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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2014 #43 **December 5, 2014**

INSIDE:

FDA BPAC Considers Implications of Changing MSM Deferral, Supports National Hemovigilance System

The Food and Drug Administration's Blood Products Advisory Committee (BPAC) met at the FDA White Oak Campus in Silver Spring, Md. on Tuesday to discuss the impact of changing FDA's contentious blood donation policy that permanently defers men who have sex with men (MSM) even once since 1977 from donating blood. The committee did not vote on whether to change the deferral, although there appeared to be cautious support for a change permitting MSM who have been abstinent for one year to donate blood. Numerous committee and audience members urged FDA to support a sustainable, well-funded hemovigilance system to track transfusion-transmissible infections (TTIs) alongside any proposed change in the policy.

The current MSM deferral policy evolved in the wake of the HIV epidemic in the 1980s to protect the blood supply from transfusion-transmitted HIV. However, as donor qualification and testing methods have become more sensitive – thus dramatically decreasing the risk of infection from transfusion – the policy has been increasingly viewed as outdated. The committee heard research and testimony from the public highlighting that the current MSM policy is medically and scientifically outdated, inconsistent with other behavioral deferrals, and unfair in the eyes of many, including national blood organizations.

This meeting comes shortly after the Department of Health and Human Services' (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) voted, for the first time, overwhelmingly in favor of moving to a deferral of one year after MSM behavior. Both the ACBTSA and BPAC have discussed the issue several times in recent years, generally highlighting the need for results from ongoing HHS-commissioned studies exploring the impact on blood safety of allowing certain gay men to donate, as well as the importance of developing a sustainable hemovigilance system to monitor the impact that this or any change in policy would have upon blood safety.

At last month's ACBTSA meeting, the committee heard updates on this long-awaited research, which provided convincing evidence that switching to a one-year MSM deferral would likely not measurably decrease the safety of the blood supply and that a sustainable TTI surveillance system is feasible (see *ABC Newsletter*, 11/14/14). Alan Williams, PhD, of the Office of Blood Research and Review (OBRR) in FDA's Center for Biologics Evaluation and Research (CBER), kicked off Tuesday's BPAC meeting with a review of the new data.

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OUR SPACE

ABC CEO Christine S. Zambricki, DNAP, CRNA, FAAN

Washington Matters

The Food and Drug Administration is working with ABC and the blood community to promote the most efficient use of apheresis plasma from unpaid volunteer donors for further manufacturing into life-saving derivatives, according to Jay Epstein, MD, director of FDA's Office of Blood Research and Review (OBRR) in the Center for Biologics Evaluation and Research (CBER). An ABC delegation including President Dave Green, President-Elect Susan Rossmann, MD, PhD, Chief Medical Officer Louis Katz, MD, and myself, met at the FDA White Oak campus yesterday with OBRR representatives to discuss these plasma requirements and other topics of interest to ABC members. In addition to Dr. Epstein, key members of the OBRR leadership team participated in the meeting.

While the meeting's focus was ABC's request for flexibility in our ability to use apheresis plasma optimally for either transfusion or further manufacture, ABC also requested that FDA reconsider variant Creutzfeldt-Jakob disease deferral criteria and consider less burdensome options for quality control testing of apheresis components. Based on the discussion, ABC is cautiously optimistic that activity on these issues will be forthcoming. This get-together closely follows the Oct. 30 meeting between FDA officials and the blood community, represented by ABC, American Red Cross, AABB, and the American Plasma Users Coalition (A-PLUS) on the same topics (see *ABC Newsletter*, 11/7/14).

In other news from Washington, two ABC members have reported the insertion of problematic language within Veterans Affairs (VA) hospital contracts. Many ABC members have the privilege of serving veterans by providing blood products to VA hospitals across the US. Unfortunately, a clause referencing the Service Contract Act (SCA) has been inserted into two blood operator contracts in recent months.

In brief, the inclusion of SCA language requires the blood center to increase wages, benefits, and record keeping to the extent that the additional cost alone may exceed the value of the entire VA contract. With the option of increasing prices to cover the increase ($1,000 toilet seats, anyone?) or eating the negative margin, blood centers are opting to continue providing needed blood products to our brave men and women without a contract.

ABC is working on your behalf here in Washington to fix this problem. If you are experiencing any SCA activity with your VA contracts, in addition to working with your local VA contractor, please send a short note to ABC describing your situation to czambricki@americasblood.org with the subject line "VA," including the SCA language and the impact of compliance to your center. We are working diligently to facilitate a solution with the US Department of Veterans Affairs and it will help us to have additional information on the prevalence and impact of the problem.

Remember, Washington matters!

Christine S. Zambricki

czambricki@americasblood.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.

America's Blood Centers
President: Dave Green
CEO: Christine S. Zambricki
ABC Publications Editor: Betty Klinck
Business Manager: Leslie Norwood
Annual Subscription Rate: $390

Send subscription queries to mnorwood@americasblood.org.
America's Blood Centers
725 15th St. NW, Suite 700, Washington, DC 20005
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

BPAC Revisits MSM Policy (continued from page 1)

Scientific Evidence Supports A Change in Policy. Among the research discussed were results from the Retrovirus Epidemiology and Donor Study-II (REDS-II), which using data from three large US blood collectors and survey data from a fourth center, demonstrated the feasibility and performance of a pilot TTI surveillance system; it also established baseline infection rates and historical risk factors of TTIs that will enable regulators to evaluate any new blood safety policy.

