

2015 #30

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ABC Summer Meeting Explores Scientific Advances and Managing Change

More than 130 members of America's Blood Centers, speakers, and industry vendors met in Loews Philadelphia Hotel from Aug. 4 to 6 for the ABC Summer Meeting and Medical Directors (MD) Workshop. The meeting, hosted by Blood Bank of Delmarva, Central Pennsylvania Blood Bank, and Miller-Keystone Blood Center, explored scientific advances like pathogen reduction, as well as challenges facing today's blood bank leaders, like how to navigate the multi-generational workforce.



Connie M. Westhoff, SBB, PhD, director of Immunohematology and Genomics at New York Blood Center, presents on Rh typing during the MD Workshop.

This year, ABC Summer Meeting attendees enjoyed a more interactive meeting with speakers who led group activities, the introduction of polling via a smartphone app, and a “hollow square” seating arrangement for the ABC Members Meeting that allowed for more input from members. The Summer Meeting was held in conjunction with the Foundation for America's Blood Centers' (FABC) Annual *Links for Life* Golf Tournament (see page 7) on Thursday, Aug. 6, and guests were treated to a number of networking events throughout the meeting.

On Tuesday and Wednesday mornings, Dan Waxman, MD, interim president/CEO and chief medical officer at Indiana Blood Center, a part of Versiti, led several of ABC's health-conscious attendees in a 60-minute wellness walk around Philadelphia prior to the educational sessions.

MD Workshop. Blood center medical directors and other executives gathered on Tuesday for the MD Workshop to discuss several current issues in blood banking including donor perception of screening questions, research on the donation policy for men who have sex with men (MSM), hepatitis E virus (HEV), and Rh genotyping.

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OUR SPACE

Gregg Boothe, Associate Director/COO, Hoxworth Blood Center & Chair of ABC's Data Warehouse Requirements Advisory Committee

When 'Sorta You' Isn't You (or Why we Need the Data Warehouse)

Many of you may have seen the recent Esurance commercials with the theme "sorta you, isn't you." In one, Giants catcher Buster Posey runs into a maternity room ready to deliver a baby stating that he is "sorta like a doctor because he wears a glove and delivers in the clutch." Needless to say, the expectant father so infatuated with Buster that he considers allowing him to deliver, but the expectant mother wants her physician, not someone "sorta like" her physician, to actually do the delivery.

Listening to the presentations at the America's Blood Centers' Summer Meeting in Philadelphia last week, I noted at least one instance in which the American Red Cross (ARC) had shared data representing the industry. While the data ARC provided is likely reflective of industry trends, it struck me that the ABC members are being classed as "sorta like the ARC." Much like the expectant mother in the commercial, I wanted us, not someone "sorta like" us, to make that delivery. ABC's Data Warehouse (DW) offers us that capability, by collecting and disseminating data from ABC member blood centers about blood collection and utilization.

ABC's DW Requirements Advisory Committee (DWRAC) has been working diligently over the past year on business intelligence questions provided by the membership. It has been a long process to standardize the metric definitions and format the initial reports that the committee ranked as most important. We shared "in process" examples with those in attendance at the Summer Meeting and showed subtle differences between some ABC members using the current data in the ABC DW from 2012.

To bring us into the present, a significant step forward occurred with the creation of new computer script modifications for BBCS and Wyndgate blood establishment computer systems (BECS) data extraction. These have been implemented at several centers and other members are working to implement the new script modifications for their specific BECS system. This will refresh the DW with up-to-date data reflective of what is currently happening within our industry. This is not only important to project where the industry is going, but also to support advocacy efforts by directly representing ABC members.

The strength of the DW is not solely in the data, but also in the capability to examine our differences and work together to improve our operations and be represented nationally. We want to ensure that our voice is heard for our advocacy and industry improvement efforts. I hope all of you, like me, want to have our institutions represented with data that is us, not "sorta like us."

Gregg Boothe

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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ABC Summer Meeting (continued from page 1)

Stephanie Willson, PhD, a survey methodologist at the Centers for Disease Control and Prevention's National Center for Health Statistics, presented her group's research investigating how blood donors read and respond to blood donor screening questions, as well as their rationale behind their responses. Their research, which involved 166 respondents from five geographic regions, suggested that respondents may not always answer questions accurately because they generally answer all questions as "Is my blood safe?" – rather than responding to the specific content of the question – this was consistent across all subgroups.

Further, donors may answer questions inaccurately because they simply do not know the answer or understand the terminology that blood bankers have developed in donor questionnaires, according to Dr. Willson. She suggested adding a "don't know" option to questions and deemphasizing that the questionnaire is about blood safety per se, although she admitted that neither may be viable solutions. The findings can be accessed [online](#) and the group is preparing a manuscript for publication in a peer reviewed journal.

Brian Custer, PhD, MPH, a senior investigator at Blood Systems Research Institute, described research regarding risk factors associated with transfusion-transmitted infections and blood donor behavior. The data have been presented to the Department of Health and Human Services' advisory committee and to the Food and Drug Administration as the agency considers changing the current lifetime deferral for men who have sex with other men (MSM) to a deferral of one year since the last exposure. Dr. Custer presented the recently published REDS-III Blood Donation Rules Opinion Study (Blood DROPS), which suggests that donor compliance with the current lifetime MSM deferral policy is far from perfect, but that donors may be more likely to comply with a one-year deferral (see [ABC Newsletter](#), 7/31/15).



