

2018 #24

July 20, 2018

INSIDE:

ABC Signs on to Coalition
Comment Letter for 2019
IPPS3

2018 Summer Meeting3

WEBINAR SAVE THE
DATE.....3

RESEARCH IN BRIEF4

RECENT REVIEWS6

REGULATORY NEWS....6

STOPLIGHT®: Status of
America's Blood
Centers' Blood Supply .7

WORD IN WASHINGTON
.....8

IN MEMORIAM9

CALENDAR.....9

POSITIONS.....10

Platelet-associated Bacterial Risks Return to the Blood Products Advisory Committee (BPAC)

The 119th meeting of the U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) took place at the agency's White Flint, Md. headquarters on July 18th and 19th. Of primary interest to the blood community was the discussion on Thursday of bacterial contamination and sepsis associated with transfusion of room temperature stored platelet components.

Emily Storch, MD, medical director from the Office of Blood Research and Review introduced and reviewed the [topic](#) emphasizing three points:

- the estimated rates of sepsis in the face of current mitigation strategies exceeds the risk tolerance of both the blood community and the agency. Particularly cited in this context was the report of platelet sepsis related deaths in the recent [Morbidity and Mortality Weekly Report](#);
- this meeting was scripted as an opportunity for the BPAC to discuss all the available mitigation strategies in a single session; and
- the agency intends to issue a revised draft guidance on this topic during 2018.

Few data not seen by the committee at their [November 2017 meeting](#) were presented. The experience at Johns Hopkins and the additional perspective from the Irish Blood Transfusion Service with their protocols for secondary culture during storage were useful. Data from NHS Blood and Transplant (NHSBT) in the United Kingdom regarding high volume, delayed primary culture with extension of dating to seven days now includes more than two million platelet doses. They have recognized a single episode of clinical sepsis with their process and four near-misses where distributed, contaminated products were interdicted prior to transfusion. Substantial discussion about the sensitivity of their surveillance (and of hemovigilance surveillance generally) followed. Debate about how that ought to influence how the BPAC viewed the NHSBT data ensued highlighting the need for a well-resourced hemovigilance initiative to evaluate the impacts of any mitigation strategies recommended in a final guidance. ABC member Blood Systems, Inc. presented their approach to "proportional volume sampling" designed to enhance the sensitivity of primary culture by increasing the volume inoculated into culture bottles.

A minor controversy about the utility, or lack thereof, from using both aerobic and anaerobic culture media in culture protocols simmered through the discussions, but the BPAC clinical microbiology and infectious diseases experts were fairly explicit about its value for earlier and broader detection of facultative and microaerophilic

(continued on page 2)

BPAC COMMITTEE MEETING (continued from page 1)

bacteria, in addition to their contribution to increasing the total volume of cultured material.

Data that support the use of point-of-care rapid assays for bacteria in transfusion services were again reviewed. Possible improvements to the licensed point-of-care tests (Verax PGD® and Immunetics BacTx®) were touched on very briefly (as were changes in the development of culture method (BacT/Alert®) in wide use in the U.S., designed to improve its specificity). The high efficacy of the FDA-approved pathogen reduction (PR) system for platelets (INTERCEPT™ Blood System) for prevention of platelet sepsis was reiterated, based primarily on hemovigilance data in the European Union. Barriers to widespread introduction of PR, familiar to many ABC member blood centers, were enumerated. These included the stringent process guard bands, lack of approval for all platelet products, for triple collections, or for seven-day storage. There were also concerns about PR costs and reimbursement in the inpatient setting.