Dr. Williams also highlighted the REDS-III Blood Donation Rules Opinion Study (BloodDROPS), which explored awareness and attitudes among MSM regarding the blood donor deferral policy. Importantly, MSM donors who do not comply with current regulations had lower HIV infection rates than reported in surveillance data for all MSM, suggesting noncompliant donors believe they have a lower risk of infection. While noncompliance with the MSM policy remains an issue, 51 percent of the noncomplying donors reported that they would follow a one-year deferral, leading the committee to believe that a one-year deferral – viewed as more science-based and fair – may improve compliance.

Other important research presented reviewed the current epidemiology of HIV infection in the US, where MSM represent 4 to 7 percent of the male population but accounted for 78 percent of the new HIV infections among males in 2010. However, several other countries have successfully switched to fixed-period MSM deferrals, including Australia, which has seen no measurable change in HIV-positive donors after switching to a one-year deferral in 2000.

Monitoring Transfusion-Transmitted Infections. Simone Glynn, MD, MSc, MPH, of the National Heart, Lung and Blood Institute (NHLBI), explored how the REDS-II findings regarding TTI infection rates and risk factors could be applied to creating a TTI monitoring system in the US. While it required significant effort, the participating blood centers in the study were able to create a common database system across the centers, highlighting the feasibility of such a TTI-tracking system.

To properly monitor any impact that a change in the MSM policy may have upon the blood supply, it is necessary to track HIV incidence in blood donors, however, estimating HIV incidence in blood donors can be challenging, as Donald Brambilla, PhD, of NHLBI, pointed out to the committee. With HIV being so rare among blood donors, it is difficult to estimate HIV incidence because a very large sample size is necessary to get precise estimates, said Dr. Brambilla.

Michele, Owen, PhD, of the Centers for Disease Control and Prevention, discussed the available assays to distinguish recent from remote HIV infection – or "recency." During a question and answer period, Jay Epstein, MD, director of OBRR, clarified that the end goal is to measure the residual risk of HIV in donated blood, and that recency testing would move FDA closer to that goal by allowing the agency to see changes in HIV incidence among donors over time.

FDA Hears From the Public on MSM Deferral. During the open public hearing, numerous lesbian, gay, bisexual, and transgender (LGBT) advocates and other groups, including the Human Rights Campaign, Lambda Legal, the University Park Undergraduate Association, and the Gay and Lesbian Medical Association (GLMA), called for an end to the current lifetime MSM deferral, viewed as discriminatory, with many asserting that while a one-year deferral is not the preferred solution, it would represent an encouraging sign of progress.

"GLMA believes policies governing blood donation should be based in science, promote adequate supplies of safe blood products, and ensure stigma is not perpetuated among MSM. Based on these principles, GLMA urges the BPAC to fully consider and ultimately recommend a revision in policy that

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BPAC Revisits MSM Policy (continued from page 3)

is based on a prospective donor's specific sexual behavior that is scientifically shown to be at-risk for HIV regardless of the donor's sexual orientation or gender," said GLMA President-Elect Jesse Joad, MD. A number of other speakers echoed these sentiments.

Jason Cianciotto, of the Gay Men's Health Crisis, added "For the overwhelming majority of men, a donation which requires 12 months of abstinence is a de facto lifetime ban. Do you require heterosexuals to be abstinent for one year?"

Patient groups representing those with blood disorders, including the American Plasma Users Coalition (A-PLUS) and the National Hemophilia Foundation cautiously supported exploring a one-year MSM deferral, but only in conjunction with a robust national hemovigilance system.

Susan Stramer, PhD, of the American Red Cross (ARC) presented 16 years of data on HIV yield, prevalence, and incidence among ARC donors, which show that HIV yield cases varied greatly each year between 1999 and 2011. However, what is clear from ARC's data – HIV transmission from blood is an extremely rare event. She noted that America's Blood Centers, ARC, and AABB have long supported the move to a one-year MSM deferral.

Committee Expresses Skepticism, Supports TTI Surveillance System. While the committee was not asked to vote on whether the lifetime MSM deferral should be changed, Committee Chair Brooks Jackson, MD, offered the committee an opportunity to comment on the ACBTSA's recommendations. While some members expressed support for a change to a one-year deferral, others were concerned that the discussion was being steered toward political considerations and away from the crux of the issue – patient safety from TTIs.

"I don't think any of the data I've seen today calms me in terms of not increasing the risk for the transfusion recipient if FDA were to change the deferral policy," said committee member, Susan Leitman, MD. "It has to be the case that more HIV-positive and other positive-marker units will enter quarantine, and if they do, there is an increased risk to staff of percutaneous injury and a very small risk of quarantine release errors."

Corey S. Dubin, president of the Committee of Ten Thousand, representing patients with bleeding disorders who contracted HIV and hepatitis from blood products, again urged FDA and HHS to support a sustainable national hemovigilance system by providing the financial commitment and support from leadership.

"The agencies understand the need for a comprehensive, national hemovigilance system and appreciate that it needs to be long-standing," said Dr. Epstein. "We have put forward financial commitments … I would like to believe that this position of the agency is reassuring."

FDA asked the committee to comment on whether serological tests for recency of HIV infection in HIV antibody positive donors are sufficiently accurate to be useful for blood safety monitoring. While some committee members questioned whether this particular issue is the logical next step in revisiting the MSM deferral policy, the committee generally agreed that the available tests are accurate and capable of distinguishing recent from long-term infections. Dr. Leitman noted that many other challenges remain to be faced – including whether donor materials are understood and screening materials are effective in preventing TTIs.