Several meeting attendees participate in an early morning Wellness Walk prior to the educational sessions.

Gilles Delage, MD, MSc, discussed the current epidemiology and risk management options surrounding transfusion-transmitted HEV. The data he presented regarding post-transfusion infections and his risk analyses suggested that HEV risk mitigation measures may be justified in certain European countries, but that it is premature to recommend such measures in North America based on the data available.

Michael Fitzpatrick, PhD, from Cellphire Inc., presented the current and untapped potential of platelets and platelet derivatives, suggesting that platelets can have many other uses outside of stopping life threatening bleeding, such as prophylaxis, and wound or burn treatment. He briefly discussed a freeze-dried platelet product (called thromosomes) being developed by Cellphire. The company plans to continue with Phase I ascending dose studies and Phase II safety/efficacy study(s) in open-heart surgery or myelodysplastic patients.

Connie M. Westhoff, SBB, PhD, director of Immunohematology and Genomics at New York Blood Center, discussed the challenges and shortcomings of RhD typing by serologic methods and an approach for phasing in RHD genotyping. She reviewed the recent recommendations of a work group convened by

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ABC Summer Meeting (continued from page 3)

AABB and the College of American Pathologists, which suggested that RHD genotyping be conducted whenever a weak D phenotype is detected by routine Rh blood typing of pregnant women and females of childbearing age (see [ABC Newsletter](#), 7/24/15).

ABC Chief Medical Officer Louis Katz, MD, led a discussion of hot topics including babesiosis, pathogen reduction, and the FDA's final rule for blood and blood components for transfusion or for further manufacturing use. He was joined by Rich Gammon, MD, medical director of OneBlood in Florida, who explained the efforts by an ABC committee to develop and publish a one-page transfusion trigger resources for clinicians (coming soon!). Marissa Li, MD, medical director, United Blood Services, reviewed the projects of ABC's Transfusion Safety Committee.

The MD Workshop concluded with member blood center medical professionals sharing their unique case studies in the Morbidity and Mortality Workshop.

SMT Workshop. Donna Strauss, executive director of Core Operations at New York Blood Center (NYBC), kicked off the SMT Forum on Wednesday morning, with a presentation on the timely topic of pathogen reduction for platelets, specifically a pathway to operationalizing pathogen reduction at NYBC. She explored operational considerations including the available technology (Cerus's Intercept system is FDA approved; Terumo BCT's Mirasol system will be submitted for approval when clinical trials are completed), implementation, availability, costs, and the decision-making process. Mark E. Brecher, MD, chief medical officer of Laboratory Corporation of America, followed with a talk on history and background surrounding the mitigation of bacterial contamination of platelets, including challenges in implementing pathogen reduction, such as the need for more platelets, cost-effectiveness, and Blood Shield law risks.



ABC Chief Medical Officer Louis Katz, MD, (left), and ABC SMT Co-Chair Chris Gresens, MD, (right), recognize Gary Levy, MD, medical director of LifeShare Blood Centers, who is retiring, for his contributions to ABC's SMT efforts over the years.

Steven A. Anderson, PhD, MPP, director of the Office of Biostatistics and Epidemiology at FDA's Center for Biologics Evaluation and Research, reviewed the risk of transfusion-transmitted variant Creutzfeldt-Jakob disease (vCJD) in the US and FDA's recent reevaluation of the vCJD blood donor deferral at the June Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) meeting. (see [ABC Newsletter](#), 6/5/15). FDA proposed significant changes to the current deferrals, supported by ABC, AABB, and ARC, which would limit the risk period in Ireland and France to 2001 and eliminate deferrals for exposure in lower risk countries, while maintaining a similar level of risk reduction. The TSEAC, in advice that suggests a different risk tolerance level, did not support the proposal.

Kathleen Rowe, director of Plasma and Market Development at Blood Centers of America (BCA), gave an eye-opening talk about her experience assisting with a clinical [trial](#) being conducted by ClinicalRM, testing convalescent plasma treatment in Ebola virus patients in Liberia. Ms. Rowe served as a subject matter expert in Liberia leading the efforts to deploy outfitted bloodmobiles for donor screening, plasma collection, and pathogen inactivation, as well as training staff and preparing the necessary standard operating procedures to collect convalescent plasma from Ebola virus survivors.

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ABC Summer Meeting (continued from page 4)

Training Liberian medical technologists proved challenging as their skills are less developed compared with US standards, explained Ms. Rowe. She described witnessing the moving “graduation” of Ebola survivors who were in the hospital for the better part of a year and the true altruism of the first convalescent plasma donor, a 23-year-old female who lost most of her family to Ebola. The team screened 67 donors who had survived Ebola virus and collected 58 convalescent plasma units. Ongoing research continues evaluating donor samples and data from Ebola survivors.

Beth A. Hartwell, MD, medical director of Gulf Coast Regional Blood Center, described the composition of liquid plasma and its use in emergency situations, including group AB vs. group A plasma. She also provided a framework for the production and distribution of liquid plasma.

Blood Center Leadership Forum. The healthcare environment in which blood centers operate is changing daily, and as such, the blood center landscape continues to evolve. Speaking on this relevant topic on Wednesday afternoon, Jen Runkle, PhD, founder of Washington-based Runkle Consulting, which has provided leadership guidance to key executives in numerous global corporations, led an interactive discussion about successfully leading through and managing change.

