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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2018 #31 **September 14, 2018**

INSIDE:

ACBTSA Weighs What Is Tolerable Risk in the U.S. Blood Supply and How That May Inform Decision-making

The 49th Meeting of the U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) took place in Arlington, Va. on Thursday, September 13th., New Chair Jackie Fredrick, MBA, the former Versiti CEO, lead a one-day meeting to begin an exploration of risk in the blood supply that will eventually result in recommendations to the Assistant Secretary of Health and Human Services (ASH). The meeting focused on risks from infection from a patient perspective including presentations from patient advocacy groups and public comments. Its purpose was to inform the committee in advance of formulating specific recommendations to the ASH on how HHS should consider a department-wide approach to decision making in this space.

Jay Menitove, MD, the past chair of ACBTSA, presented updates from the Sustainability Workgroup, similar in content to that presented at the ABC Annual Meeting in March 2018. He noted that BARDA analyses of the fiscal stability of the blood community, including data from ABC centers, are in progress and should be available in the fourth quarter in time for their inclusion in discussions at a planned next meeting of ACBTSA in April 2019.

The committee heard background information from Mike Busch, MD, PhD from Blood Systems Research Institute and Roger Dodd, PhD from the American Red Cross, each providing a historical review and data starting before the entry of HIV into the blood supply, including the investigational approaches and resulting blood community responses. Drs. Busch and Dodd also described the current risk landscapes including new estimates of residual risk for distribution of HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) infected components that cluster around 1/3,000,000.

Martin Ruta, PhD, JD the regulatory counsel at the U.S. Food and Drug Administration's (FDA) Office of Blood Research and Review (OBRR) described the agency's regulatory authority and history from the 1970s forward, and Richard Forshee, PhD, FDA Associate Director for Research in OBRR described recent risk-based analyses of issues such as variant Creutzfeldt-Jakob Disease (vCJD) donor deferrals.

An international perspective was solicited from Dana Devine PhD, the chief medical and scientific officer at Canadian Blood Services. She described the application of risk-based decision-making (RBDM) using the Alliance of Blood Operator (ABO) RBDM framework to modify strategies for the provision of Cytomegalovirus (CMV)-safe blood in Canada. Ethical perspectives, focused mainly on

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49th ACBTSA Meeting (continued from page 1)

individual patient perceptions of risk, were discussed by David Wendler PhD from the National Institutes of Health Clinical Center. He attempted to bridge to the more global societal perspectives that are needed for policy development. There was emphasis on the importance of including risk perception in the assessment of risk tolerance, addressing inaccurate perceptions of risk among stakeholders, and on the critical significance of effective stakeholder engagement that includes respect for divergent perceptions of risk.

A series of comments from interested stakeholders followed these backgrounders. Zbigniew Szczepiorkowski MD, PhD, past president of AABB, presented the perspectives of AABB, ABC, and the American Red Cross on tolerable risk by articulating six principles stressing the need for validated risk modeling to drive decisions, the vein-to-vein nature of risk and risk mitigation, the importance of resources in support of surveillance and study of threats to blood safety, the continued role of voluntary standards and, the recognition that risk tolerance necessarily varies significantly between the multiple stakeholders and within stakeholder groups. Ralph R. Vassallo, Jr., MD, executive vice president and chief medical and scientific officer at Blood Systems, Inc. and Aaron Tobian, MD, PhD, a professor of pathology at Johns Hopkins presented blood center and hospital perspectives on risk and risk mitigation concerned primarily with operational, fiscal, and regulatory pressures that are impacting their approaches to risk assessment and minimization. Several speakers representing transfusion and plasma protein therapeutics dependent patients stressed the foundational importance of their engagement in all discussions of tolerable risk and its management.

Recurrent themes throughout the presentations and the committee discussion included cognizance of the impact of donor and recipient safety policies on the adequacy of the blood supply as a critical dimension. The difficult tasks of identifying stakeholders, especially patients and transfusing clinicians, and ensuring their active engagement and inclusion throughout all stages of decision-making was seen as foundational. The committee's explicit recognition of the iterative nature of risk management was repeatedly cited. That is, an initial decision must always be reviewable based on new evidence and that review must be "baked into" whatever framework is applied to the promulgation of policy. The critical importance of eliminating unfunded safety mandates was raised. There was no sense on the committee that a consensus definition of tolerable risk could be formulated, given the unique characteristics of each infection the blood community has managed in the past five decades. Members instead agreed to the formation of work group(s) to address the many issues raised by the presenters and identify the consultations and data needed to advise the department on a rational approach to risk mitigation moving forward.

