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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2014 #40 **November 7, 2014**

INSIDE:

RECESS Trial Suggests Older Stored Blood Not Associated with Adverse Patient Outcomes in Cardiac Surgery Patients

It is well known that red blood cells (RBCs) undergo morphological and biochemical changes during storage that may impact their physiological functions. Several observational studies in recent years have suggested that subsequently, older stored RBCs are harmful for transfused patients when compared with fresher RBCs, while others have found no association. Results from a randomized clinical trial examining the impact of the age of blood in complex cardiac surgery patients found no difference in outcomes among patients transfused with older stored blood as compared with those receiving fresher blood.

Unfortunately, past observational studies have been plagued by methodological issues making it difficult to draw any meaningful conclusions – most importantly the potential for unmeasured confounding by unknown factors that affect patient outcomes. The results of the Red Cell Storage Duration Study (RECESS), presented during the plenary abstract session last week at the AABB Annual Meeting in Philadelphia, addresses this and other limitations of previous observational studies, offering more definitive answers in the debate over whether the age of blood has an impact on clinical outcomes.

"Previous observational studies were confounded because sicker patients get more blood and the more blood you get, the more likely you are to get older units because older units are issued first. Due to confounding in observational studies, it really requires randomized trials that are properly powered to answer this question," said Darrell Triulzi, MD, of America's Blood Centers' member the Institute for Transfusion Medicine (ITxM) and the principal investigator at the University of Pittsburgh. "This is the first large, properly randomized study in adults to address the question [of whether the age of blood has an impact on clinical outcomes.]"

Marie Steiner, MD, MS, from the University of Minnesota, and a large group of investigators from around the US, conducted a randomized trial from 2010 to 2014 at 33 US and Canadian medical centers to evaluate the effect of RBC storage age in transfused cardiac surgery patients. Patients undergoing complex surgery and likely to receive RBCs were randomized preoperatively to receive either leukoreduced RBCs stored for 10 or less days or for 21 days or more.

The researchers analyzed all transfusions during and after surgery through hospital discharge, death, or day 28. The primary outcome was the change in

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OUR SPACE

ABC President Dave Green

Déjà Vu All Over Again?

The year 2004 saw the Summer Olympics return to its starting place in Athens, Greece. New England dominated the USA professional sports world with the New England Patriots winning the Super Bowl and the Red Sox the World Series. Oh – and red cell demand for independent blood centers was approximately the same as it is today. What happened to the decline in demand!?

Although coming up with timely national blood product usage information is a dicey proposition, surrogate measures suggest the red cell usage we see today is very close to what we saw in 2004. The transfusion rate is certainly down considerably from a decade ago, but the transfusion volume and supporting red cell production are nearly the same. I was surprised by this realization and only stumbled upon it when I was evaluating operating budgets over the past 10 years. But once this was clear, I was pleased at the shift in perspective caused by this realization. In addition to searching for new solutions I added the fundamental question – "What's changed since then?"

We added transfusion related acute lung injury (TRALI) mitigation strategies, Chagas disease screening for first-time donors, and hepatitis B virus nucleic acid testing – adding a cumulative safety and cost impact. But, we also saw significant supply savings over the past few years to help offset these expenses. Likely the most notable change was the industry-wide increase in production to support a steady annual increase through 2008; we all know too well the subsequent plateau in demand and reduction in transfusion rates – so perhaps we have lessons learned from scaling back operations that could prove useful in the future. Changing my perspective did not necessarily solve the budget problem, but it did produce a more fruitful set of options from which to choose.

However, reflecting on changes over the past 10 years is just one approach to dealing with our challenges. Another I recommend is an in-depth review of supply chain optimization strategies in blood banking. ABC is conducting a Supply Chain Optimization Workshop from Dec. 9 to 10 in Austin, Texas. Attendees will have the opportunity to hear from experts in this field, as well as blood bankers who have successfully reengineered their programs by employing supply chain techniques. Although this type of session cannot make us experts in supply chain management principles, it most certainly gives us a fresh look at the challenges we face and connect us with those who can help us make a difference. I look forward to seeing you there!

