. 13. **CDC National Center on Birth Defects and Developmental Disabilities Division of Blood Disorders "2019 Scientific Update: Transfusion Guidelines for Thalassemia Webinar**. Registration open.

Sept. 13. **Carter BloodCare 2019 Enrichment Lab, Euless, Texas.** A continuing education program designed for medical technologists and clinical laboratory specialists, interested in transfusion medicine. Attendees can earn up to 6 hours of P.A.C.E.® credit. More details available here.

Sept. 19. **National Institutes of Health Clinical Center Immunohematology and Blood Transfusion 38th Annual Symposium, Bethesda, Md.** More details available here.

Sept. 20. **Red Cell Genotyping 2019: Patients First, Bethesda, Md.** This 9th annual symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. 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.

## 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!

## 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

**Medical Apheresis RN/Nurse (Houston, Texas).** Gulf Coast Regional Blood Center is looking for a Medical Apheresis RN/Nurse for its newly expanded, state-of-the-art apheresis center. This person is responsible for patient/donor care during apheresis procedures and must be able to apply the nursing process with patients and donors. Duties include: assisting in the development of new procedures, performing required equipment maintenance, evaluating and maintaining technical procedures, communicating with physicians regarding patient status, remaining current on national standards and trends in the area of apheresis and making appropriate suggestions as to necessary changes or updates, maintaining all records required by AABB, FDA and other accrediting agency or vendor standards, participating in management and coordination of clinical research studies if necessary. Qualifications for this position are: a graduate degree from an accredited School of Professional Nursing, a current RN license, three years of recent direct patient care nursing experience (preferably in an acute-care setting), demonstrated proficiency in peripheral intravenous access, certification in Basic Life Support or ACLS (Advanced Cardiovascular Life Support). For more information or to apply, click here. Contact name, address and telephone number: Tracy Reynolds Talent Acquisition Manager, 1400 La Concha Lane, Houston, Texas 77054-1802; Phone: (713) 791-6395.

**Medical Technologist II - San Francisco, CA (Req:191052).** Vitalant exists to help people realize their life-transforming potential by offering convenient blood donation opportunities and sharing our expertise in transfusion medicine. Founded in 1943, Vitalant is one of the nation's oldest and largest nonprofit transfusion medicine organizations. Bachelor's degree in a chemical, physical, biological, medical technology or clinical laboratory science required. Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. CA Certification as a Medical Technologist by a recognized certifying agency required or CLIA equivalent for high complexity testing required. SBB preferred. State licensure (as required by regulations). Three years' experience in a clinical laboratory setting required or SBB. Experience in developing and conducting formal training preferred. Please click here to apply.

**Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School).** The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. Service and teaching responsibilities will be shared with three other full and part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ233, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

**Quality Assurance Director (Oklahoma City, OK).** The Oklahoma Blood Institute, the nation's fifth largest blood center and Oklahoma's largest Bio-Tech company, has an immediate opening for a director for our quality assurance systems. This position will provide direct supervision for quality systems consultants, promote a quality culture within the organization and ensure that policies, procedures, processes, work instructions and training programs comply with industry standards and regulatory requirements. The position also ensures that the firm's quality plan and objectives are implemented throughout each phase of blood/tissue manufacturing and clinical services. Qualifications: Requires a Bachelor of Science degree in medical technology or related field and eligible for registration with the ASCP; minimum of five years' experience in managing quality systems; strong written and verbal communication skills. Salary Range: Competitive salary, re-location package is possible, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, tuition reimbursement and holiday pay. How to Apply: http://obi.org/careers/.

