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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Issue #24
July 8, 2016

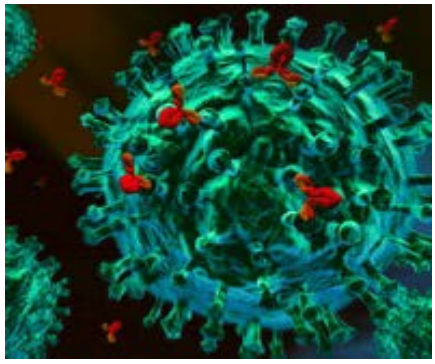
A Map for the Future

Cancer centers have been probing the human genome in an attempt to map gene expression associated with diseases such as breast, lung, and pancreatic carcinoma. But for the world of transfusion medicine, using next generation sequencing (NGS) systems has not yet become the norm.

In a recent review on the use of DNA testing for blood typing, Ross Fasano, MD, and Stella Chou, MD, indicate that even at current costs, testing for red blood cell (RBC) antigen variants may be justifiable for those patients receiving chronic blood transfusions, including those with sickle-cell disease (SCD), thalassemia, and autoimmune disorders. More precise matching could help lessen a chronically-transfused patient's chance of alloimmunization(s). This methodology is becoming commonplace for extended antigen typing, but as NGS methods improve, even accurate ABO and Rh blood group prediction will likely become feasible.

Currently, there are 346 serologically defined RBC antigens and 33 serologically defined platelet antigens identified. For most routine ABO and Rh blood typing, the common serological method is fast, reliable, and inexpensive. However, for chronically transfused patients, the use of RBC genotyping to establish an extended antigen profile—for antigens which antisera is not commercially available—could prove extremely beneficial. SCD and thalassemia patients experience alloimmunization at an alarmingly high rate when using the ABO/Rh(D) matching alone—18 to 75 percent and 4 to 37 percent, respectively.

"Right now, there is a lot of money and research going into cancer. It could happen with blood groups, especially for patients with certain transfusion needs, but we're still in development and learning phase," said Meghan Delaney, DO,



MPH, medical director for the Immunohematology and Red Cell Genomics Reference Laboratory at Bloodworks Northwest and medical director for transfusion services at Seattle Children's Hospital.

Many blood centers understand the need for improved antigen testing as

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OUR SPACE

ABC President Susan Rossmann, MD, PhD

How Can Our Association Work Best For Our Members?

As we head west to the Hawaiian Islands for the Summer Meeting, this issue has come to prominence.

In theory and bylaws, we are an association of independent blood centers who serve our communities. In practice, more and more blood centers are part of a larger group. There are the affiliations and unions at the governance level (BSI, Versiti, ITxM, etc.). These affect ABC membership directly, and at the Annual Meeting we dealt with this issue through bylaws changes. But there are also purchasing groups, blood supplier groups, at least one insurance group, and other affiliations. ABC's relations with them are varied, and changing. Most of these relations are informal, coming from overlaps of memberships. We are always interested to hear what our members want to say, in whatever forum.

As I write this, I am at a Texas state-level conference dealing with Zika. Questions about testing, and the payment for that testing, for pregnant women and other patients, are common. Various state and local public health laboratories have begun testing, and more are following suit. The public health community however, is, as always, working with limited resources. This brings up the issues of Zika for our blood community—who will they screen, when will they screen, and who will pay for it? As I write, it is not clear if or when the Congress will approve a large amount of money specifically for Zika. At this meeting, it was revealed the recent Center for Disease Control and Prevention grants gave $1.5 million to Texas—not a lot to spread through a large state. Five million went to Puerto Rico, which is entirely appropriate in proportion and indeed not enough for the size of their crisis. If more federal money is appropriated, ABC has asked for our blood centers to be considered for direct inclusion, but it is not clear if this will be an option. This is a hard ask—this has not been the system of paying for blood safety improvements (if indeed there has been any "system"). We are hoping the RAND study will provide some guidance about what the best method of paying for safety innovations and improvements, as well as other aspects of blood supply, might be going forward. However, we know it will be some months before their report comes out, and presumably quite a few more before any recommendations can be put into action.

Until then, we will work with the resources we have, in ways that we can. ABC will continue to listen to our members and advocate for them. We are interested in your input and feedback as we navigate maybe the most turbulent times in recent history. Feel free to contact me, other Board members, Christine, Dr. Katz, Mack, or other ABC staff to express your concerns.

See you in Honolulu!

srossman@giveblood.org

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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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A MAP FOR THE FUTURE (continued from page 1)

there are 56 AABB accredited immunohematology reference laboratories at centers across the country—and many more non-accredited ones as well. However, there are limitations to current molecular platforms, as doctors Fasano and Chou pointed out.

"Novel mutations, large deletions, hybrid alleles, and complex genes such as ABO and Rh pose challenges for current array-based platforms that are primarily designed to detect single nucleotide polymorphisms (SNPs) and cannot accommodate every known variant. Target enrichment next-generation sequencing alleviates some of these limitations by providing comprehensive sequence information focused on specified genomic regions," they wrote.

As the cost of NGS is going down and as the market grows, the technology is becoming more commonplace. In June, Grand View Research published a report saying the global NGS market would rise 22.1 percent from 2015 to 2022. The continuing demand, research, and development of new technologies in this industry would reduce the cost of sequencing human genomes down to as low as $1,000, noted the report. The next challenge then becomes interpreting NGS data into blood types.