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BPAC Revisits MSM Policy (continued from page 4)

"I believe that data from the available studies, especially BloodDrops, suggest we are now at clinical equipoise regarding the impact of a rationalized deferral on the overall safety of the blood supply," ABC Chief Medical Officer Louis Katz, MD, told the *ABC Newsletter*. "Evidence suggesting that donors with MSM behavior will be more compliant with the shortened deferral justifies the change, but requires that surveillance for changes in TTD risk be in place to monitor the proposition that unacceptable risk will not accrue."

The meeting agenda, webcast, and other materials can be viewed at http://1.usa.gov/1fWzZvD ♦

IN MEMORIAM – Thomas F. Zuck, MD, 81

Thomas F. Zuck, MD, a leader and pioneer in blood banking and transfusion medicine who spent more than 40 years striving to improve blood safety and availability, passed away at the age of 81 at his home surrounded by family on Nov. 26 after a long illness. Dr. Zuck is recognized for his contributions to donor screening and quality control measures developed in the aftermath of the AIDS crisis in the 1980s that helped protect the blood supply from transfusion-transmitted infections.

"I have been very lucky in my life to have the mentorship of great people – Tom was one of those individuals," said America's Blood Centers Chief Financial Officer Bill Coenen. "He never wavered in his support, and the guidance he provided me was invaluable. I will always be proud that I was also able to call him my friend. He will be greatly missed."

A past director of ABC member Hoxworth Blood Center, Dr. Zuck served as ABC president from1991 to 1993, and played a vital role in helping community blood centers comply with Good Manufacturing Practices (GMPs) required by the Food and Drug Administration beginning in the 1990s to improve the quality and safety of blood products. In honor of his numerous contributions to blood safety and transfusion medicine, ABC awards the Thomas F. Zuck Lifetime Achievement Award each year to recognize an individual for a lifetime achievement of the application of clinical/medical and scientific research to improve methods of blood collection and the safety/efficacy of products provided to patients.

Dr. Zuck began his career earning a political science degree from Carleton College, Northfield, Minn., in 1955 and a law degree from Yale Law School in 1958. Shortly after receiving his medical degree from Hahnemann Medical College in Philadelphia in 1963, he began his long and distinguished military career pursuing his interest in transfusion medicine. He received numerous honors and awards during his military service, serving as commander of the Letterman Army Institute of Research, chief of the Department of Pathology at Walter Reed Army Medical Center, and deputy director of the Armed Forces Institute of Pathology.

Following his military career, he became the director of the FDA's Blood and Blood Products Division of the Office of Biologics Research and Review in the mid-1980s during the tumultuous HIV/AIDS epidemic. During his tenure at FDA, Dr. Zuck was instrumental in the development and implementation of effective blood donor screening tests to prevent the transfusion-transmitted HIV infection. He also served

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IN MEMORIAM – Thomas F. Zuck (continued from page 5)

numerous scientific and professional societies, including a tenure as president of AABB and editor in chief of the journal *Transfusion*.

Following his retirement from the military in 1987, Dr. Zuck joined Hoxworth Blood Center as the director, shortly after which he also began serving as president of ABC (then then the Council of Community Blood Centers). While blood centers struggled to train employees and implement FDA's GMPs in the early 1990s, Dr. Zuck forged the way forward for blood center compliance with these regulations by working with Ortho Clinical Diagnostics to jointly develop the ABC/Ortho Clinical Diagnostics GMP "train-the-trainer" program. From 1991 to 1993, this program trained thousands of ABC blood center personnel and eventually became the ABC IMPAQ training program in the 2000s.

"Tom was a great man, one of the last 'larger-than-life giants' in the blood banking field. He's admired today by many, but not only because of his many contributions to the field, both scientifically and administratively, but because his moral compass never wavered. He always strived to do the right thing for blood donors and patients," said Jim MacPherson, ABC's previous CEO who served alongside Dr. Zuck as president.

Dr. Zuck was a member of FDA's HIV working group and the College of American Pathologists Committee on AIDS and Infectious Body Fluids and as chairman of the Coordinating Committee of the Retrovirus Epidemiology in Blood Donor Study (REDS). Toward the end of his career, Dr. Zuck was honored with multiple awards recognizing his achievements in the field of transfusion medicine, including appointment as a fellow of the Royal College of Physicians and receiving the W. Quinn Jordan Memorial Award from AABB. By the time of his retirement in 1999, Dr. Zuck had authored more than 70 scientific articles, multiple book chapters, and numerous abstracts.

"Tom was a mentor, colleague, and friend. His wise counsel will be missed, almost as much as his friendship," said ABC Chief Medical Officer Louis Katz, MD, a past recipient of the Thomas F. Zuck Lifetime Achievement Award.

Hoxworth Blood Center issued a statement recognizing Dr. Zuck for his accomplishments and expressing its condolences to Dr. Zuck's wife of 53 years, Sue Zuck, and his children, Frederick, and Andrew Zuck.

"Tom was like an energetic father, constantly trying to solve problems and make everything around him right. He played critical roles both in my personal and in my professional life. I will miss him tremendously," said Celso Bianco, MD, former executive vice president of ABC and a recipient of the Thomas F. Zuck Lifetime Achievement Award.

Those wishing to express their condolences can visit http://bit.ly/1yjJqcl. In lieu of flowers, the family asks that those wishing to pay their respects send memorials to The Salvation Army of Greater Cincinnati, 114, E Central Pkwy, Cincinnati, Ohio 45202; Wood Hudson Cancer Research Lab, 931 Isabella St., Newport, KY, 41071; or Hospice of Cincinnati East, 7691 Five Mile Rd., Cincinnati, OH 45230. (Source: Hoxworth Blood Center press release, 12/1/14)

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Did You Know…?