A [joint statement](#) from ABC, AABB, and the American Red Cross was presented during the open public hearing. The three organizations agreed that rates of sepsis from platelets are unacceptable and asked for guidance with maximum flexibility from the agency in the face of imperfect data. The statement endorsed the utility of any of the four basic approaches (enhanced primary culture, secondary culture during storage, point-of-care testing in the transfusion service, and PR). The critical importance of being attentive to operational issues that affect selection of the “locally” most appropriate processes by blood center/transfusion service collaborators was emphasized. These included the ability of seven-day platelet dating to mitigate the adverse impacts of some approaches on supply adequacy by pushing outdate rates down. Seven-day dating is achieved with the NHSBT process (and in information provided to the committee but not presented publicly from ABC member Héma-Québec and Canadian Blood Services) and can be achieved by using secondary culture or point-of-care rapid tests during storage. Several public and invited speakers emphasized the importance of the FDA moving with alacrity on this guidance since the patient safety issue is important and the blood community is understandably reluctant to make major initiatives ahead of guidance, only to find them in conflict with the final guidance, which would require them to be reworked.

There were interesting tangential thoughts about the potential for a variety of “non-traditional” platelet products to avoid sepsis altogether (refrigerator-stored platelets, frozen platelets, and freeze-dried platelet preparations) and the distinct patient populations that might be candidates for the various products. The committee was asked to “comment on the advantages and disadvantages of each of the various strategies to control the risk of bacterial contamination in platelets, including the scientific evidence and the operational considerations involved.” No formal votes were requested by the agency. At the end, it appeared (to blood community observers) that both the committee and the FDA were sensitive to potential impacts of the various strategies and understood both the importance of maximum flexibility and expeditious completion of the regulatory process requested by the blood organizations. Transcripts and materials from the meeting will be available on the FDA [website](#). 💧

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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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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.

ABC Signs on to Coalition Comment Letter for 2019 IPPS

ABC joined the National Marrow Donor Program (NMDP) along with a coalition of advocates in submitting a comment [letter](#) to the Centers for Medicare and Medicaid (CMS) regarding [CMS-1694-P](#): Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates. The letter raises awareness of the potential for a lack of access to patients that depend on such therapies due to a lack of funding for patients in the inpatient setting that may require them. “The lack of adequate reimbursement for [hematopoietic stem cell transplants] (HCTs) places hospitals in the impossible position when it comes to trying to provide the highest quality care to our patients and places Medicare patient’s access to life-saving HCT at risk. Access to HCTs is critical because it is the only curative treatment option for certain blood cancers, including leukemia and lymphoma, and blood disorders, such as sickle cell disease.” The coalition asks CMS to consider a similar policy for reimbursement of HCTs as is currently for living kidney donors. “Specifically, CMS could model the reimbursement for cells off of its living kidney donor policy. By separating the costs of cell acquisition from the current [Medicare Severity Diagnosis Related Groups] (MS-DRG) payment, CMS could pay for cell acquisition on a reasonable cost-basis apart from the MS-DRG, as it does for other solid organ acquisition costs and kidneys acquired from living kidney donors. While the HCT community continues to work with the Congress to pass legislation directing the desired outcome, we urge CMS not to wait on the legislative process and to protect access to these life-saving transplants now.”

2018 Summer Meeting

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

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

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

Hospital, public, and emeritus registration rates are available [here](#). Contact [Leslie Maundy](#) for available sponsorship opportunities. Click [here](#) for additional meeting information. ♦

WEBINAR SAVE THE DATE

ABC SMT Journal Club Webinar

August 7, 2018 at 3 PM EDT

Additional information including login details available to ABC members in [MCN 18-028](#).



AMERICA'S BLOOD CENTERS' 56TH SUMMER MEETING

July 30 – August 2, 2018 **Montréal, QC**

2018 SUMMER MEETING SCHEDULE

Monday, July 30	ABC Board Meeting
Tuesday, July 31	Medical Directors Workshop
Wednesday, August 1	SMT Forum Business Forum Host Event by Héma-Québec (off-site)
Thursday, August 2	ABC Members Meeting

All of us at Héma-Québec look forward to hosting our ABC colleagues, family and friends at the 2018 ABC Summer Meeting in Montréal. A striking union of European charm and North American attitude, Montréal seduces visitors with a harmonious pairing of the historic and the new, from exquisite architecture to fine dining. We hope you can take the opportunity to see what Montréal has to offer and discover its many colorful and vibrant neighborhoods which overflow with markets, museums, boutiques, restaurants and local cafés—diverse expressions of the inhabitants "joie de vivre."