James Berger, MS, MT(ASCP),SBB, the designated federal officer for ACBTSA, and the senior advisor for blood and tissue policy in the Office of the ASH notes that a webcast of the meeting will be posted to the committee website in the next week for those with interest in the presentations and discussions, and that committee members and those with expertise and interest in volunteering for workgroups can express that interest via e-mail at ACBTSA@hhs.gov.

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AABB, ABC, ARC Submit a Joint Perspective on Tolerable Risk in Blood Safety at 49th ACBTSA Meeting

AABB, ABC, and the American Red Cross presented the views of the transfusion community in a joint perspective delivered during the U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) Meeting on September 13th. The joint perspective featured six pillars that the organizations believe should shape discussions regarding tolerable levels of infectious disease risk in blood safety:

1. Validated risk-based models enable decisionmakers to evaluate blood safety in the context of a range of emerging risks and other societal priorities that must compete for limited resources; balance demands for safe blood with the need to ensure that blood is available for patients; and are useful tools to drive policymaking and evaluate blood safety;
2. A comprehensive approach to "blood safety" that is inclusive of donor safety, the safety of blood products, the safety of transfusion medicine and the safety of the patient;
3. Support for research related to new threats to the safety of the blood supply;
4. Recognition that biovigilance and hemovigilance are critical to advancing the safety of the blood supply;
5. Voluntary standards and guidance contribute to blood safety; and
6. Risk tolerability may vary significantly between different constituencies, as well as between organizations and individuals within a single constituency.

The blood community framed the U.S. blood supply as both a public trust and strategic resource. The perspective outlined the current pressures facing blood centers with rising costs for unfunded mandated safety measures, increased consolidation, a shrinking donor base, and decreased utilization, "[t]he blood sector faces mounting economic pressures from existing and emerging voluntary and mandatory safety measures, which are intended to protect the health of patients and donors but are costly to implement. Current reimbursement mechanisms are not aligned with the blood community's role in protecting the public's health. Additional challenges include changing medical practices, reduced blood utilization, a limited donor pool, and consolidation throughout the health care system." It included survey data obtained from the AABB membership that supported the importance of these six guidelines being used as priorities in discussions by the ACBTSA in risk tolerability decision-making and the inclusion of all stakeholders in the formulation of policy, "[t]oday's agenda scratches the surface of this complex topic, and representatives of physicians, blood centers, and hospitals must continue to be included in these discussions. In addition, representatives from federal departments, offices and agencies… must continue to be at the table. We also recommend including representatives of state and local governments in future discussions, since regional, state, and local factors may impact decisions related to blood safety."

The complete joint perspective is available, which includes an addendum with alternative viewpoints expressed by survey participants.

(Source: AABB, ABC, ARC Joint Perspective, 9/13/18)

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 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!