Dr. Runkle challenged attendees to explore how their organizations have implemented change in the past, what changes they are most concerned about in the future, what motivates people to change, and barriers to change. Attendees completed pre-work about change in their organizations and were able to participate during the session both through a polling app and open discussion. Dr. Runkle concluded with a working session where attendees mapped out how they would create a “change leadership plan” in 90 days.



A lively band from the Mummies group, known for their elaborate costumes, performs during a networking reception at the National Constitution Center in Philadelphia.

During the second half of the Forum, Shira Harrington, MA, founder and president of Purposeful Hire, a Washington-based executive and professional search company, discussed another important topic for the blood industry – navigating the multigenerational workforce and bridging the gap between the rising and retiring generations.

Ms. Harrington discussed some key differences between the baby boomers, Gen-X, and Millennials – including differences in communication preferences, comfort with technology, and work-life balance. Once again, attendees provided feedback before the meeting via a pre-work assignment and during the session via the polling app and open discussion. She asked attendees to discuss which generational challenges are most pressing at their blood centers – among the issues discussed were succession planning, training younger front-line staff, electronic communication, and the aging donor population.

An Evening with Our Founding Fathers. Following the Blood Center Leadership Forum, guests enjoyed a networking reception, hosted by Blood Bank of Delmarva, Central Pennsylvania Blood Bank, and Miller-Keystone Blood Center, at the National Constitution Center, surrounded by a picturesque view of Independence Hall and the city of Philadelphia. The reception offered drinks and hors d’oeuvres, as well

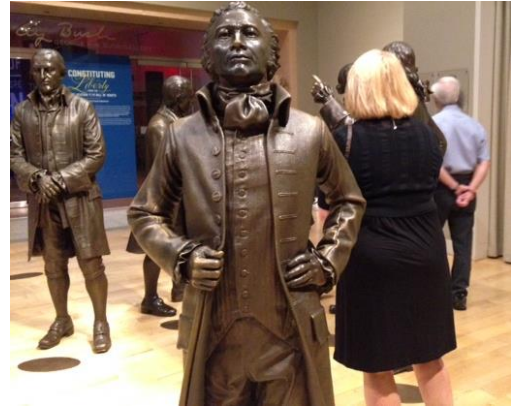
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ABC Summer Meeting (continued from page 5)

as musical entertainment by the Mummers, a group known for their elaborate costumes and annual parade on New Year's Day, as well as a Ben Franklin impersonator.

Attendees were greeted warmly by Blood Bank of Delmarva President and CEO Roy Roper, Central Pennsylvania Blood Bank President and CEO Patrick Bradley, and Miller-Keystone Blood Center President and CEO Peter J. Castagna, Jr. Guests mingled with colleagues and toured the exhibits, including Signers' Hall, which features life-size statues of those who signed the Constitution on Sept. 17, 1787.

ABC Members Meeting. Following the 5th Annual *Links for Life* Golf Tournament (see page 7) held Thursday morning, ABC members headed to the Members Meeting to hear updates on ABC's key projects and initiatives, including reports from ABC President Susan Rossmann, MD, PhD and ABC CEO Christine Zambricki, DNAP, CRNA, FAAN. Attendees learned about ABC's key accomplishments within each of its strategic goals – advocacy excellence, association excellence, education excellence, data driven excellence, and governance excellence – as well as a Foundation update. ABC announced its upcoming 2016 meetings – the Annual Meeting to be hosted in March in Jacksonville, Fla., and the Summer Meeting set for Honolulu, Hawaii in August.



ABC members explore Signers' Hall, featuring life-size bronze statues of those who signed the US Constitution, at the National Constitution Center.

ABC would like to thank all of the speakers, attendees, and sponsors who made the Summer Meeting and events a success. ABC members can find presentations from the Summer Meeting on the [ABC Member Site](#). If you attended the meeting, don't forget to fill out your evaluations via the ABC Meeting App! Contact Abbey Nunes at anunes@americasblood.org with questions regarding the app. 💧

Thanks to the Following Sponsors for Supporting the ABC Summer Meeting & Links for Life Golf Tournament





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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. ♦

Summer Meeting Attendees Support the FABC at *Links for Life* Golf Tournament

Nearly 40 golfers from blood centers and industry vendors came out on Aug. 6 in support of the Foundation for America's Blood Centers (FABC) 5th Annual *Links for Life* Golf Tournament. The event, sponsored by Blood Bank of Delmarva, Central Pennsylvania Blood Bank, and Miller-Keystone Blood Center, was held at the Woodcrest Country Club in Cherry Hill, N.J., in conjunction with the ABC Summer Meeting in Philadelphia. The Summer Meeting and *Links for Life* Golf Tournament raised nearly \$70,000 to support the FABC.



ABC CEO Christine Zambricki, DNAP, CRNA, FAAN, putts while her teammates (from left to right) Pete Castagna, Miller-Keystone Blood Center, Dan Connor, Blood Systems, and Alex Kiskovski, MAK-System, look on with rapt attention.

The *Links for Life* Golf Tournament is an annual event that supports the FABC and raises awareness of the need for voluntary blood donors. The FABC funds programs that support the life-saving mission of ABC's member blood centers, particularly through supporting educational programs for ABC member blood center professionals. Numerous blood center and industry executives came out this year to support the FABC's life-saving mission.