"Clinical sequencing based on next generation sequencing technologies is still in its infancy. In the last few years, there has been a rapid uptake in hospitals and large academic medical centers purchasing and implementing the technologies," said Elizabeth Baxter, senior director of corporate communications at Roche Tissue Diagnostics, makers of the NGS platform Genome Sequencer FLX. "In the long term next generation sequencing may have a significant impact on the future of blood banking and the transfusion medicine industry…this could be for blood products, including the potential matching of HLA platelets, but also NGS has the potential to ensure that the right person receives the right transplant and determine at an earlier time point if tissue rejection is starting to happen."

A few ABC member centers are partnering with universities and hospitals to investigate the usefulness of NGS in predicting variant RBC antigen phenotypes. In March, Bloodworks NW and University of Washington's Department of Genome Sciences announced a 42-gene panel using NGS testing led by Jill Johnsen, MD, Debbie Nickerson, PhD, and Dr. Delaney. The group has already tested 1,100 samples and compared NGS to SNP chip to evaluate 23 known blood group variants. From the first 469 samples of the 1,100-patient cohort, the team announced at the Advances in Genome Biology and Technology meeting in Marco Island, Fla., in February 2016, that they identified cases where using NGS was able to explain discrepancies seen when comparing the SNP genotyping technique to serology typing.

"There is incredible power of potential in this work," said Dr. Delaney. "If we work together to put our data into shared databases, we can learn from each other. It's a new world and I'm excited for what will come next."

In February, New York Blood Center (NYBC) and Community Blood Center of Greater Kansas City announced the creation of the National Center for Blood Group Genomics in Kansas City, Missouri, which is set to open by the end of this year. The center will be using SNP methods and NGS methods, as well as serological testing to provide precision-matching of donors and recipients. The center will "focus on developing the next generation of testing, as well as training future leaders in the field of transfusion medicine genomics."

"The National Center for Blood Group Genomics will combine state-of-the-art methods in serological investigation and DNA blood group analysis to resolve complex cases of blood type matching, determine

(continued on page 4)

MAP FOR THE FUTURE (continued from page 3)

clinical significance, and provide consultation for selection of blood for transfusion to hospitals around the country," said Christopher D. Hillyer, MD, president and CEO of NYBC, in a statement.

A March 2016 study in the journal *Transfusion*, co-authored by Connie Westhoff, PhD, director of Immunohematology and Genomics for NYBC, and William Lane, MD, PhD, director of Clinical Lab Informatics and assistant director of Tissue Typing Lab at Brigham and Women's Hospital, reported results of NGS and the major differences and alignment issues found when trying to convert conventional cDNA to human reference genome sequences for specific genes, including ABO.

"The study details the process required to convert current allele designations to the human reference genome locations. Referencing the genes' locations is very important, but it takes substantial time and effort," said Dr. Lane. "It takes a couple weeks per person right now to analyze the data, and you need really targeted assays. Once there is a common kit developed then blood centers can perform testing in-house."

Dr. Lane and the other authors of the study found comprehensive benefits to using whole genome sequencing data to predict RBC and PLT antigens over DNA chip methodologies. While the quality of some of the NGS results was too poor to decode or missing coverage, all the RBC and PLT genes had adequate sequencing coverage to allow for antigen prediction they concluded. To "fully realize this potential" they are continuing their investigations into whole genome sequencing and targeted NGS prediction algorithms that will automatically detect known antigen alleles so transfusion specialists can quickly and easily match donors and recipients.

"Our perspective is most patients and more people will have their genome sequenced and have it part of their medical records eventually. Then we can determine their ABO, Rh and extended phenotype—all that information that is just sitting in the code. Human genomes will be sequenced once, but read often," said Dr. Westhoff. "That's the vision for the future."

Citations: Fasano R., Chou S. Red Blood Cell Antigen Genotyping for Sickle Cell Disease, Thalassemia, and Other Transfusion Complications. *Transfusion Medicine Review*. May 28, 2016. DOI: 10.1016/j.tmrv.2016.05.011.

Lane W.J., Westhoff C., *et al*. Comprehensive red blood cell and platelet antigen prediction from whole genome sequencing: proof of principle. *Transfusion*. March 2016. DOI: 10.1111/trf.13416.

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer's name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Publications Editor Lisa Spinelli at newsletter@americasblood.org. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

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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.

FABC Extends Appreciation for Support for the API

The Foundation for America's Blood Centers (FABC) has ended its 21-month-long capital campaign for the America's Blood Centers Professional Institute (API). Thanks to generous supporters, the FABC has raised over $514,000 to date for the API.

The campaign began in September 2014, after the FABC board underwent a strategic planning session to determine the best way to support ABC members and the blood community as a whole. Meanwhile, ABC was in the process of developing the API, a blend of traditional and online learning aimed at reaching a wide range of blood banking professionals. Supporting the API was a natural fit for the FABC as it aligned with the FABC mission of funding educational initiatives that improve the availability and safety of blood for the sake of the patient.

Prior to the launch of the API capital campaign, a fundraising initiative had been underway to honor the late Jerry Haarmann, a blood industry visionary for over 20 years. A committee comprised of Mr. Haarmann's friends and colleagues raised over $66,000 to establish the Jerry Haarmann Leadership Program, which will be launched at a later date by the API. The Jerry Haarmann campaign was merged into the overall API capital campaign and similar naming opportunities were offered to potential contributors based on levels of giving.