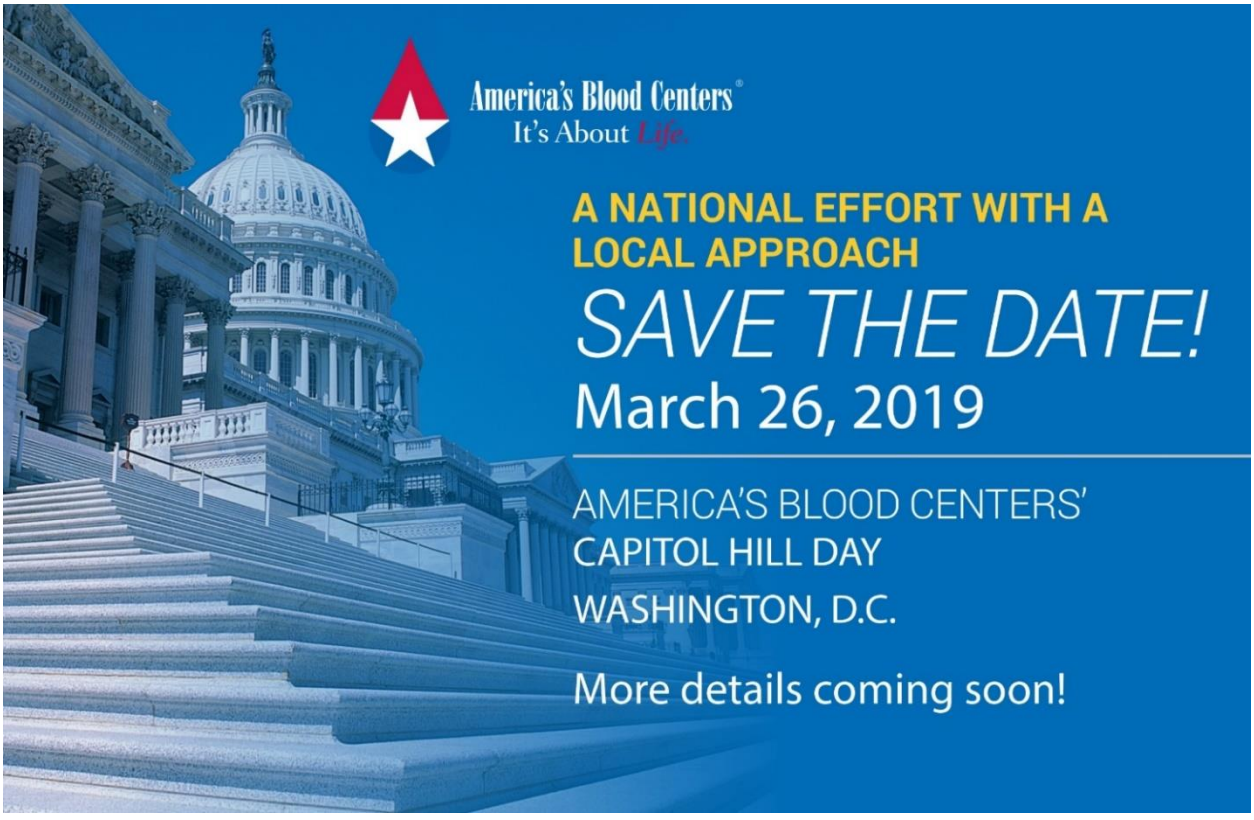
AABB Interorganizational Task Force on Domestic Disaster and Acts of Terrorism Urges Americans to Donate ahead of Hurricane Florence

The AABB Interorganizational Task Force on Domestic Disasters and the blood community have asked eligible blood donors in areas that are not in the path of Hurricane Florence to schedule appointments to donate to help maintain the nation's blood supply for patients in needs. A news release was issued by the task force on September 13th, anticipating potential disruptions in the collection of blood and platelets as the storm strikes the Carolinas. While the current national blood supply remains adequate to meet the current need, the blood community would like to ensure continuity "throughout the storm and in its aftermath." We are asking potential donors, both current and first-timers, to make a commitment to donate blood and platelets," said Dennis Todd, PhD, chair of the Task Force. "Donating now, or making an appointment to donate soon, will help to ensure that sufficient blood is available for all patients who need it."

(Source: AABB Interorganizational Task Force News Release, 9/13/18)

Upcoming ABC Webinars – Don't Miss Out!

- **Quality Integration Part I –** September 18th at 3 p.m. EDT. Additional details available in MCN 18-038.
- **Development and Implementation of a Platelet Prediction Model** – October 25 at 3 p.m. EDT. Additional details forthcoming!
- **Quality Integration Part II –** November 29th at 3 pm. EST. Additional details forthcoming!



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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.

2018 ABC Financial Ratio Survey

ABC has issued the 2018 Financial Ratio Survey. The results provide members with an important tool that can be used to assist with the management of blood programs, anonymously benchmark valuable operational data, and identify best practices. The deadline to complete the survey is October 12th. Only participating blood centers receive the final report. A link to the survey and the questions are available in MCN 18-037, which was distributed to the ABC Chief Financial Officers Forum on August 31st. Most of the financial information requested is public information that blood centers report on IRS Form 990 or their audited financial statements. Individual center data is confidential and not shared. ABC encourages all member blood centers to participate. Please contact Ruth Sylvester for additional information or questions.