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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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RECESS Trial Results (continued from page 1)

multi-organ dysfunction score through day seven; secondary endpoints included changes in multi-organ dysfunction score through day 28, serious adverse events, and mortality at 28 days post-surgery. (More details of the trial, supported by the National Heart, Lung and Blood Institute, can be found at http://1.usa.gov/1x3MNZj.)

"This is the first randomized clinical trial looking at the storage age of blood in patients undergoing complex cardiac surgery procedures, and we can say with confidence that we did not see differences … in multi-organ dysfunction scores, serious adverse events, or mortality at day 28 in patients who were transfused with leukoreduced red blood cells that were stored for longer or shorter periods," Dr. Triulzi told *Transfusion News*, summarizing the results. "There are other ongoing clinical trials in other patient groups, such as intensive care unit (ICU) patients that will answer this question in those patient populations."

These findings are consistent with another randomized controlled trial examining the age of stored blood published in 2012 [the Age of Red Blood Cells in Premature Infants (ARIPI) trial], which found no difference in outcomes among pediatric patients when comparing older with fresher blood. Bringing a close to the debate over older vs. fresher blood will depend upon the results of several other ongoing trials, such as the Age of Blood Evaluation (ABLE) randomized controlled trial, currently underway in Canada, examining the impact of the age of RBCs in ICU patients, and a study from the Cleveland Clinic in cardiac surgery patients, noted Dr. Triulzi. The Standard Issue Transfusion Versus Fresher Red Blood Cell Use in Intensive Care (TRANSFUSE) randomized controlled trial being conducted in Australia offers a look at how the age of blood impacts the general medical population by comparing fresher vs. "standard of care" blood among all patients admitted to the hospital, added Dr. Triulzi.

Abstracts presented at the AABB Annual Meeting are available online free of charge. (Source: Transfusion News, 10/30/14)

Citation: Steiner ME, *et al*. Randomized Trial Results: Red Cell Storage Age is Not Associated with a Significant Difference in Multiple-Organ Dysfunction Score or Mortality in Transfused Cardiac Surgery Patients. Transfusion 2014;54 Supplement: 15A.

Alliance of Blood Operators Offers Risk-Based Decision-Making Framework to Guide Blood Safety Decisions

The Alliance of Blood Operators (ABO) recently shared a consultation version of its Risk-Based Decision-Making (RBDM) Framework, now available online for public comment by blood services and other stakeholders. ABO's RBDM Framework offers blood services a structured approach to blood safety risk management, laying out a step-by-step methodology for planning a course of action with regard to blood safety interventions under uncertain conditions by identifying, assessing, acting on, and communicating risk.

ABO is an international network of seven non-profit blood services including America's Blood Centers, the American Red Cross, the Australian Red Cross Blood Service, Blood Systems, Inc., Canadian Blood Services, the European Blood Alliance, and NHS Blood and Transplant of England and North Wales. ABO's RBDM Project Steering Committee and its four sub-committees created a framework specifically tailored for blood services that includes health economics and outcomes tools, stakeholder engagement guidelines, and an alliance website with a members' section that will ultimately house the online framework. A group of ABO committee members shared details on the framework and its development on Oct. 25 during an educational session at the AABB Annual Meeting held in Philadelphia.

The RBDM project was born out of discussions at a 2010 ABO International Consensus Conference held in Toronto, Canada, at which participants agreed that achieving zero risk in transfusion medicine is not possible and the well-being of transfusion recipients should be central to any recommendations to improve blood safety decision making, Ralph R. Vassallo, Jr., MD, of the American Red Cross, chair of the ABO RBDM Risk Framework Committee, explained in his presentation. ABO thus set out to develop a standardized, decision-making framework to guide blood services in the midst of increasing complexity in blood safety decision-making, driven by medical, scientific, ethical, economic, legal, and public policy factors.

Judie Leach Bennett, LLB, LLM, of Canadian Blood Services, chair of the ABO RBDM Steering Committee, outlined the development of the framework "from concept to action." The framework seeks to provide a practical set of approaches to help users identify and prioritize risks to blood safety and to evaluate the effectiveness of potential risk management options, said Ms. Leach Bennett. It uses a stepwise decision-making process, together with standard tools and guidelines. The framework helps users assess risk tolerability in the context of donor and patient safety, while also providing guidelines on health economics assessments to evaluate the cost utility of mitigation options to best allocate limited resources. The framework provides guidelines on stakeholder engagement and a web portal to access these tools.