– Luc Vermeersch,
Vice-President, Finance
and Strategic Project Management

Hotel Information

Hotel Omni Mont-Royal
Hotel room rate: \$234 (CAD) + tax

**For registration information, visit
http://bit.ly/abc_summer_meeting.**

For sponsorship opportunities,
please contact Leslie Maundy at
lmaundy@americasblood.org



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RESEARCH IN BRIEF

How good are the data used by FDA for fast approval of “Breakthrough Therapies”? The blood community and others are frequently critical of the pace at which new approvals move through the U.S. Food and Drug Administration (FDA). A research letter from Yale University has evaluated the quality of the evidence used for accelerated approvals of drugs and provides a note of caution. The authors find that, compared to non-breakthrough approvals, such approvals from 2012 - 2017, relied on pivotal trials that were more likely than the traditional approvals to lack randomization, double blinding, and controls. More than half were based on a single trial, and surrogate markers were often used as primary end points, as opposed to hard clinical outcomes. The authors conclude “[P]atients and physicians may have misconceptions about the strength of evidence supporting breakthrough approvals. The FDA-required post-marketing studies will be critical to confirm the clinical benefit and safety of these promising, newly approved therapies.”

Citation: Puthumana, J. Wallach, J.D., Ross, J.S. Clinical Trial Evidence Supporting FDA Approval of Drugs Granted Breakthrough Therapy Designation. *JAMA*. 2018. [doi:10.1001/jama.2018.7619](https://doi.org/10.1001/jama.2018.7619).

What does a transfusion reaction cost? Answering this question is crucial to understanding the overall costs of transfusion therapy. Investigators from the Netherlands propose a structured, quantitative approach to obtain multiple experts’ judgments to quantify dimensions like additional days of care, physicians’ time and the proportion of reactions that are preventable. They conclude that while the costs of reactions are not

(continued on page 5)

RESEARCH IN BRIEF (continued from page 4)

trivial, that they contribute less than 1 percent of the total costs of transfusion. One in four reactions were judged to be preventable.

Citation: Janssen, M.P., Tilborgh, A.J.W., de Vooght K.M.K. *et al.* [Direct costs of transfusion reactions – an expert judgement approach](#). *Vox Sang.* 2018.

Early fibrinogen concentrates in major bleeding after trauma. This randomized, double-blind, multi-center, placebo-controlled trial from the United Kingdom evaluated the effect of administration of fibrinogen concentrates within 45 minutes of hospital admission to adult trauma victims needing activation of a standard “major h[e]morrhage protocol.” Only 27 of 39 participants received the intended intervention. The authors conclude that “early delivery of fibrinogen concentrate within 45 minutes of admission was not feasible. Although evidence points to a key role for fibrinogen in the treatment of major bleeding, researchers need to recogni[z]e the challenges of timely delivery in the emergency setting.” They believe future studies should examine obstacles to rapid fibrinogen therapy moving forward.

Citation: Curry, N., Foley, C., Wong, H., *et al.* [Early fibrinogen concentrate therapy for major haemorrhage in trauma \(E-FIT 1\): results from a UK multi-centre, randomised, double blind, placebo-controlled pilot trial](#). *Critical Care.* 2018.

How good are published transfusion guidelines? An article and editorial in *Transfusion Medicine Reviews* address the design characteristics of published transfusion guidelines. The study uses a prespecified, semi-quantitative, evaluation framework (AGREE-II) to assess overall quality, stakeholder involvement, rigor, clarity, applicability, and editorial independence. Sixteen of 30 guidelines had low overall scores, i.e. ≤50 percent, leading the authors to call for enhancement of the guideline development process. In the editorial, Walter (Sunny) Dzik, MD the journal’s editor in chief, states that “there is a very real concern that the entire guideline process, by prematurely declaring standards of-care which become difficult to override, impedes the very sort of academic research needed to identify correct transfusion practice.” He concludes with an invitation for “correspondence from those who know of studies demonstrating a beneficial or adverse effect of transfusion guidelines on patient outcomes.” Endpoints of interest are clinical outcomes rather than “uniformity of blood usage” or “reduced blood usage” that include appropriate controls.