SMT Journal Club Recording Available

A recording of the August 2018 SMT Journal Club Webinar is available to ABC Members via ABC's listservs. The webinar included the review of three key scientific/medical articles, an editorial, and clinical evidence synopsis followed by open discussion by participants, presenters, and article authors. Members of ABC interested in accessing listservs may sign-up for an account here. The publications can be found on the ABC Member website:

- Impact of Blood Type O on Mortality of Severe Trauma Patients
- How Do I Implement a Whole Blood Program for Massively Bleeding Patients?
- Pathogen-Reduced Platelets for the Prevention of Bleeding in People of Any Age
- Comparison of the Hemostatic Efficacy of Pathogen-Reduced Platelets vs Untreated Platelets in Patients with Thrombocytopenia and Malignant Hematologic Diseases-A Randomized Control Trial
- Pathogen Inactivation Strategies to Improve Blood Safety Let's Not Throw Pathogen-Reduced Platelets Out with Their Bath Water

REGULATORY NEWS

FDA announced that it is holding a Public Workshop for Pathogen Reduction Technologies for blood safety November 29-30th. The workshop is intended to "foster the development and implementation of pathogen reduction technologies for blood components intended for transfusion," according an agency announcement. It will take place at the FDA's White Oak Campus in Silver Spring, Md. Additional details are available.

(Source: FDA Announcement)

BRIEFLY NOTED

The Maturing Cell Therapy and Logistics Roundtable took place in Washington, D.C. July 25, 2018. During the event, HemaCare's Global Head of Cell Therapy Dominic Clarke, PhD discussed some of the barriers to the advancement of cell therapy. There was a focus on the need for robust and reliable starting material sourcing to assure consistent capabilities to generate products. Appropriate donor consent, supply stream logistics and quality control are key aspects that need to be addressed going forward. Allison Hubel, PhD, professor of Mechanical Engineering and director of Biopreservation Core Resource at the University of Minnesota, gave two presentations on maintenance of cell viability at collection and manufacturing and use (clinical) sites. Standardization of collection and processing, cryopreservation, transport, and thawing protocols are key aspects that need to be addressed to assure acceptable maintenance and viability of cells. Jason Acker, PhD, co-founder and director at PanThera CryoSolutions, Inc. highlighted the need to assess cryopreservation protocols on an individual basis based on cell type, since unique cell types may require different processing and cryopreservation protocols to assure product integrity. The need to standardize cryopreservation protocols for cellular products to assure ease of use for the end user, including processing, shipping, and post thaw characterization parameters was presented by Sanjibita Mishra, process engineer at Kite Pharma. Prajakta Varadkar, PhD, a CMC Reviewer for the Division of Cellular & Gene Therapies at the FDA, Erik J. Woods, PhD, HCLD (ABB) co-founder and chief science officer at Ossium Health, Inc., and Robert Lindblad, MD, chief medical officer at The Emmes Corporation, discussed regulatory processes and issues for cell therapy. Key points included how to address manufacturing control issues and what types of standardizations are needed to assure the integrity, consistency, and safety of the cell products.

The final session dealt with standardization and harmonization of cell development processes and best practices leading to improvements in cryopreservation during the manufacturing process. Panel members included Steve Unikewicz, owner and principal engineer for Unikewicz Consulting Engineers, Leonard Freedman president at Global Biological Standards Institute (GBSI), Eric James, PhD, senior managing director at Vaccine Stabilization & Logistics, and David Lewandowski, global product marketing manager, automated cryo storage at Brooks Life Science. The audience discussed the need for implementation of standards and best processes to assure optimal practices and improvements in cryopreservation during cell therapy manufacturing. Specific areas mentioned included temperature monitoring during storage and transport since cell quality can be impacted by transient temperature excursions, freezing protocols, and how to standardize/optimize these based on cell type, freezing media, volume, container geometry, and cell number. They also discussed developing a standardized thawing procedure since currently this varies a great deal across different end-users and education of end users on these aspects.

Contributed by Robert Tressler, PhD, Vice President, Laboratories, San Diego Blood Bank

RESEARCH IN BRIEF

***Blood* publishing series on management of the hemoglobinopathies.** A new series in the journal *Blood* will address the current management of this diverse group of conditions. The initial articles are open access and hyperlinked directly in the citations below. They address important treatment issues including hypoxia presenting in the face of hemolysis and hemoglobin disorders, managing the complications of the thalassemias, and older adults with sickle cell disease.

