

A B C N E W S L E T T E R

URRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2018 #22

June 29, 2018

Please Note: The *ABC Newsletter* will not be published on July 6th. We will resume regular publication on July 13th. Thank you for your continued interest.

ABC Summer Meeting Explores Expanding Cellular Therapies, Iron Depletion in Adults and Young Donors, Keys to Advocating Successfully in Washington

America's Blood Centers' members and industry partners will meet in Montreal, Canada at the Hotel Omni Mont-Royal for the 56th Summer Meeting and Medical Directors Workshop from July 31st to August 2nd hosted by ABC Member Héma-Québec. This meeting includes the Medical Directors Workshop, Scientific, Medical, Technical



(SMT) Forum, the Business Forum, and Member Meeting.

Medical Directors Workshop

YanYun Wu, MD, PhD, chief medical officer at Bloodworks Northwest will begin the workshop presenting on "Bacterial Culture platelets - Cold Apheresis Platelets vs Whole Blood-derived Platelets. She will examine the use of bacterial cultured platelets and compare the characteristics and potential of cold storage versus the use and characteristics of apheresis platelets. Attendees will also hear Robert Tressler. PhD, MS, vice president of Laboratories at San Diego Blood Bank discuss "Expanding Cellular Therapy Collections Including CAR-T," helping attendees understand the ways blood centers can leverage their collections to support external cell therapy research and development relationships. Bryan R. Spencer, PhD, a research scientist in the American Red Cross Scientific Affairs team will present on the prevalence of iron depletion in adult and teen blood donors along with the feasibility impact and relevance of different ferritin cutoffs for guiding donor management. The day will culminate with a networking reception. Other presenters at the Medical Directors Workshop include: "Urgent Reversal Strategies for Anticoagulant and Antiplatelet Agents in a New Era" (Barbara A. Konkle, MD, Bloodworks Northwest), "CMV LR, SeroNeg, Both in Neonates" (Gilles Delage, MD, MSc, Héma-Québec), "Metabolic Syndrome & Cardiovascular Disease in Individuals with Increased Ferritin & Risks of Iron Supplementation" (Joseph E. Kiss, MD. Institute for Transfusion Medicine (Blood Systems, Inc.)), and "Update on Status of 'Common Rule' plus Ethical Considerations for Biorepositories & Use of Donor Samples for Research" (Rebecca Haley, MD, Bloodworks Northwest).

INSIDE:

OUR_SPACE: Comments, Questions, and Suggestions Oh My! .2
2018 Summer Meeting Registration3
ABC Celebrates 70 Years of NHLBI3
ABC Executive Compensation Survey Launched3
WEBINAR SAVE THE DATE4
RESEARCH IN BRIEF5
RECENT REVIEWS6
BRIEFLY NOTED6
REGULATORY NEWS6
STOPLIGHT [®] : Status of America's Blood Centers' Blood Supply .8
WORD IN WASHINGTON
MEMBER NEWS9
CALENDAR10
POSITIONS10

f y O June 29, 2018



OUR SPACE

Kate Fry, Chief Executive Officer, ABC

Comments, Questions, and Suggestions... Oh My!

ABC continues to refocus its core mission on advocacy, supported by science, medical, technical (SMT) and quality and regulatory affairs, and revamp ABC operations to make us a more inclusive, member-driven association. As such, we wanted to highlight two important events occurring in the coming weeks.

First, the ABC Policy Council will meet in-person on July 18 in Chicago, Ill. to discuss progress on the <u>ABC Advocacy Agenda</u>, evaluate additional advocacy issues that have been brought to our attention since the Advocacy Agenda was developed, and drive proactive action plans for looming challenges and opportunities facing the industry. One key area on the agenda is evaluation of strategies, research, and programs to promote the value of blood and innovation at independent in the midst of a constrained fiscal environment and changing industry trends. **We hope you will provide input on this topic as well as any others you think important for the Council to discuss.** Please send any comments, questions, and suggestions to <u>me</u> and we will ensure they are included. As a reminder, the Policy Council was formed last year to garner additional member input and better synthesize member opinion on various policy options.