'130' The number of times that ABC staff members have contacted regulators, legislators, and other affinity organizations from April 1, 2014 to Sept. 1, 2014 to advocate for the needs of ABC's member blood centers.

America's Blood Centers' staff, board of directors, and committee members are working daily to support the needs of ABC's member blood centers. Whether it is through public, regulatory or legislative advocacy, educational meetings and webinars, or disaster preparedness assistance, ABC strives to support the continued success and development of independent community blood centers and their employees. Every quarter, ABC staff reports on a series of metrics to the board of directors through the ABC Balanced Measures Report. The ABC Newsletter *will highlight one metric each week. Be sure to check it out to find out how ABC is working on behalf of your blood center.*

FDA BPAC Reviews Proposed Regulatory Classification of BECS & BECS Accessories, Supports Class-II Designation

The Food and Drug Administration's Blood Products Advisory Committee (BPAC) met on Wednesday as a medical device panel in Silver Spring, Md., to comment on FDA's proposed medical device classification of blood establishment computer systems (BECS) and BECS accessories. While the committee was not asked to vote on the issue, there was general agreement with FDA's proposal that BECS and BECS accessories be classified as Class II medical devices.

BECS and BECS accessories, in the context of collection facilities, are devices that blood centers use to determine blood donor eligibility and to prevent disease transmission through donated blood. The Federal Food, Drug, and Cosmetic Act (FD&C Act) section 513, established a risk-based device classification system for all medical devices, however, BECS and BECS accessories have never been classified under this statute. Instead, BECS have been regulated through 510(k) pathway, with premarket notification requirements, since the first BECS was FDA-cleared in 1996.

FDA now seeks to classify BECS and BECS accessories under the FD&C Act section 513, and sought the committee's input on its proposed classification.

Marjorie Shulman, MBA, of FDA's Office of Device Evaluation (ODE) in the Center for Devices and Radiological Health (CDRH) reviewed FDA's medical device classification schema, which is broken down into three classes based upon the level of potential risk posed to the patient. Each class requires increasing levels of controls to prove the device is safe and effective. These include general controls, special controls, and premarket approval. General controls include prohibition against adulterated or misbranded devices, Good Manufacturing Practices (GMPs), registration of manufacturing facilities, listing of device types, and recordkeeping. Special controls may include any or all of the following: performance standards, postmarket surveillance, patient registries, and the development and dissemination of guidelines.

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BECS Classification (continued from page 7)

The three device classes are:

- **Class I Devices:** Pose the lowest level of risk to patients; are not considered "life sustaining, life supporting, of substantial importance in preventing impairment of public health, and do not present a potential unreasonable risk of illness or injury;" they require only general controls and typically do not require FDA premarket review prior to being marketed.
- **Class II Devices:** Require general and special controls and typically require premarket notification via 510(k) to FDA prior to being marketed.
- **Class III Devices:** General and special controls are insufficient and they require premarket approval prior to being marketed. These devices are life sustaining and/or life supporting, or of substantial importance in preventing impairment of human health, or present potential unreasonable risk of illness or injury in general plus special controls are not considered sufficient to ensure safety and efficacy.

Darcel Bigelow, MGA(MIS), MT(ASCP), the software team lead of the Division of Blood Components and Devices in FDA's Office of Blood Research and Review, discussed past and current BECS regulation and outlined FDA's classification proposal for these devices. Based upon a review of safety and efficacy information available on BECS devices currently in use, FDA concluded that they are not life-supporting or life-sustaining, but are of a substantial importance in preventing impairment of human health and present a potential unreasonable risk of illness or injury. For example, if a malfunctioning BECS caused the inadvertent release of blood that tested positive for a transfusion-transmitted disease, this could lead to a transfusion transmitted infection.

With these potential risks and the complexities of BECS and BECS accessories, FDA proposes that these devices be "classified as Class II devices subject to special control. Ms. Beigelow went on to outline the special controls that may be appropriate for these devices, of which a full listing is available in FDA's executive summary.

During the open public hearing, Ruth Sylvester, America's Blood Centers' director of Regulatory Services, made a statement on behalf of ABC supporting FDA's proposed classification. However, she expressed concern over confusion among ABC member blood centers regarding the vague definition of a "BECS accessory" – an entity "that expands or modifies the function of the BECS and/or indications of use of the BECS device."

"This definition is not sufficiently detailed to allow the industry to determine what is and what is not a BECS accessory. It is overly broad such that anything that connects to a BECS could be considered a BECS accessory. A clear and thorough definition for the industry is essential," said Ms. Sylvester. She added that while examples are helpful, they are not a substitute for a clear definition. AABB's director of Regulatory Affairs, M. Allene Carr-Greer, echoed these concerns in her statement to the committee.

In their discussions and comments to the agency, numerous committee members agreed with the need for a more precise definition of BECS accessories. FDA officials reassured the committee that the agency understands the need for clarity on this point and plans to address the issue. Despite some questions and concerns regarding verification and validation, the committee agreed with the appropriateness of FDA's outlined risks posed by BECS and BECS accessories, proposed Class II designation, and proposed special controls.

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BECS Classification (continued from page 8)

"I think from the viewpoint of the regulated industry – speaking mostly from a blood bank, plasma, and donor center perspective – I think FDA has found the sweet spot, or the right niche, in which to put these devices," said Toby Simon, MD, the BPAC industry representative, senior medical director of CSL Behring, and a past president of ABC. "If we were to move them to Class III, that could restrict innovation and make it too burdensome as to impede the availability of these systems. They are too important to patient safety to be Class I devices. I think the general controls serve us quite well, and that FDA has selected special controls which are appropriate."