Citations: Machogu, E. and Machado, R. How I manage hypoxia in adults with hemoglobinopathies and hemolytic disorders. *Blood*. 2018.

Coates, T. Introduction to a how I treat series on sickle cell disease and thalassemia. *Blood*. 2018

Taher, A. and Cappellini, M.D. How I manage medical complications of beta-thalassemia in adults. *Blood*. 2018.

Thein, S. L. and Howard, J. How I treat the older adult with sickle cell disease. *Blood*. 2018.

Shet, A. and Wun, T. How we diagnose and treat venous thromboembolism in sickle cell disease. *Blood*. 2018.

The influence of pathogen load on the efficacy of pathogen reduction. A complex balance among the potency of pathogen reduction processes, the amount of target pathogen present in an infected unit, and the

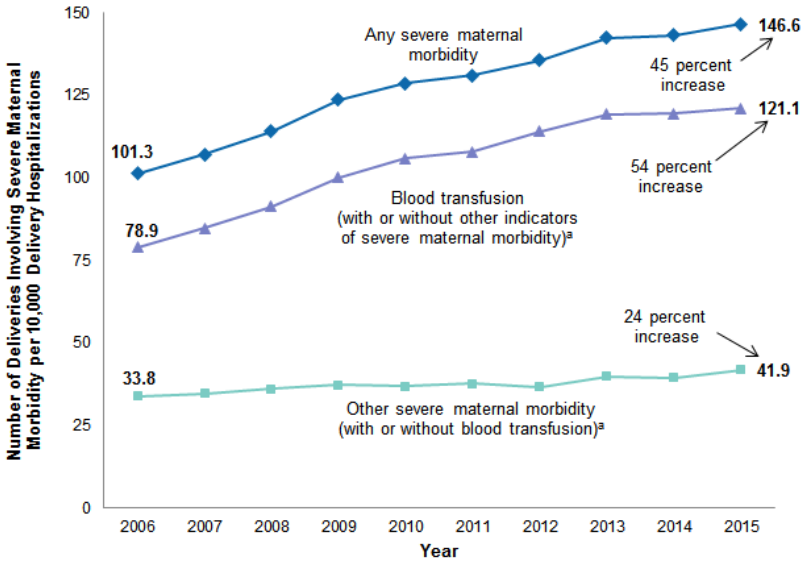
(continued on page 8)

RESEARCH IN BRIEF (continued from page 7)

infectivity of that unit exists. The measurement of pathogen loads is discussed *Transfusion and Apheresis Science*, with the intent of describing assessment of efficacy and the resulting risk for disease transmission using currently available processes.

Citation: Bah, A., Cardozo M., Seghatchian, J., and Goodrich, R. Reflections on the dynamics of bacterial and viral contamination of blood components and the levels of efficacy for pathogen inactivation processes. *Trans. Aph. Sci.* 2018.

The Healthcare Cost and Utilization Project (H-CUP) describes United States trends and disparities in hospitalizations with severe maternal morbidity. This paper presents trends from 2006 through the third quarter of 2015. Any severe maternal mortality has risen 45 percent to 146.6 deliveries per 10,000 admissions, and blood transfusion, with or without other indicators of severe maternal morbidity, has risen 54 percent in the interval to 121.1. Data stratifying these observations by a variety of demographic characteristics are provided.



Citation: Fingar, K.R., Hambrick, M.M., Heslin, K.C., and Moore, J.E. Trends and disparities in delivery hospitalizations involving severe maternal morbidity, 2006-2015. Statistical Brief #243. Healthcare Cost and Utilization Project (HCUP). 2018. Agency for Healthcare Research and Quality.