Brian Custer, MPH, PhD, of Blood Systems Research Institute, a subject matter expert on the ABO RBDM Health Economics and Outcomes Committee, offered an in-depth look at how the framework applies health economic and outcomes analysis methods to blood safety. He explained how ABO developed a consistent set of methods and tools to ascertain the impact of proposed interventions in the context of the blood system and health care. The rationale for this set of tools has been submitted for publication and is under review, he noted.

Attendees at the AABB session also heard from Peter McDonald, FCPA, of the Australian Red Cross Blood Service, who chaired the Stakeholder Engagement Committee. This committee was tasked with preparing a set of stakeholder engagement guidelines that form part of the overall framework, and help guide blood operators in working with their stakeholders whenever a risk-based decision needs to be made. Mr. McDonald highlighted that stakeholders should be included in these decisions because they

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ABO RBDM Framework (continued from page 4)

often have a right to be involved and if engaged, can become strong allies. To engage stakeholders and get feedback on the RBDM Framework itself, ABO interviewed more than 40 thought leaders, held face-to-face consultations with patient representatives and experts in the blood community, and engaged in dialogue with regulators in various countries. A web-based consultation conducted from July 23 to Aug. 5, 2014, provided opinions and other valuable feedback from 75 participants from a variety of stakeholder groups across ABO countries. Some key findings include:

- 91 percent of participants agreed the risk management principles capture the key elements of an effective RBDM;
- 96 percent agreed stakeholder engagement is critical;
- 98 percent endorsed the risk tolerability guidelines laid out in the framework as a policy foundation; and
- 87 percent agreed that the framework will enable blood operators to optimize blood safety through proportional allocation of finite resources.

The framework recently underwent feasibility testing, which was a collective exercise focusing on whether the framework could be used effectively when challenged with a credible risk scenario and whether there were any gaps in the policies on which the process was founded or in the decision-making process itself. The outputs of feasibility testing, feedback from stakeholder consultations, and input from public review of the consultation framework draft will inform the final version of the framework. ABO encourages blood centers and other relevant stakeholders to review the consultation draft of the framework and provide feedback at http://bit.ly/1uBhBzN. ♦

Miller-Keystone Blood Center and Central Jersey Blood Center Announce Intent to Merge Operations

Officials at Miller-Keystone Blood Center (MKBC), headquartered in Bethlehem, Pa., and Central Jersey Blood Center (CJBC), headquartered in Shrewsbury, N.J., announced on Thursday that they have entered into an agreement to pursue a formal merger. Together the two organizations provide 165,000 blood products in Eastern Pennsylvania and New Jersey.

"Miller-Keystone Blood Center has a long history of outstanding service and growth in the region, and shares a deep-rooted community connection with Central Jersey Blood Center," said MKBC President and CEO Pete Castagna. "Our donors, volunteers, employees, and hospital customers understand that special bond that has enabled the center to continue to meet the needs of our community."

Mr. Castagna and CJBC President and CEO Pascal George stressed in a joint press release that the two regional centers will remain committed to their local communities and meeting their blood needs.

"Central Jersey Blood Center is a very healthy organization with dedicated staff and donors," said Mr. George. "This is the right time for us to enter an alliance which will be better equipped to face the profound changes affecting our industry while further enhancing the value we bring to our hospitals. Both organizations have progressive cultures and we expect to gain efficiencies and regional visibility while retaining our local brands."

Mr. Castagna noted that this merger reflects national trends of consolidation within the healthcare industry. "The past few years have significantly challenged organizations that provide services to hospitals and healthcare systems, creating the need to respond to this changing marketplace," he said. "Our objective is to create a competitive force in the blood services field, dedicated to providing our hospital customers and their patients with the highest quality of blood products and services."