The webcast, agenda, and other meeting materials can be viewed at http://1.usa.gov/1fWzZvD. ♦

RESEARCH IN BRIEF

A working group convened by the College of American Pathologists (CAP) and AABB recently recommended the phasing in of RhD genotyping for all patients with a serologic weak D phenotype. In 2014, CAP's Transfusion Medicine Resource Committee (TMRC) reported the results of a survey of more than 3,100 labs regarding their policies and procedures for testing serologic weak D phenotypes and administration of Rh immune globulin (RhIG). The goal of RhD typing practices is to protect RhD-negative persons from inadvertent alloimmunization to the D antigen by exposure to RhD-positive red blood cells (RBCs), including RBCs expressing a serologic weak D phenotype. They found that there is no standard practice in the US for interpreting the RhD type when a serologic weak D phenotype is detected. CAP's TMRC reviewed the current status of RhD genotyping and proposed that selective integration of RhD genotyping in laboratory practices could improve the accuracy of RhD typing results, reduce unnecessary administration of RhIG in women with a serologic weak D phenotype, and decrease unnecessary transfusion of RhD-negative RBCs to recipients with a serologic weak D phenotype. In response to these findings, AABB and CAP convened a Work Group on RhD Genotyping and charged it with developing recommendations to clarify clinical issues related to RhD typing in patients with a serologic weak D phenotype. The Work Group included several blood centers, hospitals, and national blood organizations including America's Blood Centers, the American Red Cross, and the Armed Services Blood Program. They report their findings and recommendations in the recent *Transfusion* commentary, recommending that "RhD genotyping be performed whenever a discordant RhD typing result and/or a serologic weak D phenotype is detected in patients, including pregnant women, newborns, and potential transfusion recipients." They add, "While recognizing the lack of comprehensive cost-benefit analyses, the Work Group concludes that it is time to begin to phase in selective RhD genotyping."

Citation: Sandler SG, *et al*. It's time to phase in RhD genotyping for patients with a serologic weak D phenotype. Transfusion. 2014 Dec. 1. [Epub ahead of print]

The National Heart, Lung and Blood Institute (NHLBI), of the National Institutes of Health, announced on Nov. 19 that it has ended the Transcranial Doppler (TCD) with Transfusions Changing to Hydroxyurea (TWiTCH) clinical trial early. The study's Data Safety Monitoring Board determined in its first interim analysis of the study data that the study had already reached its primary endpoint – demonstrating that hydroxyurea is a safe and effective way to manage the disease and reduce the risk of stroke. Patients with sickle cell disease often experience pain crises and strokes as a result of their condition, and while blood transfusion offers a valuable treatment for these patients – long-term blood transfusions can cause complications like iron overload and alloimmunization. In TWiTCH, researchers

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Advertisement

RESEARCH IN BRIEF (continued from page 9)

from 25 medical centers in the US and Canada compared monthly blood transfusions with daily hydroxyurea pills among children with sickle cell anemia who were at high risk of stroke. Early results showed that hydroxyurea works as well as blood transfusions in reducing the risk of stroke. The study was thus halted and with the advice of their physician, participating patients will have the opportunity to receive the care they feel is best suited for them. More information can be found in the press release. (Source: NIH press release, 11/19/14)

The journal *Nature* published on Nov. 27 a special "Outlook" supplement about hemophilia treatments underdevelopment. Hemophilia is a group of bleeding disorders caused by the lack of production of proteins that make blood coagulate, usually due to genetic mutations. The development of gene therapy and new factor replacement treatments with plasma-derived and recombinant coagulation factors offer new treatment options for these patients. *Nature* and *Scientific American* published this Outlook supplement to describe the current state of hemophilia and treatments on the horizon. This free resource is available at http://bit.ly/1ySFyC4.

BRIEFLY NOTED

AABB recently announced that it is encouraging all members – both US and international – to complete the AABB Blood Survey on the collection and utilization of blood and blood products and patient blood management practices between Jan. 1 and Dec. 31, 2013. AABB will provide those who complete the survey with a complimentary report of the survey findings and analysis. Contact hemovigilance@aabb.org if your facility needs a customized link. Members should not confuse this survey with the collection and use survey being distributed by the Centers for Disease Control and Prevention and the Department of Health and Human Services, which will be less focused on patient blood management issues. The AABB Survey is designed to be the foundation for utilization and blood management benchmarking. (AABB SmartBrief, 12/3/14)

THE WORD IN WASHINGTON

Congress returned after Thanksgiving to complete unfinished fiscal year 2015 business, especially major appropriations funding the government. Current continuing resolution (CR) funding keeping the government running expires on Dec. 11. On Dec. 1, bipartisan House and Senate negotiators met in hopes of completing an "omnibus" package that funds federal activities in detail. If Congress cannot agree on an omnibus bill, the fallback is to enact a longer-term CR that keeps the federal government operating into next year when the next Congress can try to solve the problem.