Citations: Pavenski, K., Stanworth, S., Fung, M. *et al.* [Quality of Evidence-Based Guidelines for Transfusion of Red Blood Cells and Plasma: A Systematic Review](#). *Transfusion Medicine Rev.* 2018.

Dzik, S. [Editorial: Re-thinking the Value of Transfusion Guidelines](#). *Transfusion Medicine Rev.* 2018. ♦





RECENT REVIEWS

RBC transfusion thresholds in patients with cardiovascular disease. Historically, transfusion guidelines for patients with heart disease have relied on suboptimal data. The authors of this systematic review have included recent studies that increase the number of enrolled patients by one-third to examine used 30-day mortality comparing restrictive and liberal transfusion triggers as the primary endpoint. They specifically targeted patients with acute myocardial infarction (AMI) and those undergoing cardiac surgery. Two small trials (154 patients) in AMI favored liberal thresholds (risk ratio (RR) 3.88, 95 percent confidence bounds 0.83-18.13). For surgical patients (26 trials with 15,681 enrollees), no difference was found (RR 1.0, 0.86-1.16). “New trials in patients undergoing cardiac surgery establish that a restrictive transfusion strategy of 7 to 8 g/dL is safe and decreased red cell use by 24 percent. Further research is needed to define the optimal transfusion threshold in patients with acute myocardial infarction,” conclude the authors.

Citation: Carson, J.L., Stanworth, S.J., Alexander, J.H. *et al.* [Clinical trials evaluating red blood cell transfusion thresholds: An updated systematic review and with additional focus on patients with cardiovascular disease](#). *American Heart J.* 2018. 💧

REGULATORY NEWS

A notice from the U.S. Department of Health and Human Services (HHS) appearing in the [Federal Register](#) has announced organizational amendments to the Office of the Assistant Secretary for Preparedness and Response (ASPR). The reorganization is meant to better align with the 21st Century Cures Act mandate to address “manmade and naturally occurring threats which degrade public health, access to healthcare, access to emergency medical services and national security.” The new structure consists of the four offices: Immediate Office of the Assistant Secretary for Preparedness and Response (ANA), Office of Biomedical Advanced Research and Development Authority (ANB), Office of the Principal Deputy Assistant Secretary (ANC), and the Office of the Deputy Assistant Secretary Incident Command and Control (ANG). More information on the job functions of each office is [available](#) in the notice.

(*Federal Register* [Notice](#), 7/18/18)

The U.S. Food and Drug Administration (FDA) issued a [statement](#) warning of the dangers of synthetic cannabinoid use. It addresses potential threats not only to synthetic cannabinoid users, but also the potential threat for blood products. “[W]e’re also concerned about the potential contamination of donated blood products,” said FDA Commissioner Scott Gottlieb, MD, Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research, and Janet Woodcock, MD, director of the Center for Drug Evaluation and Research in the joint statement. “The FDA has received several reports of donors who used synthetic cannabinoids contaminated with brodifacoum. Because of its long half-life, the bleeding risk from brodifacoum, which prevents vitamin K from being reused within the body, can persist for weeks. Consequently, potential safety concerns exist for both the blood donor and the donated blood components, given the potential impact on coagulation because of its long-acting vitamin K antagonist activity. For that reason, the FDA recently shared information with blood establishments about this risk... We’ll continue to monitor this issue and take additional steps as appropriate along with our federal partners at the CDC and [the Drug Enforcement Administration], state and local health departments, and blood establishments.” Last month the Centers for Disease Control and Prevention (CDC) issued an update on the outbreak alert regarding potential life-threatening vitamin K antagonist associated coagulopathy from the recreational use of synthetic cannabinoids (“K2” and “Spice”). CDC continues to warn individuals of the potential risks associated with synthetic cannabinoids and is recommending health care providers screen presenting patients with unexplained bleeding and a possible history of synthetic cannabinoid for vitamin K-dependent

(continued on page 7)

REGULATORY NEWS (continued from page 6)

antagonist coagulopathy, to check whether the individual(s) have recently donated blood or plasma and report potential cases to their local and state health departments and blood centers.