Second, the <u>ABC Summer Meeting</u> in Montreal is quickly approaching! In addition to the Medical Directors Workshop and SMT Forum, this year's meeting has a dedicated set of sessions related to health policy trends and tactics for effective advocacy engagement. We are excited to have a stellar lineup of industry leaders and external experts as part of an increased advocacy presence at ABC meetings. The ABC Members Meeting will also provide a forum for robust member discussion on key topics facing the industry. <u>Registration</u> has been extended until Tuesday, July 9th; don't miss an opportunity to participate in key discussions and have your voice heard.

Thank you for your involvement in these and other ABC activities. As always, please send us your comments, questions and suggestions!

Katheindry

Kate Fry Chief Executive Officer

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2018 by America's Blood Centers. Reproduction of the *ABC Newsletter* is forbidden unless permission is granted by the publisher. (ABC members need not obtain prior permission if proper credit is given.)

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 thoughtleader in the advancement of evidence-based medical and scientific solutions related to health and safety. America's Blood Centers

Chief Executive Officer: Kate Fry Chief Medical Officer: Louis Katz Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$390

Send subscription queries to <u>Imaundy@americasblood.org</u> America's Blood Centers 1717 K St. NW, Suite 900, Washington, DC 20006 Phone: (202) 393-5725 Send news tips to <u>newsletter@americasblood.org</u>.





The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

2018 Summer Meeting Registration

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

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

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

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

ABC Celebrates 70 Years of NHLBI

The National Heart, Lung, Blood & Blood Institute (NHLBI) celebrated its 70th Anniversary this week with a congressional reception on Capitol Hill this week. America's Blood Centers and the American Red Cross were two of several co-sponsors of the NHLBI Constituency Group along with the National Coalition for Heart and

Stroke Research. The event featured remarks from Director of the National Institutes of Health Francis Collins, MD, PhD, Director of NHLBI Gary Gibbons, MD, and Eugene Braunwald, MD of



NHLBI Director Gary Gibbons, MD (podium) addresses attendees during the 70th Anniversary Reception including ABC CEO Kate Fry $(2^{nd} from far left)$.

Brigham and Women's Hospital, Harvard Medical School.

ABC Executive Compensation Survey Launched

ABC's annual Executive Compensation Survey has launched. The survey is a benchmarking tool for executive leadership and human resources professionals at ABC member blood centers that features aggregate

-3-



WEBINAR SAVE THE DATE

ABC SMT Journal Club Webinar

August 7, 2018 at 3 PM EDT

Additional details coming soon!

data on salaries and benefits for C-suite members—including chief executive officers, chief operating

officers, chief financial officers and medical directors. Blood centers are grouped by center size and budgets.

As with all ABC surveys, data is strictly confidential and anonymized. With this information, ABC can provide a strategic overview of the industry and where blood organizations need to position themselves to compete in the future. All members are encouraged to participate in the survey and should have received the survey link via email. If you have

not received the link or have any questions, please contact <u>Sameer Ughade</u>. The survey closes July 20th.



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 <u>newsletter@americasblood.org</u> 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.

56th Summer Meeting (continued from page 1)

SMT Forum & Business Forum

The SMT Forum will kick off day two includes a presentation on "Low Titer Group O Whole Blood Supply and Demand Strategies: Actually Making It Work" by David Oh, MD, chief medical officer at Hoxworth Blood Center. Dr. Oh will identify the advantages and disadvantages for a blood center to manufacture and distribute low titer group O whole blood, while explaining the need to collaborate with hospital services. Additionally, attendees will be updated on several emerging issues in transfusion medicine by ABC Chief Medical Officer Louis Katz, MD. Other presentations include: "Anti-A/B Titer Harmonization Study" (Gregory A. Denomme, PhD, Versiti (BloodCenter of Wisconsin)), and "CLIA: Laboratory Regulations, Competency and other Mysteries" (Anne Chenoweth, MBA, MT(ASCP)cm, CQA(ASQ) AABB).