Key Congressional committees that are important to America's Blood Centers will have several new members for blood centers to come to know when the new Congress convenes in January 2015. Check out the names below and see if your blood center's district is represented by a key committee newbie. New Republican members of the Medicare-writing House Energy and Commerce Committee include Reps. Richard Hudson (R-NC), Kevin Cramer (R-ND), Markwayne Mullin (R-OK), Larry Buschon MD (R-IN), Susan Brooks (R-IN), Bill Flores (R-TX) and Chris Collins (R-NY). In addition, House Democrats named Rep. Frank Pallone (D-NJ) the ranking democrat on the panel, defeating Rep. Anna Eshoo (D-CA) to succeed retiring Rep. Henry Waxman (D-CA). New Republican members of the Medicare-writing House Ways and Means Committee include Reps. George Holding (R-NC), Kristi Noem (R-SD), Pat Meehan (R-PA), and Jason Smith (R-MO). House Democrats have not yet made rank and file committee assignments. House Democrats named Rep. Corrine Brown (D-FL) ranking member of the House Veterans Affairs Committee, succeeding retiring Rep. Michael Michaud (D-ME). Senate Democrats added to their leadership team Sens. Mark Warner (D-VA) and Elizabeth Warren (D-MA). Senate rank and file committee assignments have not yet been made by either party. ♦

INFECTIOUS DISEASE UPDATES

EBOLA

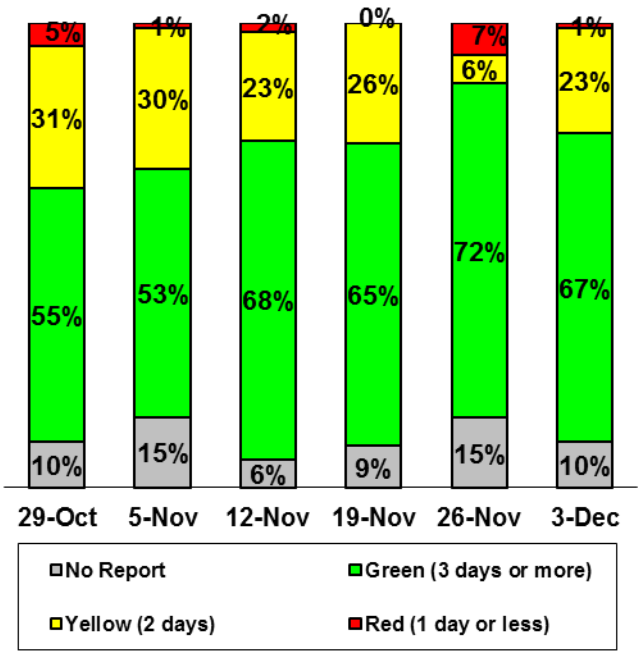
The Centers for Disease Control and Prevention recently announced in a bulletin on Dec. 2 that state health officials have identified and designated 35 hospitals with Ebola treatment centers, with more expected in the coming weeks. "An increasing number of US hospitals are now equipped to treat patients with Ebola, giving nationwide health system Ebola readiness efforts a boost," said CDC. Ebola treatment centers are staffed, equipped, and have been assessed by state officials to have current capabilities, training, and resources to provide the complex treatment necessary to care for a person with Ebola while minimizing risk to healthcare workers. More information can be found in the CDC announcement. (Source: CDC bulletin, 12/2/14) ♦

We Welcome Your Articles

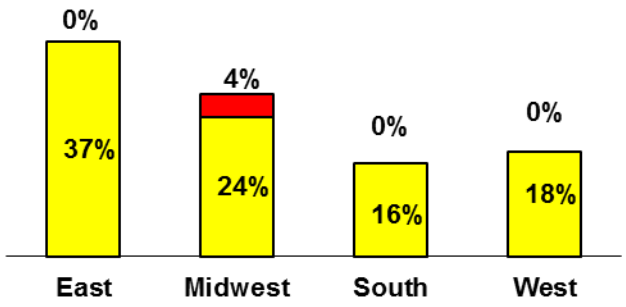
We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer's name and title will be included 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 Betty Klinck at newsletter@americasblood.org. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, December 3, 2014



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

More than 3,500 people presented to donate, leading San Diego Blood Bank to collect 1,091 units of blood during its Chargers Drive XXXVI presented by the San Diego County Credit Union. The annual drive was held on Nov. 25 at the Town & Country Convention Center in San Diego. The blood center said this year's drive was particularly successful, with an increase in units collected and overall event attendance from 2013. The blood drive also attracted 307 first-time donors. "Chargers Mania" continues through Dec. 8 at all San Diego Blood Bank centers and blood mobiles, with donors being awarded commemorative Chargers Drive XXXVI T-shirts. This year, the San Diego Blood Bank added many new areas for health, wellness, and entertainment. Chargers Drive XXXVI attendees enjoyed an expanded "Wellness Zone" with interactive exhibits and activities, food sampling, and more. The San Diego Blood Bank offered free blood typing to the first 500 people who were interested. In addition to donating blood, attendees met Chargers players and Chargers Girls cheerleaders, enjoyed entertainment, and took advantage of free bone marrow registry testing. The event also featured a special exhibit of the human heart. Attendees also had a chance to participate in a special VIP meet-and-greet reception where they met Chargers players and other VIPs in an exclusive reception.