(Source: FDA [Statement](#), 7/19/18)

The FDA issued a final guidance entitled “[Use of Electronic Health Record \[EHR\] Data in Clinical Investigations](#)” this week. It defines EHRs as “an individual patient record contained within the EHR system.” The guidance is meant to aid clinical investigators, contract research organizations, sponsors, and institutional review boards and others when using EHR data in clinical investigations regulated by the FDA. The agency intends for the guidance to modernize and streamline clinical investigations with the stated goals of: [f]acilitate the use of EHR data in clinical investigations [and] [p]romote the interoperability of EHR and [electronic data capture] systems.

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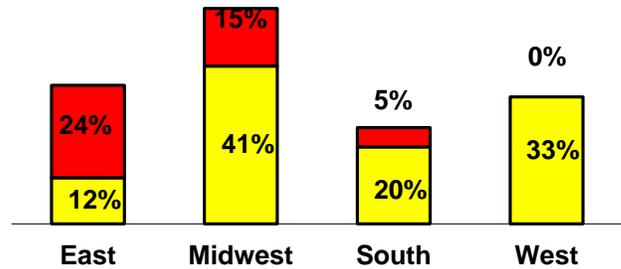
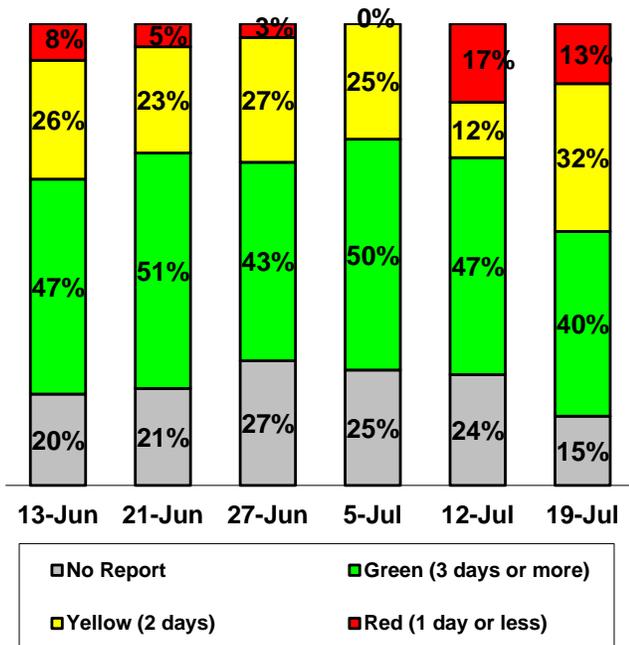
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(FDA [Guidance](#), 7/18/18) ♦

STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

Total ABC Red Cell Inventory

Percent of Regional Inventory at 2 Days Supply or Less, July 19, 2018



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

Daily updates are available at:
www.AmericasBlood.org



WORD IN WASHINGTON

The House Energy and Commerce Committee [approved](#) the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (H.R. 6378). ABC, AABB, and the American Red Cross submitted [joint comments](#) to the Senate earlier this year that recommended recognizing the role that blood centers play in emergency preparedness and response in addition to financial costs incurred to ensure availability of a safe and robust blood supply when needed. The House bill states that, “the Secretary of Health and Human Services shall submit to Congress a report containing recommendations related to maintaining an adequate national blood supply, including challenges associated with continuous recruitment of blood donors, ensuring adequacy of blood supply in the case of public health emergencies, and implementation of safety measures and innovation.” Additionally, language was added to include blood banks as stakeholders in disaster preparedness and response planning that should be consulted by the Assistant Secretary of Preparedness and Response (ASPR) in identifying, developing, and updating guidelines while considering the financial implications for blood banks and other healthcare entities. A vote on the bill is expected on the House floor next week.