The Business Forum will conclude the day with a look at impact of healthcare disruption and consolidation and its impact for blood centers in a presentation by Anu R. Singh, managing director, Kaufman, Hall & Associates, LLC. Attendees will also receive an update on new developments in health policy and the resulting opportunities and challenges for blood centers from Tim Casey, policy advisor at Polsinelli. A panel discussion on how to "win" in Washington, D.C. will also take place and feature success stories and strategies for successful advocacy with regulators and legislators moderated by Rob Purvis, senior vice president & chief marketing officer at New York Blood Center and chair of the ABC Policy Council, with panelists including ABC CEO Kate Fry, Heather Cutler, director of PAC Compliance at Express Scripts, MaryAnne Sapio, vice president of Federal Government Affairs at the American Association of Nurse Practitioners, and Tim Casey. Héma-Québec will host a networking event for all attendees that evening.

Member Meeting

The Member Meeting on Thursday will provide ABC members with the opportunity to hear updates on ABC's progress on key initiatives within its advocacy agenda. Member blood centers will have the opportunity to weigh-in on the issues that are impacting them most and let their voices be heard in an open forum helping shape the policy and strategy decisions of the organization.

<u>Registration</u> for both the 56th Summer Meeting and Medical Directors Workshop is open. Please make your hotel reservations by July 9th to ensure best availability and the group rate. Contact <u>Leslie Maundy</u> for available sponsorship opportunities.



RESEARCH IN BRIEF

Eight Ebola transmissions from persistent infections after the West African epidemic are described. These eight cases from March 2015 to April 2016 occurred after the local peaks had happened during the 2014–16 Ebola epidemic. Some led to short chains of forward transmission. Epidemiological and, for <u>RESEARCH IN BRIEF</u> (continued from page 5)



several cases, nucleic acid sequence analysis have been used to make the case that they arose from persistent, asymptomatic infection acquired during the main epidemic. Sexual, other close contact, and mother-to-infant are the proposed routes of transmission. The authors conclude by advocating for biological monitoring of survivors for up to 18 months after release from Ebola treatment units and "[I]n addition, blood and semen donations should be systematically tested or restricted in contexts where [Ebola virus] circulates." The relevance for areas without local transmission is unclear.

Citation: Subissi, L., Keita, M., Mesfin, S. *et al*. <u>Ebola Virus Transmission Caused by Persistently Infected</u> Survivors of the 2014–2016 Outbreak in West Africa. J. Inf. Dis. 2018.

RECENT REVIEWS

What do pathogen reduction (PR) processes do to platelets? The adoption of PR for platelets is being driven by risks from bacterial contamination to a great extent, and consideration of other transfusion transmissible infections and graft-versus-host disease as well. Changes in platelet number and function after PR treatment have been documented in clinical trials with some evidence that a modest increase in the number or frequency of transfusion may be required. The processes being developed inactivate pathogen and host nucleic acids, but these are not the only macromolecules affected by the photochemical reactions involved. Belgian investigators summarize other effects that may impact platelet function and should serve as a cautionary note about potential impacts of PR on plasma and red blood cells moving forward.

Citation: Feys, H.B., Van Aelst, B., Compernolle, V. <u>Biomolecular Consequences of Platelet Pathogen</u> <u>Inactivation Methods</u>. *Transfusion Med. Rev.* 2018.

What are non-blood bankers reading about transfusion-transmitted infectious (TTI) diseases? The *Journal of Clinical Microbiology* has published a review of TTI by Emory University scientists. This review includes a good reference list of the history of donor testing, current methods, and some speculation about the future. It is also suitable for non-blood bankers, including non-physician/scientists at blood centers who may be new to blood banking.