"Thanks to all the golfers who participated in the *Links for Life* Golf outing at Woodcrest Country Club at this year's ABC Summer Meeting," said Peter Castagna, Jr., president and CEO of host Miller-Keystone Blood Center. "We were blessed with a perfect day of weather, a challenging yet beautiful venue, and a group of golfers that had fun and enjoyed the spirit of competition. I would like to especially acknowledge the ABC staff and sponsors for making it a first class event."

Golfers set out for the course on a bright sunny day and enjoyed a continental breakfast prior to tee off. At registration, golfers received a *Links for Life* golf towel and a sleeve of golf balls and were able to sign up for the longest drive and closest to the pin contest with two mulligans for \$25. Many golfers also purchased raffle tickets for a chance to win an Apple Watch Sport.

After an invigorating and challenging 18 holes, participants began trickling onto the picturesque outdoor patio for a barbecue lunch and awards ceremony. FABC Board Chair Roy Roper, president and CEO of host Blood Bank of Delmarva, thanked the golfers on behalf of the three hosting blood centers and announced the award winners.

With a score of 64, this year's winning team included: Jeff Bryant, of Inland Northwest Blood Center; Larry Smith, of Rhode Island Blood Center; and Steve Gergar, of Miller-Keystone Blood Center. Brad

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Cherry, of Stanford Blood Center, took home the prize for the longest drive and Whitney Green, of Roche Diagnostics, won the closest to the pin contest.

Later that evening, the golfers were treated to a reception on the 33rd floor of the Loews Philadelphia Hotel, complete with a scenic view of the city. Mr. Roper again thanked the golfers for supporting the Foundation and announced the lucky winner of the Apple Watch Sport raffle – Margie Boraz of Macopharma USA.

“I personally want to thank our sponsors and golfers for supporting our FABC fundraiser,” said Mr. Roper. “It was a beautiful day on a fun course. Congratulations to the tournament and contest winners!” ♦



The 5th Annual *Links for Life* Golf Tournament winning team (from left to right): Larry Smith, Rhode Island Blood Center; Jeff Bryant, Inland Northwest Blood Center; and Steve Gergar, Miller-Keystone Blood Center.



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There are four (4) \$800 scholarships available for this workshop. Application and additional details are included in registration.

The Institute for Transfusion Medicine (ITxM) is thrilled to host the upcoming ABC Financial Management Workshop in Chicago. We anticipate lively discussion and exchange of ideas on how best to manage financially through these uncertain times in blood banking, mainly due to the cost cutting pressures within healthcare and the decrease in blood use. This will be an excellent opportunity to network with your peers and share your expertise on good financial practices and understanding of not only knowing how your business is doing financially, but why. We look forward to seeing you at our LifeSource facility in Rosemont in September.

– Jim Covert
President and CEO, ITxM

Sponsorship opportunities available. Contact Abbey Nunes at anunes@americasblood.org for details.



Chicago O'Hare airport (ORD - 3 miles), a hub for United and American, is served by all major US airlines; Midway airport (MDW - 29 miles) is served by discount carrier Southwest Airlines.

RESEARCH IN BRIEF

A study in *JAMA Surgery* suggests that a patient's change in hemoglobin (Hgb) from admission to the lowest Hgb level during hospitalization (nadir Hgb) may be an important factor to guide red blood cell (RBC) transfusion, rather than just the nadir Hgb. Aside from the use of simple Hgb triggers, some investigators have suggested that the percent change in the Hgb level should also be used to guide appropriate transfusion, particularly in surgical patients. Previous research suggested that a large percentage change or "delta" in the Hgb level (Δ Hgb) of 50 percent or more was more strongly associated with worse outcomes, even when the absolute Hgb level remained greater than the commonly cited 7-8 g/dL RBC transfusion threshold. To assess any association between Δ Hgb and outcomes in patients undergoing major gastrointestinal surgery, Timothy M. Pawlik, MD, MPH, PhD, and colleagues of Johns Hopkins, Baltimore, Md., conducted a retrospective review of prospectively collected transfusion data on patients undergoing gastrointestinal surgery at Johns Hopkins from Jan. 1, 2010 through April 30, 2014. Specifically, they characterized how the Δ Hgb and nadir Hgb levels correlated with overall morbidity, as well as ischemic complications in patients undergoing pancreatic, hepatic, or colorectal resection. The study included 4,669 patients among whom the median Δ Hgb after surgery was 40 percent. Compared with patients who had a Δ Hgb level <50 percent and a nadir Hgb level of ≥ 7 g/dL, patients with a Δ Hgb level of ≥ 50 percent, whose nadir Hgb level was less than 7 g/dL were at a high risk of developing post-operative complications. A Δ Hgb of 50 percent or greater was strongly correlated with a risk of ischemic complications, even if the nadir Hgb level was ≥ 7 g/dL. "These data, as well as data from two other studies, suggest that future studies investigating the relationship between transfusion strategies and perioperative outcomes should focus not only on Hgb triggers but also on the change in Hgb level associated with any procedure or hospital stay," write the authors. Samuel A. Tisherman, MD, of the University of Maryland, Baltimore, adds in an accompanying commentary, "This finding alone does not justify transfusion. A patient's Δ Hgb may be a summative marker of preoperative risk factors and perioperative blood loss, yet the current data justify further study of Δ Hgb." He notes that individual patient factors aside from Hgb level and hemodynamics need to be considered when making the decision to transfuse. He concludes, "There is no doubt that blood loss is bad, but not all patients who experience blood loss benefit from transfusion."