Rh genotyping in sickle cell disease (SCD). Alloimmunization after transfusion is a major complication in the management of SCD despite serologic matching of donors and recipients for multiple antigens in the Rh system. While this has been attributed to receipt of unmatched transfusions at institutions that do not routinely perform extended phenotyping of donors and recipients, a major contribution may be from serological insensitivity for antigens that vary at the genotype level and are more common in SCD patients. Investigators at the Children's Hospital of Philadelphia, ABC member New York Blood Center, and the American Red Cross have assessed the contribution of this phenomenon and hypothesize about the potential value of wider use of genotyping to the support of SCD patients. Twenty nine percent of RHD and 53 percent of RHCE alleles were found by genotype to be altered in patients and African American (AA) donors. When the authors modeled RH genotype matching in comparison to Rh serological matching they estimate that twice the number of AA donors would be required by the former strategy. They conclude that prophylactic RH genotype matching, given a large pool of AA donors, could reduce pressure on the RhD negative blood supply, but that cost and data management barriers are limiting factors. The authors of an editorial ask if such matching can actually reduce alloimmunization, whether the capacity for genotyping is widely enough available to support such a standard of care, and how the results and implications of genotyping can be made available across the multiple sites of care that characterize many of the patients under consideration.

Citations: Chou, S.T., Evans, P., Vege, S. *et al.* RH genotype matching for transfusion support in sickle cell disease. *Blood*. 2018.

(continued on page 9)

RESEARCH IN BRIEF (continued from page 8)

Hendrickson, J.E. and Tormey, C.A. Rhesus pieces: genotype matching of RBCs. *Blood*. 2018.

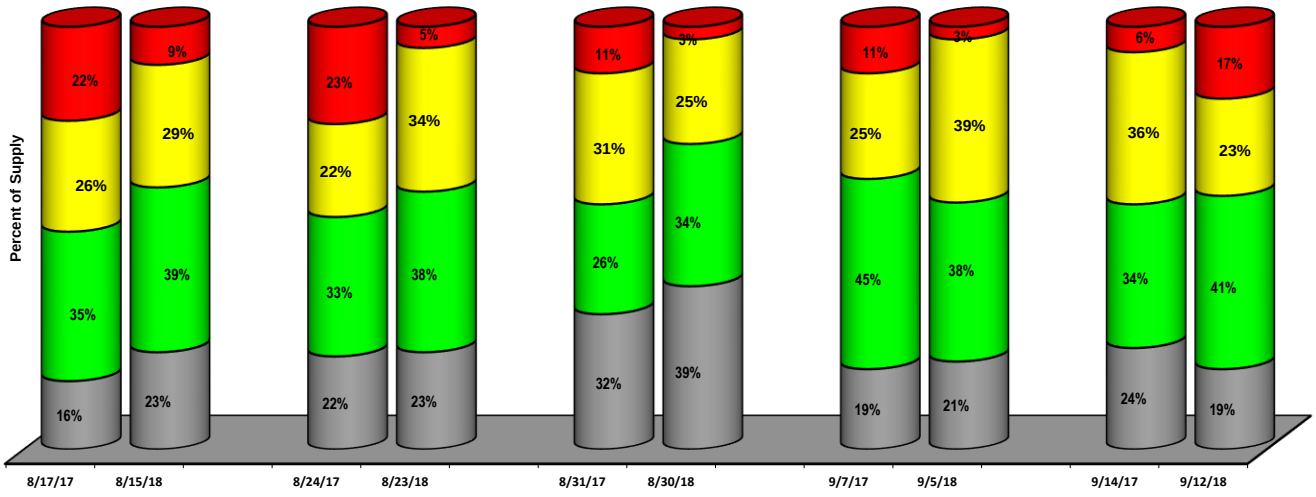
What are the economic benefits of robust funding for biomedical research? Advocacy for increased research support should recognize more than the medical benefits of such funding. A summary article in the *British Medical Journal* describes the findings from a series of articles that have attempted to quantify the returns of biomedical research to the United Kingdom economy. The authors have published on models that assess the impact of research dollars used to study musculoskeletal and cardiovascular disease and cancer over time horizons of 15-17 years. They estimate internal rates of return of 7, 10, and 9 percent annually.

Citation: Grant, J. and Buxton, M.J. Economic returns to medical research funding. *BMJ*. 2018.

What is the minimal infectious dose of hepatitis B virus (HBV) by transfusion. Occult HBV is infection with negative nucleic acid tests (NAT) and HBsAg assays. It is not a major issue in the United States, where anti-HB-core testing is in use. Taking data from three donors with occult HBV who transmitted to recipients via their donations, investigators have reduced the estimate for the minimal infectious dose of the virus by this route from 100 to 16 genome copies/mL. This has implications especially for developing NAT testing platforms in countries where the prevalence of anti-HB-core is too high for its use as a donor screen.