Citation: Dean, C.L., Wade, J., Roback, J.D. <u>Transfusion-transmitted infections: an update on product</u> screening, diagnostic techniques, and the path ahead. J. Clin. Micro. 2018. ♦

BRIEFLY NOTED

The International Society of Blood Transfusion (ISBT) is hosting a free webinar open to both nonmembers and members on transfusion-associated circulatory overload (TACO). The webinar will take place on Wednesday, July 18th at 9 AM EDT with Alexander Vlaar presenting. <u>Registration</u> is required and open for interested individuals. Questions may be directed to the <u>Communications Coordinator</u>.

(Source: ISBT Announcement, 6/27/18) •

REGULATORY NEWS

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has released the agenda and briefing documents for the upcoming Blood Products Advisory Committee (BPAC) meeting. The BPAC will meet on July 18–19th at the FDA White Oak campus. The

<u>REGULATORY NEWS</u> (continued from page 6)

draft agenda and briefing documents for the discussion of bacterial contamination of platelets and reclassification of certain HIV diagnostic assays can be accessed on the FDA's <u>website</u>. The latter topic does not address donor screening assays. The <u>statement</u> on the platelet topic from last fall's BPAC discussion is being reviewed for any needed revisions. ABC welcomes input from all members. Please send feedback to <u>Louis Katz</u>, MD and <u>Ruth Sylvester</u>.

(Source: FDA 2018 Meeting Materials, Blood Products Advisory Committee, 6/26/18)

CBER held its 2018 Science Symposium this week. The program can be reviewed <u>here</u>. The topics discussed were very diverse, as is the mission of CBER. The blood community may have particular interest in:

- Blood Safety and Availability: Regulatory and Scientific challenges for Emerging and Re-emerging Infectious Diseases (John Hobson, PhD, Deputy Director, Office of Blood Research & Review);
- Benefit–Risk Assessment to Support Management of Transfusion- Transmission Risk of Infectious Diseases (Hong Yang, PhD, Principal Investigator, Office of Biostatistics and Epidemiology);
- The Human Cell Atlas (Aviv Regev, PhD, Massachusetts Institute of Technology (MIT), Chair of the Faculty and Core Member, Broad Institute of MIT and Harvard);
- High-throughput Sequencing for Adventitious Virus Detection to Enhance Safety of Biologics (Arifa Khan, PhD, Principal Investigator, Office of Vaccines Research & Review);



• Bioinformatics of Microbiome: Challenges and Solutions at FDA (Vahan Simonyan, PhD Lead Scientist & Project Director, High-Performance Integrated Virtual Environment, CBER).

A video recording of the public symposium will be available soon on the FDA's <u>website</u> for one year.

(Source: FDA Website, 6/19/18)

The Department of Health and Human Services Assistant Secretary for Preparedness and Response (ASPR) has <u>announced</u> a <u>grant opportunity</u> aimed at improving coordinated patient care during disasters. The grant is a pilot project to develop and grow a Regional Disaster Health Response System (RDHRS). The purpose of the RDHRS is to ensure that local healthcare systems and facilities are included in and influence state- and regional-level disaster planning and response efforts. The RDHRS will bring together various elements of emergency response, including healthcare, public health, emergency management, EMS, and specialty expertise in areas such as chemical, biological, pediatric, and infectious disease readiness. The areas will form a consortium with processes, procedures, partnerships and plans needed to meet the public health and healthcare demands in disasters before the disaster occur. These partnerships require one or more hospitals, at least one of which is designated as a trauma center; one or more other local







<u>REGULATORY NEWS</u> (continued from page 7)

Total ABC Red Cell Inventory

healthcare facilities, and one or more political subdivisions, one or more states, or one or more states and one or more political subdivisions. This funding opportunity will fund two awards for one year with \$6 million available in total funding. Success in the first year could see the project expand should funding be available in future years. Applications are due by August 15th.