Citations: Pawlik TM, *et al.* Effect of Relative Decrease in Blood Hemoglobin Concentrations on Post-operative Morbidity in Patients Who Undergo Major Gastrointestinal Surgery. 2015 July 29. [Epub ahead of print]

A phase III trial published in *Blood* suggests that an investigational treatment developed by Baxalta can effectively stop bleeding in patients with von Willebrand disease (VWD), the most common hereditary bleeding disorder for which few treatments exist. Bruce Ewenstein, of Baxalta, and colleagues, including researchers at America's Blood Centers' member BloodCenter of Wisconsin, a part of Versiti, evaluated the safety and hemostatic efficacy of a recombinant von Willebrand factor (rVWF), BAX 111, for the treatment of bleeds in 37 patients with severe VWD at trial sites in the US, Europe, Australia, Japan, Russia, and India. The primary endpoint was the number of patients experiencing successful treatment for bleeding episodes. Secondary endpoints included additional efficacy measures, pharmacokinetics, the number of infusions, and the number of units administered per bleeding episode. All of the patients (100 percent) treated with rVWF (BAX 111) achieved success for control of bleeding, defined as a mean efficacy rating of <2.5 on a four-point scale. Further, one infusion was sufficient to control 81.8 percent of bleeds, with a median of two infusions required to treat major bleeds. No thrombotic events or severe allergic reactions were observed. The most common adverse events in the study were headache, vomiting/nausea, and anemia, which were not considered to be related to the treatment. Both the Food and Drug Administration and the European Medicines Agency granted orphan drug

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RESEARCH IN BRIEF (continued from page 9)

designation to the therapy in November 2010, which is reserved for products that meet medical needs for a disease that is classified as rare (affecting fewer than 200,000 people in the US). Orphan exclusivity is not granted until the time of regulatory approval. It is currently under review for approval by FDA. More information can be found in the Baxalta [press release](#).

Citation: Gill JC, *et al.* Hemostatic efficacy, safety and pharmacokinetics of a recombinant von Willebrand factor in severe von Willebrand disease. *Blood*. 2015 Aug 3. [Epub ahead of print] ♦

RECENT REVIEWS

A meta-analysis recently published in the *Journal of Perinatology* suggests that the use of tranexamic acid (TXA) is beneficial compared with not using TXA in reducing blood loss after cesarean section (C-section). The rate of C-sections has increased in both developed and developing countries in recent decades, and one of the most common complications is postpartum hemorrhage. TXA, a synthetic derivative of the amino acid lysine, has been used in the treatment of bleeding for many years. H-M Yin, MD, of Shengli Oilfield Central Hospital in Shandong, China, and colleagues conducted a meta-analysis of randomized controlled trials (RCTs) to evaluate whether TXA could significantly reduce blood loss after C-section when compared with no TXA. Eleven RCTs were included in this analysis with a total of 1,276 women in the TXA group and 1,255 in the no TXA group. Total blood loss during and after the C-section was significantly less in the TXA group than in the control group. Further, there was a significant reduction in intraoperative and postpartum blood loss in the TXA group, and declines in hemoglobin and hematocrit values after C-section were both significantly less in the TXA group compared with the control group. The difference of postpartum hemorrhage rate was statistically significant between groups, and the need for blood transfusion was slightly less in the TXA group than the control group. The authors suggest that given the significant differences between groups in this study, further randomized, larger scale trials are needed to provide more evidence to demonstrate the efficacy of TXA in preventing blood loss after C-section.

Citation: Wang HY, *et al.* Tranexamic acid and blood loss during and after cesarean section: a meta-analysis. *J Perinatol*. 2015 Jul 30. [Epub ahead of print] ♦

BRIEFLY NOTED

The Government Accountability Office (GAO) recently published a [report](#) regarding federal investment, information sharing, and challenges in regenerative medicine. GAO found that seven federal agencies invested – either by conducting or funding research – approximately \$2.89 billion in regenerative medicine research in fiscal years 2012 through 2014. Most (88 percent) was invested by the National Institutes of Health. Agencies funded research related to their missions, including basic research to enhance general scientific knowledge, clinical research to move scientific discoveries into practical applications, and research to develop regulatory science. Blood centers involved in conducting cellular therapy research may be interested in this [report](#). ♦

REGULATORY NEWS

The Food and Drug Administration recently approved seven-day platelets collected via both Fenwal and Terumo BCT collection devices, provided that the platelets are tested with a bacterial detection device cleared by FDA as a “safety measure.” With the clearance of point-of-issue bacterial detection tests (and more recently, pathogen reduction), the blood community has sought regulatory approval permitting platelets to be stored for seven days instead of the current five days. FDA announced on Aug. 3 that it had provided FDA clearance to Fresenius Kabi for a labeling change that permits blood centers to use the Fenwal Amicus system for the storage of Amicus-derived platelets in plasma for up to seven days. The new indication states that facilities that wish to store apheresis-derived platelets for seven days must label every product with a statement that the product must be tested with a bacterial detection device cleared by FDA and labeled as a “safety measure.” Currently, the Verax Platelet PGD test is the only rapid bacterial detection test for platelets cleared as a safety measure. Subsequently, FDA provided 510(k) clearance to Terumo BCT for a labeling change extending the storage of platelets in plasma from five to seven days, as well as offering wireless capability for the software applications used with the Terumo BCT Trima Accel Automated Blood Collection System. As with the Fenwal clearance, seven-day platelets collected via Terumo BCT’s Trima Accel device must be tested with a bacterial detection device cleared by FDA and labeled as a “safety measure.” While this approval does not encompass pathogen reduced platelets, America’s Blood Centers Chief Medical Officer Louis Katz, MD, speculated that the expense and operational issues surrounding point-of-issue testing might move more facilities toward pathogen reduction, if and when seven-day dating can be extended to those products. More information can be found in the [Fresenius Kabi](#) and [Terumo BCT](#) press releases. The FDA approval documents for the Fresenius Kabi approval can be found [here](#). (Sources: Fresenius Kabi press release, 8/3/15; Terumo BCT press release, 8/10/15)