Thanks to the donors who invested in education, the funds that have been raised so far have brought the concept of the API to reality. Since the campaign launched, a few examples of what ABC has been able to do with the funds raised are:

- Launched a new ABC member website site (June 2015) – The new site provides members with a user-friendly experience to access all of ABC's resources and information, including all educational offerings through the API
- Hiring of a director for education programs & grants (August 2015) – The director develops and manages education programs and processes to drive a learning and continued education culture that delivers member value and satisfaction via the ABC Professional Institute (API)
- Developed and launched the ABC mobile event application (March 2015) –

(continued on page 6)

FABC would like send a special "Thank You" to our donors who were able to give $1000 or more.

Click for a complete list of donors.

$150,000

Abbott

$100,000 to $149,999

FRESENIUS KABI
caring for life *

$50,000 to $99,999

MAK-SYSTEM INTERNATIONAL GROUP

Roche

$25,000 to $49,999

HemaTERRA TECHNOLOGIES

TERUMOBCT
Unlocking the Potential of Blood

HOLOGIC®
The Science of Sure

$10,000 to $24,999

Blood Centers of America (BCA)*
Key Biologics*

INSIDE ABC (continued from page 5)

Allowing ABC meeting and workshop attendees to easily access meeting/workshop information both prior to and during the event (schedule, speaker details, sponsor details, updates, attendee contacts, surveys/evaluations)

- Competitively bid and selected a learning management system provider, with system development and implementation in progress
- Developed curriculum for first API course – "Introduction to the Blood Banking Industry," which will launch with the LMS
- Developing curriculum for customer service and leadership programs, which will launch later this year in a pilot program to ABC members

These programs will help build a stronger blood community by investing in ABC member staff, ensuring all who are new to the industry have access to standardized training about the industry as a whole and help to develop the future leaders of our blood centers; not to mention, greatly reduce the cost of training and development for our member blood centers big and small.

"The API campaign was a huge success. I really believe that the new vision at ABC has energized both the FABC board and the donors. We look forward to concluding a few more contributions which have been in the pipeline for some time. We are excited to unveil the first installment of the API project at the ABC Summer Meeting in Hawaii. Thank you to our generous donors and indefatigable staff," said Pascal George, FABC Chair.

"*The API campaign was successful in mobilizing member blood centers, individual donors and vendor partners behind a common aim with incredible results. Thank you to all of our generous donors whose spirit of giving carried the day, and to the FABC Board and staff, particularly Jodi Zand whose tireless organization and expertise were critical to maintaining the momentum of the effort. I would also like to give a virtual standing ovation to immediate FABC Past-Chair Roy Roper, whose energy and devotion to this campaign made all the difference,"* said Christine Zambricki, DNAP,CRNA,FAAN, ABC CEO.

Donations are still being accepted for the API. If you would like to donate, please visit: http://bit.ly/APICmpgn or contact Jodi Zand.

ABC staff will continually update our members and industry partners on the status of the API as well as other new offerings. Please find time to join our webinar later this summer introducing the new API resources to our members. Details will follow.

$5,000 to $9,999
Todd Tracey*
Digi Trax

$2,500 to $4,999
IRX Therapeutics
Christine Zambricki*
Theresa Ragozine
Blood Systems, Inc.*

$1,000 to $2,499
Dr. Jim AuBuchon
PCT, a Calidurus Company
Hoxworth Blood Center
Greg Ballish
Roy Roper*
Kevin Belanger*
Mike Parejko*
Marc Pearce
Mr. & Mrs. Mike Smith*
Jenny & Darin Ficenec *
Jackie Fredrick*
Dean Gregory*
Marge & John Pierce*
Jagrit Malhorta*
Coffee Memorial Blood Center*
David & Pamela Allen*
Michael Anania*
Richard Gamble*
Michelle & Dirk Johnson*
Michael Dash*
Dr. Susan Rossmann

* - Donors who donated to The Jerry Haarmann Memorial Campaign

RESEARCH IN BRIEF

An extended study on malaria vaccine RTS,S/AS01 found initial protection against the virus, however, by the fifth year into the study, the vaccine had lost efficacy. This latest study went beyond the four-year studies already published on RTS,S/AS01, a recombinant vaccine against the pre-erythrocytic stage of the parasite, and revealed a rebound effect five years after vaccination for those patients in areas with higher-than-average exposure to parasites carrying malaria. Three other sites where the vaccine is in use are now participating in this extended phase three trial.

Early investigations on the three-dose regimen for RTS,S/AS01 showed a decline of vaccine efficacy against all malaria episodes, from 36.3 percent (95 percent confidence interval [CI], 31.8 to 40.5) in the second year to zero by the fourth year. In January 2016, the World Health Organization (WHO) gave support to a four-dose regimen in the 5-to-17-month age group. The WHO did not discount the less effective two and three doses trials being given to six to 12-week-old infants, or the older age group, but rather recommended more pilot implementation studies in three to five sub-Saharan countries with moderate-to-high levels of malaria transmission.