Mr. George added, "The union will improve blood recruitment efforts and enhance the availability and utilization of the region's blood supply. Both Central Jersey and Miller-Keystone believe that the joining of our functions will achieve cost savings through economies of scale, joint blood recruitment and collection, shared access to quality assurance programs, and a common data enterprise system." (Source: Joint MKBC and CJBC press release, 11/5/14) ♦

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.

Procleix

Procleix NAT Solutions

By Hologic and Grifols

Innovative solutions to increase lab efficiency

In today's evolving NAT landscape, labs need versatile and efficient screening solutions to deliver safe blood for patients. Procleix NAT solutions offer comprehensive blood and plasma screening products to help you achieve safety and operational efficiency.

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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.

Did You Know…?

'21' is the number of times ABC was mentioned in the US media since Jan. 1 (2.33 per month).

ABC-earned media mentions include: Associated Press, Columbia News Tonight (Columbia University, New York, N.Y.), Naples Daily News (Naples, Fla.), Huffington Post – online, *New York Magazine*, *The New York Times*, *The Ka Leo* (University of Hawaii), *The Daily Record* (Parsippany, NJ.), *The Register-Guard* (Eugene, Ore.), *Highland Community News* (Highland, Calif.), the *Press-Register* (Mobile, Ala.), the *Portland Press Herald* (Portland, Maine), *University Herald News* – online, Al Jazeera – online, *Los Angeles Times*, *Kansas City Star* (Kansas City, Mo.), *Quad City Times* (Davenport, Ioawa), and KWQC-TV 6 (Davenport, Iowa).

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.*

Blood Community Leaders Meet with FDA Representatives to Discuss Plasma Regulation Flexibility

Several leaders in the blood community met with representatives from the Food and Drug Administration on Oct. 30 to discuss matters of interest, primarily the ongoing efforts to increase the flexibility of FDA's plasma regulations. The meeting was held at the invitation of FDA in response to letters sent by the blood community.

Attending the meeting on behalf of the blood community was America's Blood Centers' President Dave Green, president of the Blood Centers Division of Blood Systems, Inc.; ABC Chief Medical Officer Louis Katz, MD; ABC CEO Christine Zambricki, DNAP, CRNA, FAAN; American Red Cross Chief Medical Officer Richard Benjamin, MD; Mark Skinner, JD, president of the World Federation of Hemophilia; and Theresa Wiegmann, JD, director of Public Policy and special counsel at AABB. Representing FDA were Karen Midthun, MD, director of FDA's Center for Biologics Evaluation and Research (CBER); Peter Marks, MD, PhD, CBER's deputy director; Diane Maloney, JD, CBER's associate

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director for policy; Ginette Michaud, MD, deputy director of CBER's Office of Blood Research and Review (OBRR); and Lorrie McNeill, director of CBER's Office of Communication, Outreach, and Development.

Current FDA regulations regarding the sale of plasma to fractionators to be made into plasma protein therapeutics do not allow for the maximum use of the gift given by donors. Whole blood plasma can be shipped as "recovered plasma" to create essential plasma derivatives at any time during its shelf life. While apheresis plasma for transfusion bears the same labeling as whole blood plasma, FDA requires untransfused apheresis plasma to expire (one year from the date of collection) before it can be sent for fractionation. Because this adds medically unjustified operational complexities to its use, it is generally not done.

ABC and others in the blood community seek to increase the flexibility of these regulations, allowing blood centers to better meet the expectation of volunteer blood donors that every component of their donated blood be used maximally to save and enhance patient lives. The need for these critical plasma products has increased in recent years, and will continue to rise. Adding more plasma from blood centers would enhance supplies and help keep prices as low as possible.

FDA representatives were receptive to the issues brought forth during the meeting and expressed their willingness to work together with blood industry stakeholders to move forward on plasma regulation flexibility. ABC members can access presentation slides and other materials from the Oct. 30 FDA meeting at http://bit.ly/1uxKv4n. A recent ABC webinar describing ABC's progress on this and other advocacy initiatives is available to ABC members at http://bit.ly/1Grbkuj.