The International Council of Commonality in Blood Banking Automation (ICCBBA) recently distributed a number of updates last week regarding ISBT 128, the international standard for the identification and labeling of products of human origin. ISBT 128 recently made available the ISBT 128 Standard Technical Specification v5.3.0, which is a comprehensive description of the rules surrounding the use of ISBT 128, as well as guidance in the interpretation of these rules. It can be accessed [here](#). ICCBBA also released v6.7.0 of the ISBT 128 product description code database. The new database and version control sheets can be downloaded [here](#). Published alongside the new description code database, ICCBBA has released v6.7.0 of the Standard Terminology for Medical Products of Human Origin, which provides definitions to all ISBT 128 terminology. It is available [here](#). ICCBBA also announced the availability of an implementation guide for ISBT 128 in North American Eye Banks v1.1.0, available [here](#). It is intended to provide guidance to North American eye banks accredited by the Eye Bank Association of America in the implementation of ISBT 128. ICCBBA also made available the implementation guide, Use of Data Matrix Symbols with ISBT 128 v1.2.0, available [here](#). (Source: ISBT 128 e-mail, 8/6/15)

The Food and Drug Administration recently published a [Guidance](#) for Industry titled “Recommendations for Premarket Notification (510(k) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation.” This guidance provides recommendations to submitters and FDA reviewers in preparing and reviewing premarket notification submissions for HLA *in vitro* diagnostic device test kits. Although the guidance applies specifically to 510(k) submissions for HLA test kits, some of the recommendations in this guidance may also be applicable to human neutrophil antigen (HNA) and human platelet antigen (HPA) test kits. The guidance provides detailed information on the types of studies FDA recommends for validation of HLA test kits as 510(k)s and used for matching donors and recipients in transfusion and transplantation. (Source: FDA Guidance for Industry, 8/5/15) ♦

GLOBAL NEWS

Global Blood Fund (GBF), a non-profit organization that promotes and supports voluntary non-remunerated blood donation in low- and middle-income countries, recently facilitated the donation of a bloodmobile from the Scottish National Blood Transfusion Service to blood services in Lebanon. Currently, only just over 10 percent of blood in Lebanon is given by volunteer donors, with hospitals relying predominantly on family and replacement donors. Thanks to GBF and local non-profit Donner Sang Computer, this trend may be changing. In a country struggling to cope with an influx of more than 1 million Syrian refugees, the re-homed vehicle is helping to engage new blood donors to meeting the increasingly challenging needs of an embattled healthcare system. According to GBF, being able to offer new donation opportunities to previously under-served communities is growing both the donor base and the blood supply. (Source: GBF e-mail, 7/31/15) ♦

INFECTIOUS DISEASE UPDATES

DENGUE VIRUS

An experimental tetravalent vaccine against dengue fever was safe and efficacious over a long-term follow-up, according to a study published July 27 in *The New England Journal of Medicine*. Pooled data from two phase III trials and a phase IIb study showed a reduction in dengue disease among children who got the vaccine, according to Melanie Saville, MBBS, of Sanofi Pasteur in Lyons, France, and colleagues. The analysis also showed that overall, the vaccine was associated with a reduction in the rate of hospital admission for dengue. However, the safety analysis was complicated because the vaccine appeared to be less safe for children under 9 years old than for those older than 9, with relative risks of dengue admission of 1.58 and 0.50, respectively. The vaccine, CYD-TDV, is the most advanced candidate and could be registered and reviewed by the World Health Organization in 2016, noted Ms. Simmons. The vaccine was given as three doses – at baseline, and at six months, and 12 months – and participants were followed for efficacy and safety for 13 months after the final dose. The long term safety analysis included more than 35,000 children, ages 2 to 16 years, from Asia-Pacific and Latin American countries. The primary endpoint of the analysis was hospital admission for virologically confirmed dengue. Based on the pooled results, the relative risk for hospital admission for dengue was 0.84 among all participants. However, children under 9 were at a greater risk of being admitted to the hospital for dengue. The pooled rates of efficacy for symptomatic dengue during the first 25 months were 60.3 percent for all participants, compared with 65.6 percent for those 9 and older and 44.6 percent among those younger than 9. The authors conclude that these trials have been “hugely informative,” delivering major insights into disease burden, clinical epidemiology, and immunity but that more research is needed to continue developing a vaccine with long-term efficacy.