In this randomized, phase-three trial, 223 children with 1,002 episodes of clinical malaria who received the four dose regimen of RTS,S/AS01 and 224 children with 992 episodes in the control group were examined for further analysis. The children have been followed for seven years and the scientists found the vaccine had an efficacy of 4.4 percent (95 percent CI, −17.0 to 21.9; P=0.66) in the intention-to-treat analysis and 7.0 percent (95 percent CI, −14.5 to 24.6; P=0.52) in the per-protocol analysis. Vaccine efficacy declined each year, with negative point estimate by year five (intention-to-treat analysis: −43.5 percent; 95 percent CI, −100.3 to −2.8 [P=0.03]; per-protocol analysis: −56.8 percent; 95 percent CI, −118.7 to −12.3 [P=0.008]). John Clemens, MD, and Vasee Moorthy, MD, PhD, noted in an editorial to the *New England Journal of Medicine*, that it would be "unwise to postpone the planning of the WHO-recommended pilot implementation studies" at these trial sites.

Citations: Olotu A., Fegan G., Wambua J., *et al*. Seven-Year Efficacy of RTS,S/AS01 Malaria Vaccine among Young African Children. *New England Journal of Medicine*. June 30, 2016. DOI: 10.1056/NEJMoa1515257.

Clemens J., Moorthy V., Implementation of RTS,S/AS01 Malaria Vaccine — The Need for Further Evidence. *New England Journal of Medicine*. June 30, 2016. DOI: 10.1056/NEJMe1606007.

A large study explored the motivations and opinions of potential donors with viral infections and found the overarching driving factor was "to help someone in need." The multi-center, case-controlled, study was conducted from 2010 to 2013 by the American Red Cross, Blood Systems, Inc., New York Blood, Center and OneBlood, which supply 50 percent of the blood donations in the U.S. The researchers examined completed interview questionnaires from 2,589 participants. Of those participants, 1, 587 were control donors, 196 were HIV positive, 292 had hepatitis B, 316 had hepatitis C, and 198 were infected with human T-cell lymphotropic virus. More than 90 percent of both infected donors and uninfected controls cited wanting "to help someone in need" as their prime impetus for giving blood.

Potential donors were asked four questions on motivation, influences and opinions about donor eligibility. Of the donors with HIV, 13 percent considered the donor selection policies to be unfair, compared with 1, 2, 0.5, and 6 percent of donors with HBV, HCV, and HTLV and controls, respectively.

Citation: Vahidnia F., Stramer S., Kessler D., *et al*. Motivations for donating and attitudes toward screening policies in U.S. blood donors with viral infection. *Transfusion*. June 28, 2016. DOI: 10.1111/trf.13678.

BRIEFLY NOTED

The first Zika-related case of microcephaly in a child born in Florida was reported by the Florida Department of Health. The Haitian mother, who had contracted Zika overseas, came to Florida to deliver her baby. As of June 23, 2016, the Center for Disease Control and Prevention had reported seven live infants born in the continental U.S. with birth defects from Zika, including microcephaly, and five babies stillborn at delivery with birth defects from the virus. (Source: Florida Department of Health, June 28, 2016.)

The Walter Reed National Military Medical Center began treating platelets with the pathogen reduction technology in May. The platelets were collected at the donor center apheresis section of the Armed Services Blood Bank Center (ASBBC) in Bethesda, Maryland. Navy Cmdr. Leslie Riggs, director of the Navy Blood Program, said the ASBBC is the only military donor center to have the technology right now, but other Department of Defense locations will acquire this technology in the future. (Source: Armed Service Blood Program newsletter, June 28, 2016.)

The National Institutes of Health are planning to launch a multi-year study on HIV-to-HIV transplants within the next six months. The announcement comes on the heels of successful HIV-to-HIV organ transplantations at Johns Hopkins Medicine and Mount Sinai Health System. (Source: MedPageToday.com, June 26, 2016.)

Using the CRISPR/Cas9 genetic editing system, a research team found a gene that reduced levels of all flavivirus infections tested. During a genome-wide CRISPR/Cas9-based screen, researchers found when nine genes were removed, West Nile infection in cells was reduced. And when another six separate genes were removed, other flavivirus infections Zika, dengue, Japanese encephalitis, and yellow fever, were also reduced. Two of the identified genes are components of the signal peptidase complex (SPC). By genetically removing the Signal Peptidase Complex Subunit 1 (SPCS1) gene in human cells, scientists reduced levels of all flaviviruses tested, including West Nile, dengue, Zika, yellow fever, Japanese encephalitis, and hepatitis C viruses.

Citation: Zhang R., Miner J., Gorman M., *et al*. A CRISPR screen defines a signal peptide processing pathway required by flaviviruses. *Nature.* Early Online, June 17, 2016. DOI:10.1038/nature18625.

Patients with chronic myeloid leukemia, who are taking imatinib mesylate have nearly the same life expectancy as the general population today, a study from Sweden found. Scientists analyzed records of 2,662 patients with CML, diagnosed from 1973 to 2013, and were 50 years or older. The records were pulled from the Swedish Cancer Registry. After taking imatinib mesylate, a tyrosine kinase inhibitor, vast improvements in the life expectancy of these patients were seen over the study period. Patients of all ages diagnosed in 2013 will, on average, lose < 3 life-years as a result of CML, concluded the researchers.