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MEMBER NEWS (continued from page 12)

Rolf Benirschke and special guests Hank Bauer, Louie Kelcher, and Charlie Joiner participated in a panel to discuss how the Chargers Drive was established, and relive the days as Mr. Benirschke's teammates when he was struck with ulcerative colitis early in his Chargers career. The place kicker nearly died after two surgeries in eight days in November 1979 but surprised everyone by returning the next season to continue his record-setting career for seven more years. Proceeds from the VIP meet-and-greet benefit the San Diego Blood Bank's general programs and services, such as the expansion of their fleet of bloodmobiles. (Source: San Diego Blood Bank press release, 11/26/14)

Blood Bank of Delmarva (BBD) opened its fifth, permanent donation center, the Concord Center, on Monday. The center is located at the Christiana Care Concord Health Center in Chadds Ford, Pa. Joseph MacArthur, the first donor at the new location, is pictured here with Noah Osner, lead tech in Donor Services. The 3,000-square-foot Concord Center has 10 donor beds and is on the second floor of the health center in Suite 2300. The center will begin with whole blood donations, but will be equipped to accommodate all donation types, including double red cell and platelets. (Source: Blood Bank of Delmarva press release, 12/1/14)

Lifeblood, Memphis, Tenn., presented local charity, Memphis Union Mission, with a $2,673 check on Nov. 25 to help provide 1,600 meals to those in need in the Mid-South region just in time for Thanksgiving. Founded in 1945, the Memphis Union Mission has helped men, women, and children who are homeless, struggling with addiction, or in crisis by providing meals, shelter, and medical services. "We enjoy giving back to the community," said Jean Newman, executive assistant at Lifeblood. "And this was a way Lifeblood employees could help another nonprofit in our city do something very important, help fight hunger." The Mission provides more than 250,000 meals annually to hungry mid-southerners. Steve Carpenter, director of development at the Mission said, "The Memphis Union Mission is grateful to the team at Lifeblood for raising money to help feed and care for people in need in Memphis. We are especially touched, considering that Lifeblood already makes such a difference in people's lives through their vital work." (Source: Lifeblood press release, 12/1/14)

Memphis Union Mission Director of Development Steve Carpenter receives a $2,673 check awarded by Lifeblood CEO Susan Berry-Buckley.

The University of Oregon Duck and Oregon State Univeristy Beaver fans came together in November to help save thousands of lives through Lane Blood Center's 13th Annual Civil War Blood Drive. More than 7,100 people gave blood during the blood drive, which ran statewide from Nov. 1 to 23. The Beavers won by the narrowest margin in the competition's history – just 47 votes. Lane Blood Center holds this annual blood drive to help boost donations during the holiday season when donations tend to dip due to busy holiday schedules. Lane Blood Center sent a thank you to all Oregon residents who came out to donate, and a special thanks to the University of Oregon Alumni Association and the Oregon State University Alumni Association for their help publicizing the contest to students and faculty of both schools and for hosting blood drives.

COMPANY NEWS

Verax Biomedical has filed a 510(k) application with the Food and Drug Administration to expand the use of its Platelet PGD Test to include all FDA-approved platelet types, Verax announced in a Dec. 1 press release. The Verax Platelet PGD test is a point-of-issue assay used to detect bacterial contamination of platelets on the day of issue at the hospital. It is currently approved for use in leukoreduced apheresis platelets and whole blood derived platelets. With this submission, Verax seeks approval to screen platelets stored in platelet additive solution (PAS) and pre-storage pooled platelets (Acrodose™). If the application is approved, the PGD test will be available for all platelet types licensed by FDA in the US. More information is available in the press release. (Source: Verax press release, 12/1/14)

MEETINGS

Dec. 12 **FDA Public Workshop: Immunology of Protection from Ebola Virus Infection, Rockville, Md. and Webcast.**

The Food and Drug Administration, the National Institutes of Allergy and Infectious Diseases, the Department of Defense, the Centers for Disease Control and Prevention, and the Biomedical Advanced Research and Development Authority will co-host a workshop titled "Immunology of Protection from Ebola Virus Infection" on Dec. 12 in Rockville, Md. The workshop will discuss the important aspects of Ebola virus and vaccine immunology in order to inform future clinical, scientific, and regulatory decision-making related to vaccines against Ebola. **On-site registration for this workshop has already reached capacity**, but you may submit a request to be placed on the waitlist or view the webcast at http://1.usa.gov/1s26lH4.

March 26-28 **TransFuse 2014: Transformative-Fusion of Innovative Patient Blood Management, Phoenix, Ariz.**

The Mayo Clinic will host the TransFuse 2014 conference from March 26 to 28 at the JW Marriott Desert Ridge Resort in Phoenix, Ariz. This three-day multidisciplinary conference explores current state-of-the-art techniques and program development to implement a patient blood management program in hospitals. This summit is organized by leaders in blood management from Mayo Clinic, Hartford Hospital, Loyola University, and Cleveland Clinic. More information and registration details can be found at http://mayocl.in/1fwOU9Q

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.

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: mnorwood@americasblood.org.

POSITIONS AVAILABLE

Key Account Manager. The Blood & Tissue Center of Central Texas, located in Austin, hiring a Key Account Manager to identify, solicit, and successfully source donor sponsor groups with an employee/member base exceeding 250 and have the ability to support the BTC Blood Program. This charismatic professional must understand the value of prospecting and have an aptitude for building strong rapport with high-level business partners. Qualified candidates must have a bachelor's degree in Sales or Marketing with five to seven years of experience in corporate sales and account development or seven to 10 years of relevant work experience in lieu of a degree. Prefer some experience in the blood center environment. Strong oral and written communication skills that effectively reach all levels of personnel and business contacts needed. Must be a highly motivated self-starter with excellent organizational skills, strong interpersonal skills, and have the ability to develop and persuasively deliver presentations. Must be at least 21 years old, hold a valid driver's license, provide a copy of an acceptable driving record, and show proof of liability insurance. Applicants may send cover letter, resume, and salary requirements to resumes@tcms.com. Please include position title in subject line.