**Quality & Regulatory Affairs Specialist.** The Stanford Blood Center is seeking a Quality & Regulatory Affairs Specialist. Under the general supervision of the Director of Quality and Regulatory Affairs, this position will per

(continued on page 12)

POSITIONS (continued from page 11)

form the quality and regulatory affairs duties and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, validations, and assist with development, as necessary. Develop, perform and report departmental, system audits, and safety inspections. Perform Good Manufacturing Practice (GMP) and safety training, trend analysis of events and quality indicators, root cause analysis, process improvement, corrective and preventive actions; maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports, when required. Core Duties include: Review validation plans, procedures, training documents, PDIF records, product and equipment QC for regulatory compliance and assist with development and training as necessary. Develop, perform and generate departmental reports and system audits. Develop, revise, institutional QRA SOPs and training. Perform GMP, QRA and safety training. Perform trend analysis of events, complaints, and quality indicators with subsequent performance of root cause analysis, and process improvement. For complete job description and to apply, visit www.stanfordhealthcarecareers.com and reference job # 51343

**Director of Donor Recruitment (Tulsa, OK).** Do you have a passion for community service, leadership and sales? Are you a goal-oriented people person? Oklahoma Blood Institute is seeking qualified candidates for Director of Donor Recruitment in the Tulsa area. This is a vital and rewarding position that will play a key role in expanding our footprint and sharing our lifesaving mission in Oklahoma. The Director of Donor Recruitment will lead a donor recruitment team to success; providing clear direction, as well as employing effective management and strategic planning to ensure collection goals, performance expectations and departmental objectives are met. Qualifications: Three to five years of work experience directly related to blood banking. Associate's degree is required, bachelor's degree preferred. Public speaking/presentation experience required. Excellent verbal and written communication skills. Benefits: Oklahoma Blood Institute offers a competitive salary, excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, tuition reimbursement, etc. Apply online only at http://obi.org/careers/. EEO M/F/D/V/Drug Free Work Environment

**Director of Donor Recruitment (Little Rock, AR).** Do you have a passion for community service, leadership and sales? Are you a goal-oriented people person? Arkansas Blood Institute is seeking qualified candidates for Director of Donor Recruitment in the Little Rock area. This is a vital and rewarding position that will play a key role in expanding our footprint and sharing our lifesaving mission in Central Arkansas. Arkansas Blood Institute is part of one of the fastest-growing independent blood centers in the U.S., providing blood to more than 30 hospitals in Arkansas, including four major hospitals in Little Rock. Arkansas is home to 52 state parks set on gorgeous mountains, lakes, streams and forests. Little Rock is beautifully located along the Arkansas River and has more than fifteen miles of scenic riverfront, cultural and historic attractions, entertainment and world-class dining. Qualifications: Three to five years of work experience directly related to blood banking. Associate's degree is required, bachelor's degree preferred. Benefits: Arkansas Blood Institute offers a competitive salary, excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and a relocation package for candidates who do not reside in the Little Rock area. Apply online only at http://arkbi.org/careers/. EEO M/F/D/V/Drug Free Work Environment

**Chief Medical Officer.** The Chief Medical Officer is responsible for the following: Build and leverage cross functional collaborative relationships to achieve shared company goals. Support donor recruitment through presentation to key decision makers in clients and prospects. Participate in senior management business and clinical strategy development and implementation. Participate as a staff representative to the Board of Directors. Is encouraged to conduct research in areas related to hematology and blood banking. Obtain support, funding and grants. Review research efforts with the CEO. Review and approve all controlled documents. Develop and recommend departmental policies, procedures and programs to ensure departmental adherence to Quality Program. Provide leadership and direction for management and employees. Establishes performance goals, allocates resources and assesses policies for department directors. Recommend and develop new services and programs. Review processes with the intent of improving efficiency and reducing costs. Involved with medical aspects of new product development and preparation of articles and abstracts for presentation and publication. With VP, Quality and Regulatory Affairs review blood collection quality control issues and policies. Develop and implement strategic goals related to the quality improvement, management programs and accreditation standards. Assist with the accreditation process and maintaining the San Diego Blood Bank standards for both blood collection and processing. Click here to view the full job description and to apply.

**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

(continued on page 13)

POSITIONS (continued from page 12)

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 sub-specialty 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. We have two openings; one based out of the Jacksonville, Florida area and the other based out of the Ft. Lauderdale area, both locations have some of the most gorgeous beaches in the nation! If you want to 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.