Citation: Bower H., Björkholm M., Dickman P., *et al*. Life Expectancy of Patients With Chronic Myeloid Leukemia Approaches the Life Expectancy of the General Population. *Journal of Clinical Oncology*. June 20, 2016. DOI:10.1200/JCO.2015.66.2866.

Researchers found 351 U.S. businesses engaged in direct-to-consumer marketing of stem cell interventions offered at 570 clinics that do not appear to be compliant with federal regulations. In an examination of Internet-based marketing claims revealed widespread promotion of such interventions by businesses based in the U.S. and, as the authors suggested, need to be more vigilant in overseeing this industry. Some "hotspot" cities where these "clinics" were located included Beverly Hills, California, with 18 clinics identified, New York (14), San Antonio , Texas (13), and Los Angeles (12).

Citation: Turner L. and Knoepfler P. Selling Stem Cells in the U.S.A.: Assessing Direct-to-Consumer Industry. *Cell Stem Cell*. June 30, 2016. DOI: http://dx.doi.org/10.1016/j.stem.2016.06.007.

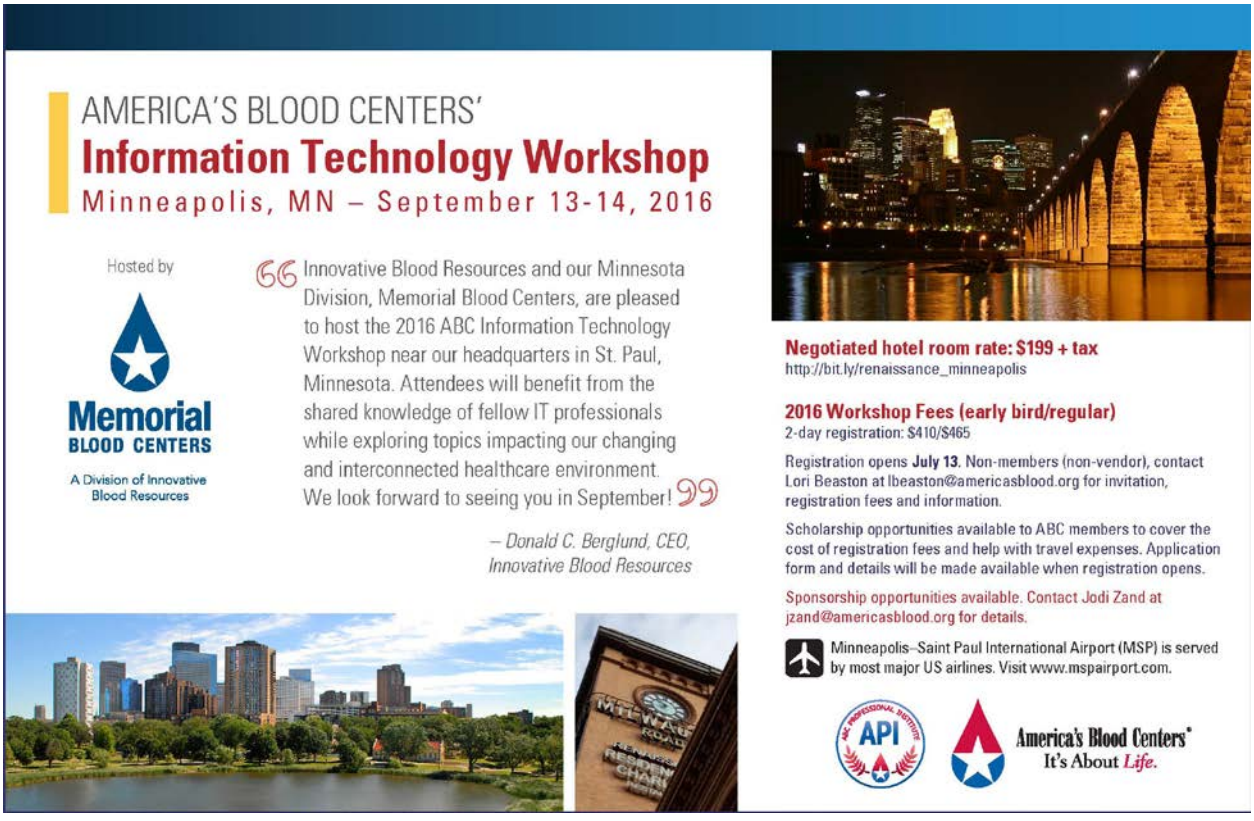
RECENT REVIEWS

Whole blood (WB) may provide a valuable therapeutic option for both military and civilian traumatic resuscitation settings, concludes a new review. Since the 1960s, doctors in both civilian and military settings have predominantly used component therapy over WB when treating trauma patients, mainly over concerns about the function of platelets in stored WB. However, the military has recently been increasing its use of fresh WB (stored at 22˚ C for <24 hours) in areas where the ability to store blood components is limited or unavailable. After reviewing extensive data from as far back as 1918 from the military and civilian settings, the authors provided *in vitro* evidence supporting the view that cold-stored WB can be an option for both pre-hospital and in-hospital civilian trauma resuscitation settings. The authors noted, however, a trial comparing the use of cold-stored WB to standard conventional components should be conducted in both the pre-hospital and in-hospital trauma resuscitation settings to further evaluate cold-stored WB efficacy.