(Source: [H.R. 6378](#))

America’s Blood Centers was one of 52 organizations that signed on to a [letter](#) of support for the Sickle Cell Disease Research, Surveillance, Prevention and Treatment Act submitted to the Senate Health, Education, Labor and Pensions Committee. The letter was written in support of bipartisan legislation introduced in the Senate by Sens. Tim Scott (R-S.C.) and Cory Booker (D-N.J.). This legislation would “authorize a national [sickle cell disease] surveillance program with the goal of improving data collection on impacted patients in states with a higher prevalence of the disease...[and] reauthorizes the existing Health Resources and Services Administration’s [sickle cell disease] Treatment Demonstration Program.” It is the companion bill to [House Resolution 2410](#), which passed the House on Feb. 26th. Earlier, this year ABC joined 66 other organizations in signing a letter thanking Sens. Scott and Booker for their efforts in introducing the bill in the Senate and promoting the importance of sickle disease awareness nationally. “It is critical that we understand the full breadth of what we’re facing in the fight to cure Sickle Cell Disease,” said Sen. Scott in a news [release](#) earlier this year. “This legislation marks a significant step forward in our efforts to combat Sickle Cell on all fronts – research, surveillance, prevention and treatment. We owe it to those suffering every day to do everything possible to find a cure. I want to thank Senator Booker for helping introduce this important legislation, and I look forward to gaining even more support from our colleagues in the Senate.” ABC members can view the full letter of support on the ABC member [website](#).



Rep. Huffman (left) and NCCBB Administrator Tom Schallert (right) chat during a tour of NCCBB.

Rep. Jared Huffman (D-Calif.) visited Northern California Community Blood Bank (NCCBB) earlier this month. He toured the facilities and learned about the lifesaving work being done locally by NCCBB and discussed local and national issues facing the blood community. Members of ABC can reach out to their congressional members individually at any time using the [ABC Action Center](#).

(Source: NCCBB Announcement 7/13/18) 💧



IN MEMORIAM



Kenneth Lawson passed away on Sunday, July 15th. Mr. Lawson served as the executive director of Siouxland Community Blood Bank for 20 years beginning in 1972. He was also elected to the Sioux City Council and later Sioux City Mayor. Mr. Lawson was a native of Fairmont, Minn. and worked as a television broadcaster, in addition to serving in the 185th Tactical Fighter Group that was deployed to South Korea in 1968 and 1969.

(Source: *Sioux City Journal*, [Former Sioux City Mayor Kenneth Lawson dies at 86](#), 7/17/18) ♦

CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2018

July 24. **Health and Human Services' (HHS) Tick-borne Working Group Webcast Meeting.** More details available [here](#).

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

Sept. 5-7. **3rd European Conference on Donor Health and Management, Copenhagen, Denmark.** More details available [here](#).

Sept. 11. **37th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available [here](#).

Sept. 12. **8th Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD.** More details available [here](#).

Oct 15-16. **510(k) Submissions Workshop, Washington, D.C.** More details available [here](#). ♦

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

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

Vice President, Community Engagement. Responsibilities: Work with executive management and the board in the development of We Are Blood's corporate community engagement strategy and provide strategic direction and oversight of its community engagement programs: marketing, public relations, communications, donor engagement, corporate outreach, development, community outreach, blood and platelet recruitment, and volunteer services. Develop and maintain key relationships in the community that promote and enhance awareness of We Are Blood and its mission. Provide strategic direction and oversight of We Are Blood's community engagement programs: marketing, public relations, communications, donor engagement, corporate outreach, development, community outreach, blood and platelet recruitment, and volunteer services. Ensure We Are Blood's donor engagement goals are met, including mobile drive and fixed site and platelet donor recruitment. Provide strategic direction of We Are Blood marketing and communications (including collateral materials development, newsletters, events, etc.) and supervise the team. Requirements: Four to seven years of management experience; College degree or equivalent work experience; Experience in development, strategic communications and relationship management; Excellent presentation skills with experience in public speaking; Must be at least 21 years old, have a valid Texas driver's license, acceptable driving record and proof of liability insurance. Click [here](#) for full description. **To Apply: Send your CL & Resume to resumes@tcms.com.** EEO Employer: Minorities/Women/Veterans/Disabled