Now Accepting Nominations for ABC's 18th Annual *Awards of Excellence* and 2014 FABC Awards

America's Blood Centers is now accepting nominations for the 18th Annual *Awards of Excellence*. This program provides ABC member blood centers with the opportunity to offer national recognition to local individuals, civic groups, media, and corporations for their commitment to community blood programs.

Award recipients will be announced in January 2015. The *Awards of Excellence* reception will be held on the evening of Monday, March 23, 2015, at the Ritz Carlton, Pentagon City in conjunction with ABC's 53rd Annual Meeting in Washington, D.C. This year, ABC is introducing a new format for the awards program.

The evening reception will be in the form of a "rolling dinner," during which award recipients will have more opportunities to meet ABC members and other award recipients. Posters of the recipients with descriptions of their award will be displayed throughout the ballroom for all attendees to view and learn more about the awardees and their winning submissions. The evening will conclude with the award recipients and guests being treated to the "ABC's Got Talent" show, at which the top five winners of the online talent show will perform live to compete for a grand prize (see page 3 for details).

The following awards will be presented during the *Awards* ceremony: Media of the Year Award, Corporation of the Year Award, Larry Frederick Award, National Partner of the Year Award, Outstanding Humanitarian Service Award, Creative Blood Drive Award, Productive Blood Drive Award, School

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Blood Drive Award, Thomas F. Zuck Lifetime Achievement Award, and the President's Award. (Travel and hotel expenses of award recipients are the responsibility of the nominating blood center.)

ABC encourages its member centers to take advantage of this opportunity to recognize their supporters by submitting nominations before Friday, Dec. 12. More information about the awards, criteria, past recipients and nomination forms can be accessed at http://bit.ly/10uHSCq.

ABC Welcomes API Curriculum Development Committee to Washington

America's Blood Centers hosted the ABC Professional Institute (API) Curriculum Development Committee in Washington, D.C., yesterday for a planning meeting on the structure of the API and the certificate programs to be offered. Pictured from left to right are: Mike Parejko, Mississippi Valley Regional Blood Center; Lisa Clawson, BloodSource; Martin Grable, Community Blood Center of the Carolinas, Richard Gammon, OneBlood; Joe Yelo, Blood Bank of Delmarva; Nora Hirschler, Blood Centers of the Pacific; ABC CEO Christine Zambricki; Michelle Johnson (committee chair), Carter BloodCare; Steve Eason, Carter BloodCare; and Laurie McGraw, Gulf Coast Regional Blood Center. See next week's Newsletter for more on this meeting! ♦

We Welcome Meeting Notices

Do you have a symposium, conference, workshop, or annual meeting that you would like to publicize in the *ABC Newsletter*? If so, please send a meeting notice or press release to the editor, Betty Klinck at newsletter@americasblood.org. Notices should contain the following information: the exact date(s) of the meeting; the formal title of the meeting; the sponsoring organization or agency; the location of the meeting; a short (fewer than 35 words) description of the curriculum, agenda, or topics to be covered; a contact person or a website address with more information. Notices will be published at the discretion of the editor in the Meetings section of the Newsletter.

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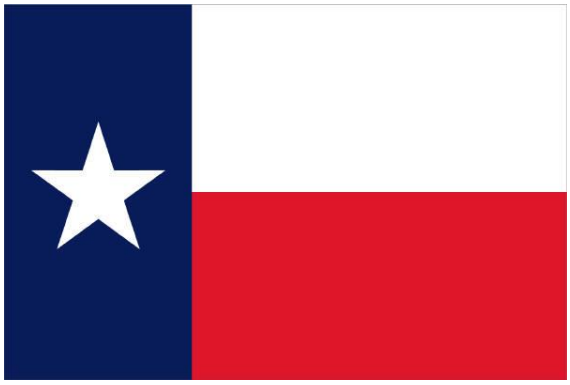
There are Four (4) $800 scholarships available to ABC members to cover the cost of registration fees and help with travel expenses. Application link and additional details included in registration.

"We are excited that ABC has chosen Austin for its Supply Chain Optimization Workshop. You can expect informative presentations and stimulating dialogue. Supply chain optimization is a hot topic, and the host city is totally cool. We look forward to seeing y'all in Austin this December."