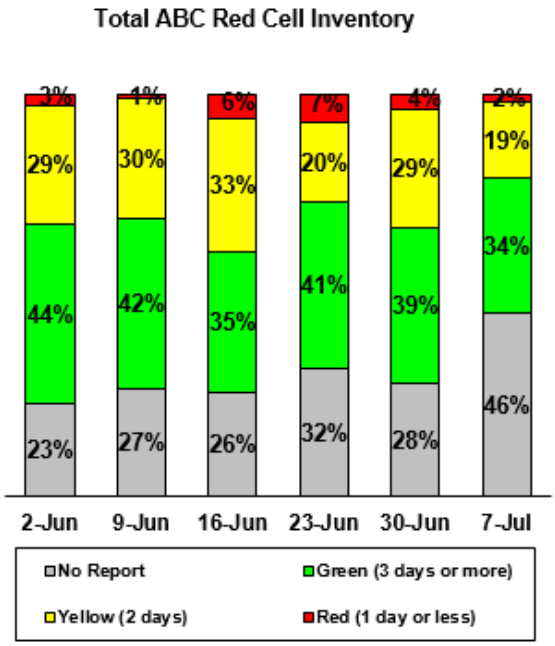
Citation: Bahr M.P., Yazer M.H., Triulzi D.J., and Collins R.A., Whole blood for the acutely haemorrhaging civilian trauma patient: a novel idea or rediscovery? *Transfusion Medicine*. June 29, 2016. DOI: 10.1111/tme.12329.

REGULATORY NEWS

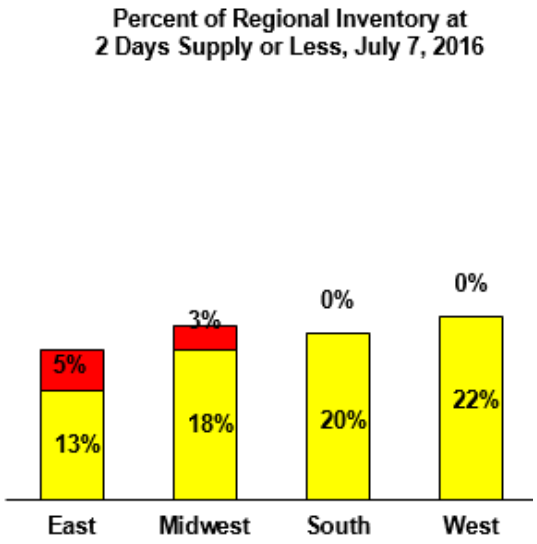
The Food and Drug Administration has released a draft agenda for their public hearing titled "Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products (HCT/Ps)." The hearing is set for September 12 and 13 from 9 a.m. to 5 p.m. at the National Institutes of Health, 9000 Rockville Pike, Building 10, Masur Auditorium in Bethesda, Maryland, and includes a very tight schedule of five minutes per organization to speak. The hearing was created to obtain comments from a broad spectrum of professionals in the field on four draft guidance documents the FDA released on regulating HCT/Ps. For more information, and to register, click here. (Source: FDA, June 29, 2016.)



STOPLIGHT®: Status of the ABC Blood Supply, 2015 vs. 2016



Daily updates are available at:
www.AmericasBlood.org



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

AMERICA'S BLOOD CENTERS
54TH SUMMER MEETING

API ABC Professional Institute

America's Blood Centers®
It's About *Life.*

"In the late 1700s, Polynesian navigators voyaged thousands of miles of open ocean and discovered Hawaii.

Using modern day wayfinding techniques, together we will explore ways to navigate the challenging times ahead facing the blood banking industry. Let the island host culture inspire us with its Aloha Spirit, high energy of world-famous Waikiki, natural beauty, entrancing hula and the thrill of fire knife dancing. Discover our paradise this summer."

– *Kim Anh Nguyen, MD, PhD, president and CEO, Blood Bank of Hawaii*

Blood Bank of Hawaii
Give Blood. It's Safe. It's Simple. It Saves Lives.

Honolulu International Airport (HNL) is served by most major airlines. Visit http://www.honoluluairport.org.

August 1-4, 2016 – Honolulu, HI
Hilton Waikiki Beach on Kuhio
special room rate: $240 + tax

Future Leader Scholarship Program

Supported by the FABC, these scholarships offer non-C-suite blood center executives the opportunity to advance professionally by attending the ABC Summer Meeting. Details available upon registration.

Registration Fees

ABC Summer Meeting: $760
Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation and registration fees and information.

Meeting Schedule

Monday August 1:
Links for Life Golf Tournament
Links for Life Golf Reception
Tuesday, August 2:
Medical Directors Workshop
Hospitality/Networking
Wednesday, August 3:
SMT Forum
Blood Center Leadership Forum
Host Event by Blood Bank of Hawaii
Hospitality/Networking
Thursday, August 4:
ABC Members Meeting

For sponsorship opportunities contact Jodi Zand at jzand@americasblood.org.

INFECTIOUS DISEASE UPDATES

A campaign aimed at vaccinating 11.6 million people in the Democratic Republic of Congo against yellow fever is set to begin on July 20, said the country's health minister. The minister said the aim was to cover everyone in the capital Kinshasa and nearby provinces. As of June 17, there were 3,294 suspected cases of yellow fever reported in Angola and 1,106 in DRC. More than 11 million doses of the yellow fever vaccine have been sent to Angola since February this year and more than 2 million to the DRC from the World Health Organization (WHO) and its partners. The WHO has suggested using one-fifth of the standard vaccine dose to those vaccinating in Angola and neighboring countries as stockpiles of the vaccine are running low. (Sources: WHO website, June 17, 2016; AABB SmartBrief, June 28, 2016.)