Transfusion Safety Officer. We have an opportunity for an experienced Hospital Transfusion Safety Officer to join the Medical Services team at Bloodworks. The Hospital Transfusion Safety Officer acts as on-site consultant for physicians and nurses at an assigned hospital regarding the administration of blood and blood components. The role provides expertise and training on blood ordering, distribution, administration, monitoring, and transfusion reactions. Requirements for this position include: RN/BS - Nursing, Nurse Practitioner, or Physician's Assistant with current Washington State license, certified Medical Technologist with a minimum of three years of Blood Bank experience, or other qualified medical or nursing training may also be considered. Two to four years' experience in leadership roles in nursing and/or transfusion therapy is preferred. Experience with providing in-service education for health professionals is preferred. Prior experience with transfusion administration is preferred. Specific Job Skills: Knowledge of standards of practice regarding transfusion administration. Valid State Driver's License with acceptable driving record in Washington State; possess and maintain a driver's license for at least one year. **WORKING CONDITIONS:** Frequent regional travel, some overtime, on-call, evening meetings. This position has direct exposure to blood borne pathogens. Salary is DOE, DOQ.

Interested candidates should apply [here](#). Bloodworks Northwest is an EOE.

Medical Technicians. Join our team! LifeServe Blood Center currently has two part-time openings for medical technicians at our Des Moines, IA location. This laboratory reference position serves hospital patients across Iowa, Nebraska and South Dakota. Testing includes basic blood banking and complex antibody identification. Primary Responsibilities for this Position Include: Accepts, verifies, processes, and tests incoming samples; Performs various testing procedures, including immunohematology, on donor and patient blood products; Performs quality control, equipment maintenance and calibration; Utilizes computer system to obtain necessary data and to record test results; and participates in the ongoing monitoring for each testing process to identify errors or potential problems. Education and/or Experience: MT/MLS or MLT from American Society for Clinical Pathology or equivalent; bachelor's degree in medical technology or chemical, physical or biological science or related scientific field from an accredited college or university or an equivalent combination of education, certification, training and or experience; and meet current CLIA or ABB requirements for testing personnel. Interested applicants should visit our website: <https://www.lifeservebloodcenter.org/about-us/join-our-team/> and click on JOIN OUR TEAM. LifeServe Blood Center is fully committed to equal employment opportunity. All applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, age, sexual orientation, gender identification, genetic information, marital status, pregnancy, disability, veteran status or any other legally protected status.

Compliance Officer, Blood Transfusion Service (Job ID: 3067738). Massachusetts General Hospital (MGH) in Boston, MA is seeking qualified applicants for the Compliance Officer, Blood Transfusion Service (BTS) position. The Compliance Officer is a key resource in the highly regulated environment of the BTS at MGH which is an AABB accredited, FACT accredited, FDA licensed facility. The Compliance Officer reports directly to the Director (Responsible Head) and has broad responsibilities for compliance, quality assurance and performance improvement. Must be completely familiar with pertinent regulations for FDA, AABB, FACT, NMDP, CLIA, TJC, Commonwealth of Massachusetts, NRC and OSHA. MT(ASCP) or equivalent and bachelor's degree in Medical Technology, Clinical Laboratory Science or related science field, subspecialty certification (ASCP)BB or SBB, minimum five years of experience in a transfusion service, blood bank apheresis program or donor center is required. For more details or if you are interested in applying for this position, please visit www.mghcareers.org

(continued on page 11)

POSITIONS (continued from page 10)

and apply for **JOB ID:** 3067738. Massachusetts General Hospital is an Equal Opportunity Employer. *By embracing diverse skills, perspectives and ideas, we choose to lead. Applications from protected veterans and individuals with disabilities are strongly encouraged.*