SBB Community Education Coordinator (Pomona, CA). Are you a Medical Technologist looking to get out of the lab and need a new challenge? In this position you will plan and coordinate the Blood Transfusion Medicine/Science education programs, monitor the schedules, resources and content of the education programs. Provides support to the instructional staff in the didactic and practical phases of the SBB program, coordinate schedules of Transfusion Medicine Fellows, visiting physicians and technologists. Functions as the liaison between the State of California Department of Health Services and the American Red Cross Southern California Region for purpose of maintaining accreditation as a provider of continuing education for California Clinical Laboratory Scientists. Qualifications: MT (ASCP) or equivalent; preferably SBB, five years' experience in a hospital or blood center. California State Clinical Laboratory Scientist (or eligible). We offer excellent benefits including health/dental/vision insurance, 401(k) and 403(B) and more. To apply visit: www.americanredcross.apply2jobs.com, position number BIO49750. EOE M/F/D/V

Sr. Director, IRL. The American Red Cross Blood Services is accepting applications for a Sr. Director, IRL position - work location is flexible. The Sr. Director will cover a multi-state territory with travel to local facilities as needed. In addition to possessing a track record of success in IRL, ideal candidate will be business/sales-minded, deadline-driven, solution-oriented and a change-agent leader. To review the full posting details and apply online please visit**:** http://bit.ly/1zVnBlv**.**We are a nonprofit organization that offers employees growth and development, opportunity for advancement, team spirit, competitive salaries and a comprehensive benefits package. Key areas of responsibilities: Oversee activities, provide guidance and support to management and staff to ensure that activities are in compliance with regulations. Long range planning, strategy and management of Immunohematology Reference Laboratories operations and activities for their area. Develop and implement strategies for IRL operations, to include budgeting and staffing. Represents the IRLs to senior management at the national level. Minimum qualifications: Masters in a related field or SBB (ASCP) certification/equivalent. 10 plus years directly related experience including seven plus years of IRL management.

Customer Relations Specialist. Indiana Blood Center is currently seeking a Customer Relations Specialist. Under the direction of the Director, Production, the Customer Relations Specialist is responsible for assessing, recommending, and implementing plans to achieve exceptional customer relations in Blood Services in order to retain current customer base. Works with Blood Services leadership and with peers at affiliate centers to develop plans to generate growth. Is responsible for current customer relationship management and frontline pursuit of new customer prospects. Builds relationships with customers and captures VOC (voice of customer). Supports customer product and inventory needs at the point of hospital blood banks. A bachelor's degree from an accredited college or university in Clinical Laboratory Science or related field; Medical Technologist or Medical Laboratory Scientist

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POSITIONS (continued from page 15)

(ASCP—American Society for Clinical Pathology) certification required. Minimum of three to five years' job related experience in blood banking/transfusion services; minimum of two years' experience in Customer Service or Customer Account management preferably in association with a blood center; experience with Customer Relationship Management tools, customer surveys and metrics for continuous validation of value delivered to customer is preferred. Valid driver's license required with acceptable driving record that meets IBC's established guidelines. Indiana Blood Center is an Equal Opportunity Employer. Please apply online at www.indianablood.org.

Manger, Regional Donor Recruitment. United Blood Services is seeking an influential and results driven Manger, Regional Donor Recruitment for its Rio Grande Valley region. Under minimal direction, this position is responsible for developing and directing the blood center's strategic donor recruitment and marketing plan to achieve annual collection goals. This position is responsible for management oversight of the department at the blood center. Requirements: Bachelor's degree required. Five (5) years related experience required. To include, three (3) years supervisory experience required. Must have a participative management style, strong team development, and coaching skills. Employment application required, available at www.unitedbloodservices.org. Deadline to apply is **12/12/14**. Email to colivares@bloodsystems.org, mail to 1400 S. 6th St. McAllen, TX 78501 or fax to (956) 213-7549. UBS is an Equal Opportunity/Affirmative Action employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, or protected veteran status.

Director of Donor Marketing (CTTM). Be a part of a dynamic and forward thinking affiliation of blood centers in this changing healthcare environment! This key position is responsible for donor recruitment and donor event management and database marketing. We will rely on you to manage a cross-functional coordinated effort to develop and implement strategy to maximize collections across CTTM. Position is accountable for executing successful campaigns, initiatives and promotions, and understanding and differentiating between activities to increase collections. This role is key in branding and messaging to foster a customer-focused culture resulting in increased donor/sponsor loyalty and new growth through tactical efforts targeted to collection strategies. We will rely on you to evaluate donor marketing programs across CTTM, determine effectiveness of campaigns, and leveraging programs. The ideal candidate will have a bachelor's degree a minimum of five years' experience in marketing or business development with at least five years as a cross functional project management leader. A minimum of five years business to business sales experience required. BloodCenter offers a competitive salary, commission plan, and benefits package. Apply online at www.bcw.edu. Equal Opportunity Employer of Minorities, Females, Protected Veterans, and Individuals with Disabilities.

Medical Director. Provide oversight on all medical aspects of the regional blood center operations, including the reference laboratories, research, medical community relations and collections. Develop and implement medical policies and procedures for the blood region as needed; coordinate communications between the blood services region, the local and national medical community and National Headquarters; provide timely medical and technical consultation in transfusion medicine to operation units and customers. We offer excellent benefits including health/dental/vision insurance, 401(k) and 403(b). Positions available in several locations including Salt Lake City, UT (BIO46548) St. Louis, MO (BIO47188) and Columbus, OH (BIO42182). For more information or to apply visit: www.americanredcross.apply2jobs.com. EOE M/F/D/V