PEOPLE

Richard Pazdur, MD, is the new acting director for the Food and Drug Administration's (FDA) Oncology Center of Excellence, an integral part in the Vice President's National Cancer Moonshot Initiative. Dr. Pazdur is charged with leading the effort toward developing and executing the regulatory approach necessary in the clinical review of the new cancer products for the Initiative. A long-time regulator, Dr. Pazdur has been with the FDA for nearly 20 years, serving in such roles as the director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research; and director of the Division of Oncology Drug Products. Prior to his time with the FDA, Dr. Pazdur was a professor of medicine at the University of Texas M.D. Anderson Cancer Center in Houston, Texas, and was on the faculty of Wayne State University in Detroit.

COMPANY NEWS

Cerus Corporation received a grant of 2 million Swiss Francs, along with its two Swiss partners, from the Swiss Red Cross Humanitarian Foundation to complete studies developing a whole blood (WB) pathogen inactivation system for use in Africa. WB transfusion is the most common type of blood transfusion in Africa with no approved WB pathogen inactivation system in place. The African blood supply is often threatened due to diseases endemic to the region, including malaria, dengue, chikungunya, and yellow fever and from a significant rate of infected local blood donors with viruses such as HIV and hepatitis. The announcement comes less than two weeks after Cerus announced an agreement with the Biomedical Advanced Research and Development Authority for potential funding of up to $180 million to advance its pathogen reduction technology known as INTERCEPT. (Source: Cerus press release, June 30, 2016.)

The Food and Drug Administration (FDA) has approved Epclusa to treat adult patients with chronic hepatitis C virus (HCV) both with and without cirrhosis. For patients with moderate to severe cirrhosis, Epclusa is approved for use in combination with the drug ribavirin. Epclusa is a fixed-dose combination tablet containing sofosbuvir, a drug approved by the FDA in 2013, and velpatasvir, a new drug, and is the first to treat all six major forms of HCV. According to the FDA, the dramatic results of the drug included no virus detectable in 95 to 99 percent of the patients with no or mild cirrhosis 12 weeks after finishing treatment and 94 percent "cured" patients with moderate to severe cirrhosis. (Source: FDA press release, June 28, 2016.)

MEETINGS

August 1 **6th Annual Links for Life Golf Tournament, Honolulu, Hawaii**

Held in conjunction with the Summer Meeting, the Links for Life golf tournament has developed into a successful and fun annual fundraiser for the Foundation for America's Blood Centers. This year's tournament will take place at the beautiful Kaneohe Klipper Marine Golf Course in Honolulu, Hawaii. Ranked as one of the world's best military courses, your golf score will be second to the breathtaking ocean and mountain views you will enjoy while playing. There is a $200 registration fee, which includes transportation to and from the course, lunch, green fees, cart, beverages and snacks on the course and a reception with dinner and cocktails back at the meeting hotel. Sponsorship opportunities are also still available for vendors. Contact Jodi Zand for more information.

August 1 - 4 **ABC 54th Summer Meeting, Honolulu, Hawaii**

Registration is open for the ABC 54th Summer Meeting in Honolulu, Hawaii, hosted by Blood Bank of Hawaii, on August 1 to 4 at the Hilton Waikiki Beach on Kuhio Ave. It will feature the ABC Medical Directors Workshop and the Foundation for America's Blood Centers Links for Life Golf Tournament. Contact Lori Beaston for more information.

Sept. 8 **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.**

This free, first-come-first serve, public workshop titled the Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products subject to premarket approval, including stem cell-based products. The workshop will take place at White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room in Silver Spring, Md.

Sept. 12 - 13 **FDA Public Hearing on HCT/Ps, Bethesda, Md.**

This public hearing was created to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found here.

Sept. 13 – 14 **ABC IT/Workshop, Minneapolis, Minn.**

Experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.

Oct. 31 – Nov. 1 **FDA 510(k) Submissions Workshop, Washington, D.C.**

The FDA and industry experts are coming together to teach the basics of 510(k) submissions. Learn about the FDA's updates to the 510(k) process, considerations

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MEETINGS (continued from page 12)

for determining a product's regulatory route to market, factors to consider when planning and assembling a 510(k) submission. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register here.

Nov. 2 **FDA IDE Submissions Workshop, Washington, D.C.**

Learn the regulatory and practical guidelines governing when an investigational device exemption is required during this interactive workshop. The workshop will take place at Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register 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) 393-5527; e-mail: lmaundy@americasblood.org.