(ASPR <u>Grant</u>, 6/25/18) •

STOPLIGHT[®]: Status of America's Blood Centers' Blood Supply



Percent of Regional Inventory at 2 Days Supply or Less, June 27, 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 Subcommittee on Health advanced the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018. "[This] bill will provide a framework for our emergency preparedness infrastructure to plan for threats such as disease outbreaks," said Subcommittee Chairman Rep. Michael Burgess, MD (R-Texas). "As a physician, I have always supported programs that improve access to care and enhance the patient experience, and the bills before us today seek to accomplish that goal." ABC, AABB, and the American Red Cross (ARC) submitted joint comments to the Senate earlier this year that recommended recognizing the role that blood centers play in emergency preparedness and

(continued on page 9)

WORD IN WASHINGTON (continued from page 8)

response in addition to financial costs incurred to ensure availability of a safe and robust blood supply when needed.

(Source: House Energy and Commerce Committee <u>News Release</u>, 6/27/18)

The Senate Appropriations Committee approved the fiscal year 2019 budget for the Department of Health and Human Services (HHS) on Thursday along with 11 other appropriations bills. The Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies advanced draft legislation earlier this week that would provide \$90.1 billion to the U.S. Department of Health and Human Services in funding. This would be more than \$2.3 billion more than last year's funds. It also allocated increased funds specifically to the National Institutes of Health (\$2 billion) and Biomedical Advanced Research and Development Authority (BARDA) (\$562 million).

Representatives from HHS testified on Capitol Hill last week to address questions on cybersecurity and the roles and responsibilities of individuals at the Healthcare Cybersecurity and Communications Integration Center (HCCIC) before the House Energy and Commerce Subcommittee on Oversight and Investigation. Parts of the hearing were closed to the public as the subcommittee made inquiries into the measures being taken by the agency following a Government Accountability Organization (GAO) report that identified potential vulnerabilities in computer systems at several agencies including the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and the National Institutes of Health. Recordings and transcripts of the hearing are <u>available</u>.

MEMBER NEWS

Blood Bank of Hawaii recently celebrated William "Bill" Kinaka, JD reaching the 150 pint milestone. Mr. Kinaka began donating close to 30 years ago. "I want to keep going," said Mr. Kinaka. "There is no age limit. [I'd] rather be giving than receiving," he joked. In addition to being a regular blood donor, Mr. Kinaka actively encourages others within the community to also donate particularly during the challenging holiday season. "[Y]ou donate one pint of blood, you give the gift of life that cost[s] nothing," added Mr. Kinaka, who approximates that he has recruited close to 150 donors over the years.



mates that he has recruited close to 150 donors over the years.

(Source: Maui News, Retired Maui attorney reaches blood donation milestone, 6/20/18)

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 <u>calendar of events</u> includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!



CALENDAR



Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (<u>lmaundy@americasblood.org</u>) 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 18-19. FDA Blood Products Advisory Committee Meeting, Silver Spring, MD. More details available here.

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

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

Sept. 11. **37th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available <u>here</u>.

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.

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: <u>lmaundy@americasblood.org</u>.

POSITIONS

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.

Division Director. Hoxworth Blood Center seeks a qualified, experienced Division Director to maximize the blood products collected and increase our ability to deliver existing and new products to customers. This Senior Level Director reports directly to the COO. Primary responsibilities: Eliminate inefficient processes, provide meaningful donor satisfaction data, collect new products for our donors, reduce products lost, ensure collection records are completed and issues are resolved within 24 hours, maximize donor operations so Hoxworth has a combination of blood products to resource share \$650,000 in products by end of year one, increase recovered plasma sold and implement the collection of Source Plasma. Requirements: bachelor's degree with nine (9) years of experience; or associate's degree with at least eleven (11) years of experience. Degree must be in a related field and related experience requires at least five (5) years of direct supervision. Apply to http://www.uc.edu/hr/careers.html.