Citation: Candotti, D., Assennato, S.M., Laperche, S. *et al.* Multiple HBV transfusion transmissions from undetected occult infections: revising the minimal infectious dose. *Gut*. 2018.

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



The order of the bars is (from top to bottom), red, yellow, green, and no response

No Response | Green: 3 or More Days | Yellow: 2 Days | Red: 1 Day or Less

Daily updates are available at:
www.AmericasBlood.org

WORD IN WASHINGTON

The House and Senate are reported to have reached an agreement on a short-term spending bill that will fund the federal government through December 7th. The continuing resolution serves as a stopgap measure that averts a government shutdown. Funding for the federal government was scheduled to run out at the end of this month. The *Washington Post* reports that the continuing resolution will also be attached to multiple spending bills including one that funds the U.S. Department of Health and Human Services, which is speculated to receive significant increases. "It doesn't make a lot of sense to shut down the government and we'll fight that fight when it comes, but this isn't the time to have it," said Rep. Tom Cole (R-Okla.), a senior member of the House Appropriations Committee, according to the *Washington Post*. "I don't presume to speak for the [P]resident but our leadership tells us that they've been in constant communication with the administration and that we're proceeding on plan, so I assume that's the case."

(Source: *Washington Post*, Congress planning to avert government shutdown, 9/13/18)

PEOPLE

Photo courtesy of NIH

Kelly Gebo, MD, MPH is the new chief medical and scientific officer of the *All of Us* Research Program. She will be responsible for the *All of Us* scientific agenda. "Kelly has the right combination of research skills, leadership experience, and passion for personalized medicine for the job," said Eric Dishman, director of the *All of Us* Research Program in National Institutes of Health (NIH) announcement. "I'm delighted to have her join our team in this new position. She brings a wealth of expertise in cohort research, data quality and analysis, and clinical care, and with continued input from diverse stakeholders across the country, will help us further develop our scientific roadmap for this project." Dr. Gebo is a professor at Johns Hopkins University and holds a medical degree from their school of medicine in addition to a master's in public health from the Johns Hopkins Bloomberg School of Public Health. "I am thrilled to serve in this new role as Chief Medical and Scientific Officer for the *All of Us* Research Program," said Dr. Gebo. "I look forward to working with participants, providers, and researchers as we collaborate to collect high-quality data and enable groundbreaking research."

(Source: NIH Announcement, 9/10/18)

MEMBER NEWS

San Diego Blood Bank is collaborating with PACIFIC Digital Group on a selfie campaign to raise awareness of the need for blood and encourage blood donations from millennials using the hashtag #DonateASelfie "We are so grateful to PACIFIC for their support, and with the awareness raised from this we can continue to provide critical services to our neighbors in need," said David Wellis, PhD, San Diego Blood Bank CEO in a news release. The campaign features the tagline "extend your arm for something besides yourself" and includes a dedicated website and videos created by PACIFIC, who historically provide pro bono services to non-profits. "Giving back to our community is a big part of PACIFIC's core business principles," said Norman Brauns, CEO and founder of PACIFIC. "Supporting organizations that promote causes we believe in is truly rewarding."

(Source: KUSI News, #DonateASelfie campaign for San Diego Blood Bank, 9/9/18)

COMPANY NEWS

Mediware Information Systems, Inc. has become WellSky as part of a strategic transformation according to a news release issued this week. "WellSky signifies a fundamental promise we make to our customers — that together we can realize care's potential," said WellSky CEO Bill Miller in the release. "We stand at the forefront of innovation that will eliminate the fragmentation that exists in health and community care. As our customers face pressure to improve care delivery to every person they serve, WellSky will be there. We will be their trusted partner and the indispensable technology platform that will help them succeed." The transformation merges 30 brands under one name. "The market has been asking for this kind of leadership, and with a unified brand and exciting vision for the future, WellSky is poised to make an enormous, positive difference for both providers and patients," added Sharon Harder, an industry consultant and president of C3 Advisors. Additional information can be found on the new WellSky website.

(Source: WellSky News Release, 9/11/18)

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.