Senior Director of Blood Operations. LifeShare Blood Center is seeking a Senior Director of Blood Operations (SDBO). The SDBO is responsible for the management, organization, and leadership of LifeShare Donor Center locations. Regional Directors of each location report to this position. The SDBO is responsible for the oversight of reaching collection goals and ensuring community involvement of the Regional Directors. The SDBO must ensure that all personnel are following expected processes, policies, and SOPs. Responsible for team members to adhere to all cGMP, SOP, FDA, AABB, and other regulatory bodies, as well as departmental policies and procedures. Responsible for meeting quality standards while actively ensuring compliance. Requirements include bachelor's degree in health or related field, four plus years' blood banking experience or five years in progressively responsible management position and/or five years working in or leading sales team. Demonstrated experience in leading teams in a regulated environment preferred. Must have working knowledge and understanding of CLIA, FDA, OSHA and AABB regulations and statutes, as well as cGMP. Knowledge of strategic planning, budgeting, organizing and implementing required. To apply, please visit: www.lifeshare.org/careers.

Part Time MT/ MLT/ MLS (MedCity Dallas & JPS Hospital in Fort Worth, TX). The Medical Technologist will report to the Manager or designee of Reference & Transfusion Services. The incumbent will participate in all activities in the R&T Services to include but not limited to: 1. Support Carter BloodCare's vision, mission and core values. 2. Maintain compliance with Carter BloodCare's attendance policies. 3. Perform testing and services associated with assigned departmental duties. These duties are in the scope of complexity according to accrediting agencies. 4. Participation in competency, proficiency, and educational opportunities. By accomplishing these duties, the MT ensures that daily operations in the R&T laboratories meet and follow all established guidelines, provide excellence in service and meet the needs of all R&T customers. Shifts: Nights (MCD), weekends (JPS). Qualifications: Associates or bachelor's degree in Biology/Chemistry/Laboratory Sciences or related field required. MLT (ASCP), MT (ASCP), BB (ASCP), MT (AMT) or equivalent required. Recent graduate from an accredited Clinical Laboratory Sciences (CLS) program within the last five years and currently board eligible. Carter BloodCare is an EEO/Affirmative Action employer. We maintain a drug-free workplace and perform pre-employment substance

abuse testing. To apply go to <http://www.carterblood-care.org/>, click on Careers.

Director of LifeCord. LifeSouth Community Blood Centers is currently seeking an individual to join our team as the Director of LifeCord in Gainesville, FL. This position is responsible for overseeing the cord blood collections and cellular therapy initiatives within the organization through the LifeCord program. LifeCord is a public, community-based cord blood bank that collects and stores umbilical cord blood for the purpose of clinical cures and basic research in the field of stem cell transplantation. LifeCord is a program of LifeSouth which performs community and donor education, cord blood collection and processing, distribution of cord blood units and evaluation of transplant outcomes. LifeCord also works to increase the diversity of donors from which cord blood is collected. Bachelor's degree required. Concentration in healthcare or science-related field preferred. Two years of management or supervisory experience required. Valid driver's license required. Must meet and maintain LifeSouth driver's eligibility requirements. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Follow this link to apply: <https://lifesouth.careerplug.com/jobs/791065/apps/new>.

Medical Director. LifeSouth Community Blood Centers is currently seeking an individual to join our team as a Medical Director in Gainesville, FL. The selected candidate will be expected to contribute significantly to LifeSouth's strategic goals and provide medical oversight for the company. M.D. or D.O. degree with post-graduate training in blood banking/transfusion medicine required. Must obtain and maintain an active medical license in Florida, Georgia and Alabama. Must be board certified or eligible in blood banking/transfusion medicine, pediatrics or clinical pathology. Valid driver's license for state of residence is required. Must meet and maintain LifeSouth driver's eligibility requirements. Must be willing to travel as necessary. Must be on call as necessary. Starting pay based on qualifications and relevant experience. Travel and relocation expenses are reimbursable. Background check and drug test required. Equal Opportunity/Affirmative Action Employer/DFWP/Tobacco Free. Follow this link to apply: <https://lifesouth.careerplug.com/jobs/789460/apps/new>. 💧