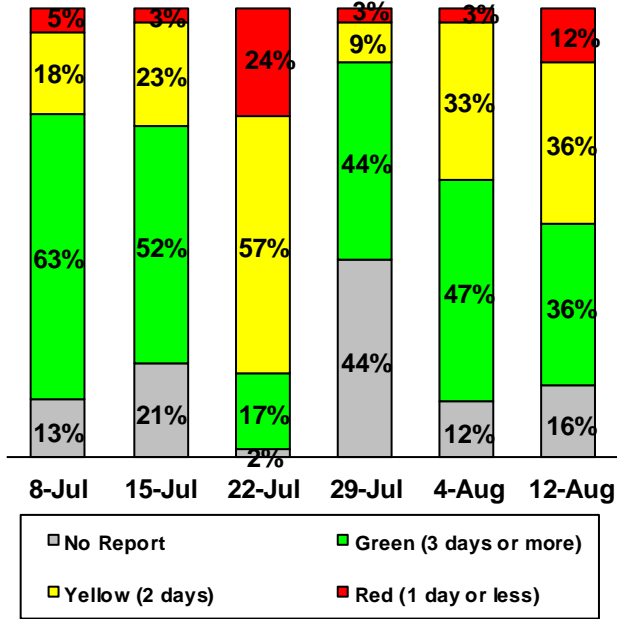
Citation: Hadinegoro SR, *et al.* Efficacy and long-term safety of a dengue vaccine in regions of endemic disease. *N Engl J Med.* 2015 July 27. [Epub ahead of print] ♦

We Welcome Your Letters

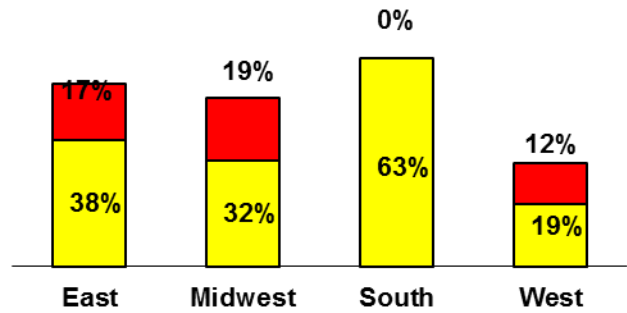
The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. 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.

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, Aug. 12 2015



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

MEMBER NEWS

Rock River Valley Blood Center, Rockford, Ill. recently held its 8th Annual “Team Up Beloit” Blood Drive Week with radio stations 105.9 The Hog and The Big AM 1380. More than 160 donors turned out to save lives from July 20 to July 24 at blood drives held at local businesses and community organizations throughout Beloit, Wis. All donors who presented to give blood were rewarded with two vouchers good for any regular season home baseball game of the Beloit Snappers, the minor league baseball team of Beloit. The blood drive event helps to boost donations during the summer months when donations tend to dip due to the lack of school blood drives and donors breaking from their usual donation patterns for summer vacations. (Source: RRVBC press release, 7/18/15)



Local radio station 105.9 The Hog promoting Rock River Valley Blood Center’s week-long blood drive event.

Lane Blood Center, Eugene, Ore., announced on Aug. 6 that it is initiating two projects to support the brave men and women fighting wildfires throughout the Pacific Northwest. The blood center wants to show the fire crews that it appreciates their hard work protecting the local region’s lands,

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MEMBER NEWS (continued from page 13)

homes, and property, said the blood center in a press release. For every unit of blood donated during the month of August, Lane Blood Center will contribute \$1 to the Wildland Firefighters Foundation. This non-profit organization supports the families of firefighters who have been injured or killed on the job. Blood center staff members are pledging contributions to this fund as well. Additionally, the center is collecting high-protein snack items for the firefighters: trail mix, energy bars, dried fruit, and jerky, as well as hygienic wipes. The blood center is encouraging all community members to support local firefighters by giving blood and/or donating to the cause. (Source: Lane Blood Center press release, 8/6/15) 💧

**COMPANY NEWS**

America's Blood Centers' member, Gulf Coast Regional Blood Center, Houston, Texas, is going to be the source plasma pilot site for the Donor-ID and Aurora (DXT) integration, making it the first Healthcare-ID customer to implement this process, Healthcare-ID announced in an Aug. 3 [press release](#). The integration of Donor-ID with the Aurora device allows the setup parameters, like the donor's name, target plasma value, etc., to be sent from the Donor-ID to the Aurora device (via DXT). Once the procedure is completed on the Aurora device, the data is then passed back to Donor-ID (via DXT) to allow for printing and/or storing of the procedure data and events, explained the Healthcare-ID press release. Gulf Coast Regional Blood Center went live on Donor-ID in 2000. Bart Block, director of Management Information Systems for Gulf Coast Regional Blood Center, said, "We were very pleased with the ease and functionality of Donor-ID's Aurora integration during the recent joint validation. It is very reassuring to know this important piece of our source plasma project will be implemented seamlessly." (Source: Healthcare-ID press release, 8/3/15) 💧

MEETINGS

June 2-5, 2016 **2016 SCABB Annual Meeting & Exhibit Show, Houston, Texas**

The South Central Association of Blood Banks (SCABB) will hold its 2016 Annual Meeting & Exhibit Show June 2 to 5 at the Omni Houston Hotel. More information can be found [here](#).

June 5-6, 2016 **SCABB Advanced Immunohematology & Molecular Symposium, Houston, Texas**

The South Central Association of Blood Banks (SCABB) will hold the 2016 Advanced Immunohematology & Molecular Symposium (AIMS) from June 5 to 6 at the Omni Houston in Texas. AIMS has accompanied the annual SCABB conference for the past five years. It is designed to be targeted toward people passionate about immunohematology and seeking continuing education in the fields of immunohematology and/or reference lab work including molecular testing. More information can be found [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 Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: lnorwood@americasblood.org.