POSITIONS AVAILABLE: GET THESE THREE FROM DRAFTS FOLDER

Medical and Scientific Director. The Irish Blood Transfusion Service (IBTS) is seeking to recruit a Medical and Scientific Director (M&SD). The M&SD is the chief medical advisor to the Board and Executive of the IBTS. The crucial aspect of the role is to ensure that the IBTS provides safe blood for the people of Ireland. He/She will be responsible for leading the development of medical, technical and research policy in IBTS and to provide strong leadership for all clinical staff to include line management responsibility for all consultant medical staff. As IBTS Medical & Scientific Director, accountable to the Chief Executive, the M&SD shares responsibility for the quality of the services provided by IBTS and for both strategic direction and the financial well-being of the organization. This will include a central role in driving forward a culture of change, innovation and service transformation. The successful applicant must hold a current appointment at consultant grade in Haematology or equivalent in an EU member state, or if not currently employed within the EU is eligible for such an appointment by qualification and experience and have at least ten years satisfactory experience (after becoming entitled to full registration) in the practice of the medical profession, including not less than four years satisfactory experience in haematology or in blood transfusion medicine. This is a very senior appointment so experience of working as a Head of Department would be essential. Initial enquiries in confidence to the Chief Executive of the IBTS.

Reagent Donor Program Technologist (Department: Reference Laboratory; Location: St. Paul, MN; Status: Part-Time, 0.5 FTE (20 hours per week), and Non-Exempt; Shift: 1st Shift with some flexibility to shift start and end times as well as duration). This position supports the organization wide strategic direction for the Reagent Donor Program which includes screening of donors and units, preparation of reagents for blood donor antigen screening, scheduling of donors, platelet and plasma sales, and coordination of unit shipment. This position will work directly with the assistant manager of the Reagent Donor Program in promoting on-going Commercial Research, Molecular Testing and new business opportunities. Supports and promotes organizational goals, mission and vision. To apply please go directly to our website with an updated resume: http://bit.ly/298H2R

Assistant Manager Component Lab (Location: St. Paul, MN; Status: Full-Time, 1.0 FTE (40 hours per week), Exempt; Schedule: Monday-Friday, Second Shift). Be a leader, mentor, coach in our metro Component Lab and work directly in the processing of blood routed to patients in our community. Make a live-saving difference every day! Purpose: The Assistant Manager, Component Laboratory supervises personnel and coordinates operations associated with routine processing and testing of blood and blood components during the evening shift. The Assistant Manager acts as the CLIA

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POSITIONS (continued from page 13)

Technical Consultant for hematology and microbiology. The person in this position assists the Manager to ensure that the Component Laboratory is meeting quality requirements and participates in laboratory projects and IBR initiatives. To apply please go directly to our website with an updated resume: http://bit.ly/29jiHN

Manager of Clinical Services—RN (Gulf Coast Regional Blood Center, Houston, Texas). Working under the director of Cellular, Apheresis and Transfusion Services, the position is responsible for specified clinical services, including apheresis procedures and collections (including collection of Peripheral Blood Stem Cells) and management of a community-based transfusion safety

program. Coordinates efforts to monitor transfusion services and to provide cellular therapy and related apheresis services for donors and patients. This position has supervisory responsibilities. Visit www.giveblood.org for full job description. Education/Experience: Graduate of accredited School of Professional Nursing; current RN license in good standing. Three years of related clinical, transfusion service, supervisory or quality assurance experience or training. Prior project management or leadership experience preferred. Thorough knowledge of transfusion practices and related issues. Flexibility to serve as clinical resource for patient/donor therapeutic procedures in routine, complex and emergency situations. Familiarity with apheresis, dialysis automation desired. Effective venipuncture skills with comprehensive knowledge of pathophysiology, hemo-dynamics, fluid and electrolyte balance are preferred. Current unrestricted RN license from another state acceptable; must acquire a Texas license within 90 days of hire. Apply at www.giveblood.org. The Blood Center is an Affirmative Action/Equal Employment Opportunity Employer.

Medical Director (Gulf Coast Regional Blood Center, Houston, Texas). Assists the Chief Medical Officer in the guidance and direction of management in the development and implementation of policies, goals and objectives related to the organization's medical services. Serves as designee of the Chief Medical Officer to ensure compliance with Bureau of Biologics, FDA and CMS regulations, AABB, and company SOP Manual and other standards/regulations; approve technical services not covered by stated standards. Assumes role of CLIA Lab Director. Provides medical guidance and direction as it relates to various donor care, health, product manufacturing and injury matters. Serves as an ex-officio member of the Medical Advisory and Education & Research Committees; supervises residents and fellows during rotation. This position has supervisory responsibilities. Requirements: Doctor of Medicine or Doctor of Osteopathy degree from an accredited university with five years of combined education and experience in blood banking/transfusion medicine or related fields. Board certified or board-eligible in Pathology, Hematology, or another applicable area of medicine. Specialty training and/or certification in Blood Banking, Hematology, or a similar related area is highly desirable. Apply at www.giveblood.org. The Blood Center is an Affirmative Action/Equal Employment Opportunity Employer.

Chief Medical Officer. The Chief Medical Officer is responsible for the medical activities of the San Diego Blood Bank. Oversees the operation of Laboratory Services. The position accomplishes this through a respectful, constructive and collaborative style, guided by local, state and national regulations and the objectives of the company. The position provides medical oversight, expertise and leadership to ensure the delivery, potency, purity and safety of blood services and products. Responsibilities also include the strategy, development and implementation of innovative blood collection programs that include collaboration with all operational and strategic business partners. M.D. or D.O. degree; Subspecialty board certification in Hematology (IM) or Transfusion Medicine (Pathology) preferred. Certifications/Licenses: Active Unrestricted California Medical License. San Diego Blood Bank is an Equal Opportunity Employer. EEO/Minority/Female/Disability/Vets. Apply at: https://sandiegobloodbank.applicantpro.com/jobs/.