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

Sept. 24-26. **The MedTech Conference, Philadelphia, PA.** More details available here.

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

Nov. 29-30. **FDA Pathogen Reduction Technologies for Blood Safety Public Workshop, Silver Spring, Md.** More details available here.

2019

Feb. 4-6. **15th Annual FDA and the Changing Paradigm for HCT/P Regulation, Washington, D.C.** More details available here.

March 22-26. **2019 ABC Annual Meeting, Washington, D.C.** More details coming soon.

May 14-16. **ADRP Annual Conference, Indianapolis, Ind.** More details available here.

May 22-23. **IPFA/PEI 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens", Krakow, Poland.** 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: lmaundy@americasblood.org.

POSITIONS

Quality Specialist - Transfusion Medicine. Dartmouth-Hitchcock is seeking a Quality Specialist to join our Transfusion Medicine team at our Level-1 academic medical center in New Hampshire. The Quality Specialist is responsible for planning, monitoring, coordinating and improving the processes used in the Transfusion Medicine Department along oversight for Quality Control, Quality Assurance, Quality Improvement, Document Control, and Regulatory Compliance. Responsibilities: Communicating quality activities to management and unbiased observations to ensure compliance with current manufacturing practice as defined by FDA. Managing the transfusion medicine service quality plan. Facilitating internal assessments and audits, to assess the effectiveness of process improvement initiatives. Coordinating with the transfusion safety officer on issues related to quality of services provided by the Transfusion Medicine Service. Requirements: A bachelor's degree with four years of experience in blood banking. MT (ASCP) or equivalent certification. Familiarity with cellular and tissue transplantation and blood donor program services preferred. A current working knowledge of all relevant laws, regulations, and industry standards required by FDA, CMS, TJC, FACT, AABB, CAP, NMDP, and OSHA. Specialty laboratory certification and advanced training/certification in Quality Systems Management preferred. **Applicants are encouraged to apply online at:** Careers.Dartmouth-Hitchcock.org. Dartmouth-Hitchcock is an equal opportunity employer.

Director of Marketing and Donor Recruitment. MEDIC Regional Blood Center, based in Knoxville, TN, seeks qualified applicants for its Director of Marketing and Donor Recruitment position. This position is responsible for developing and directing the blood center's donor recruitment staff and strategic plans to achieve collection goals and promote community participation. Scope of responsibilities includes oversight of all mobile and fixed site recruitment, marketing and social media campaigns. Must have the ability to oversee daily operations as well as plan for and execute strategic long-term goals. Must be able to facilitate recruitment operations activities related to donors and management recruitment and marketing staff with budgetary responsibility. Position will require working closely with Collections staff to facilitate efficient and effective blood drives. Must be an effective leader with ability to adapt to change. Demonstrated experience in sales/territory management skills, strong leadership and team building skills, excellent verbal and written communication, public speaking skills and computer competency and literacy. Bachelor's degree required with a minimum of five years management experience. Prior blood center experience preferred. Competitive salary and benefits. This position reports to the Chief Executive Officer. MEDIC is an Equal Opportunity Employer. Apply online at hr@medicblood.org.

Director, Donor Recruitment. LifeStream (San Bernardino, CA) located 60 miles east of Los Angeles and 50 miles west of Palm Springs seeks qualified applicants for its Director, Donor Recruitment position. This position is responsible for developing and directing the blood center's donor recruitment department/plans to achieve collection goals. Scope of responsibilities includes oversight of all mobile and fixed site recruitment. Requires the ability to oversee the daily operations, as well as strategically work toward the long-term goals. Must be able to facilitate all operational activities related to recruitment of donors and management of recruitment staff within the expected budget guidelines. Must be an effective leader and have the ability to adapt to change. Excellent salary (with bonus program) and benefits including relocation package. Bachelor's degree required. Demonstrated experience in sales/territory management skills, strong leadership and team building skills, excellent verbal and written communication and public speaking skills and computer literacy. Prior blood center experience preferred. Minimum three years management experience. Successful candidate must demonstrate ability to work closely with Marketing and Collections Managers/Directors to facilitate efficient and effective blood drives. This position reports to the Vice President/Operations. LifeStream is an Equal Opportunity Employer, M/F/D/V. Apply online at: https://www.lstream.org/careers/..