POSITIONS AVAILABLE

Operations Supervisor-Donor Centers. (Department: Metro Collections- Coon Rapids & Plymouth Donor Centers; Location: St. Paul, MN; Job Type: Full time, 1.0 FTE, Exempt). To ensure collections operations at donor centers are run in a manner that results in safe and compliant blood products and service that consistently delights donor and sponsors. To ensure a working environment for staff on the applicable team that is supportive and productive through recognition, feedback, coaching and development. Knowledgeable about, and performs all type of blood collections including automated blood collection procedures (double Red Cell, Plasma, Platelets, Platelets plus Red Cell, Platelets plus Plasma). To apply please go directly to our website with an updated resume: <http://bit.ly/1EsI6bj>.

Assistant Manager Donor Testing. (Department: Donor Testing Lab; Reports To: Manager Donor Testing Lab; Status: Full time, 1.0FTE, Exempt; Schedule: Monday – Friday, 2nd Shift) Manages testing laboratory 2nd shift staff and coordinates operations associated with testing blood donors for infectious disease and immune-hematology during these shifts. Provides adequate training and performance appraisals. To apply please go directly to our website with an updated resume: <http://bit.ly/1LaQkK3>.

Director of Donor Recruitment and Production Planning. (Reports to: C.O.O. / C.F.O; Department: Donor Recruitment; Status: Full-Time, 1.0 FTE (40 hours per week), Exempt). Directs all Northland, Metro and Lincoln divisions of donor recruitment and donor contact management activities. Utilizes exceptional sales and account management skills to ensure goal attainment and efficient recruitment of blood donors to Innovative Blood Resources mobile and donor center facilities. Develops and implements strategies and tactics to manage customer relationships with existing and new blood drive sponsors to ensure customer satisfaction, improved processes, and increased production. Works closely with leadership to ensure effective production planning. Directs the management of the demand and supply optimization, and works collaboratively with the Donor Services leadership team to meet goals. To apply please go directly to our website with an updated resume: <http://bit.ly/1fc6qHB>

District Director Donor Care. United Blood Services in Scottsdale, Arizona is looking for an individual to

lead the Donor Care Department. Bachelor's degree in related field required. Knowledge of general business and management practices required. Five (5) years previous healthcare-related experience along with three (3) years supervisory experience required. Blood banking or healthcare-related experience preferred; must possess strong communication, analytical and statistical, leadership, organizational, problem-solving and human relation skills. Salary: DOE. Candidates must apply via <http://www.unitedbloodservices.org/careers.aspx> (req#15000806). Our organization is an equal employment/affirmative action employer. If you need accommodation for any part of the employment process because of a medical condition or disability, please send an e-mail to accommodation@bloodsystems.org or call (844) 220-2612 to let us know the nature of your request. A representative will respond to accommodation requests within two business days. Please note that this email/phone number is for medical/disability accommodations only and any other inquiries will not receive a response. EEO is the Law. For more EEO information about applicant rights [click here](#). Our organization participates in E-Verify, for more information [click here](#). EEO/Minorities/Females/Disabled/Vets. All candidates who receive a conditional written offer of employment will be required to undergo a pre-employment drug test in accordance with the company's established guidelines.

Hospital Services Manager. Blood Bank of Hawaii, a medium-size blood center (50,000 RBC distributions annually), has an exciting opportunity for a Hospital Services Manager. This leadership position is responsible for supervising and coordinating the operations, staffing and management of the Hospital Services department to include hospital satisfaction in meeting blood product needs, assuring quality customer service to all customers, and management and coordination of blood and blood component inventories. The ideal candidate will have knowledge of federal and state regulations as they relate to blood center operations, and

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POSITIONS (continued from page 15)

at least five years of blood center experience. Three or more years of supervisory experience required. We offer a competitive salary and excellent benefits. Please apply via our website: www.bbh.org.

Director – Business Development. The National Blood Collaborative, LLC (NBC) is seeking one experienced sales and marketing professional to manage the daily operations of the organization. NBC is an entity created by seven outstanding blood centers that focuses on emerging blood and cellular industry opportunities. Primary responsibilities consist of obtaining new business for NBC in both the blood and cellular marketplace. The ideal candidate possesses strong communication skills and industry related experience, including product development responsibilities. Relocation is not required. However, over-night travel (25 percent) is required. Salary and bonus opportunity commensurate with experience. Interested candidates should forward their resume and cover letter to

NBC@kybloodcenter.org. For more information, go to www.nationalbloodcollaborative.org. NBC is an equal opportunity employer.

Director Mobile Operations. The director provides guidance and oversight of Innovative Blood Resources (IBR) mobile operations and programs within the Metro and Northland divisions. This position reports to the chief operational officer/chief financial officer. Directs, strengthens and grows mobile operations to meet the needs of IBR's strategic plan and ensure consistent and compliant blood collection operations that exceed customer expectations. Responsible for overall management and control of mobile transportation including staff, budgets and work processes. Directs the activities and provides guidance, support and tools to staff to ensure safe, timely and economical services. For a detailed job description and to apply: <https://home2.eease.adp.com/recruit/?id=18173212>. ♦