– Marshall Cothran
Chief Executive Officer
The Blood & Tissue Center
of Central Texas

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

Austin-Bergstrom International Airport (AUS) is served by most major US airlines and offers non-stop service to 42 destinations; check *www.austintexas.gov/airport* for more information.



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RESEARCH IN BRIEF

Two abstracts presented at the AABB Annual Meeting in Philadelphia last week suggested that septic transfusion reactions caused by bacterial contamination of platelets is underreported and that additional measures to prevent transfusion bacterial contamination of platelets are necessary. While criteria for the recognition of transfusion-transmitted bacterial contamination have been established, identifying this condition is still challenging because these criteria often overlap with those for febrile non-hemolytic transfusion reactions (FNHTRs). In one study presented during the Abstract Plenary Session, H. Hong, and colleagues of the University Hospitals Case Medical Center in Cleveland and

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RESEARCH IN BRIEF (continued from page 10)

the Case Western Reserve University, retrospectively evaluated the sensitivity and specificity of current septic transfusion reaction criteria in identifying patients with true transfusion-transmitted bacterial contamination of platelets. Patients receiving platelets from Jan. 1, 2007 to Dec. 31, 2013 at the University Hospitals Case Medical Center with transfusion reactions reported to the transfusion service were analyzed, which is passive surveillance. Bacterial culture was performed on every platelet dose at the time of issue, which is active surveillance. Transfusion reactions were correlated with platelet and post-transfusion blood cultures. Transfusion reactions were categorized using the National Health Safety Network (NHSN) Biovigilance Guidelines from the Centers for Disease Control and Prevention. During the study period, 43,375 leukoreduced platelet products were transfused. Transfusion reactions were reported in 284 (0.65 percent). Of these, 127 reactions (45 percent) were categorized as FNHTR/febrile-like transfusion reactions, 111 (39 percent) as allergic transfusion reactions, and 46 (16 percent) as other transfusion reactions. Of the 124 patients with FNHTR/febrile-like transfusion reactions whose records were reviewed, 53 (43 percent) met the criteria for septic reactions that should trigger investigation for bacterial contamination. However, bacterial contamination at the time of issue and of the residual platelet units eventually turned out to be negative for all of these cases. While 20 platelet units were found to be contaminated by culture at the time of issue, septic reactions occurred in only five of these cases, and none of them had been reported to the transfusion service. The sensitivity of NHSN sepsis criteria was calculated to be 8.6 percent and specificity 99.97 percent. "These findings document the poor sensitivity of sepsis criteria, the value of active surveillance and the need for improved recognition and reporting of septic platelet transfusion reactions," concluded the authors. In a study by the same group presented during a transfusion transmitted diseases session, the researchers retrospectively evaluated all bacterially contaminated platelets at their institution over the last five years and analyzed the associations among bacterial species, load, and transfusion reactions. Of 43,374 leukoreduced platelet units transfused, 20 bacterially contaminated platelet units were detected. Five patients (25 percent), transfused with platelets contaminated with staphylococci or streptococci, developed septic transfusion reactions, with bacterial loads of 1.4×10^5 to 7×10^6 cfu/mL. No reaction occurred in six patients receiving platelets with high bacterial loads ($>10^5$ cfu/mL) or in nine with low bacterial loads ($<10^5$ cfu/mL). A significantly higher transfusion reaction incidence was noted in recipients of high bacterial loads compared to low loads ($p < 0.0001$). Of the five transfusion reactions, two presented with non-febrile hypotensive transfusion reactions, two with FNHTR, and one with both FNHTR and hypotensive reactions. "Although rare, our study shows the continuing problem of bacterial contamination of platelet products, despite recent interventions," concluded the authors. They add that their findings highlight the utility of active surveillance to identify bacterial contamination and differentiate transfusion reactions associated with bacterial contamination from other etiologies.

Citations: Hong H, *et al*. Sensitivity and specificity of septic transfusion reaction criteria in identifying septic reactions to platelet transfusions. Transfusion 2014:54 Supplement: 17A

Hong H, *et al*. Correlation between transfusion reactions and bacterially contaminated platelet transfusions. Transfusion 2014:54 Supplement: 28A.

BRIEFLY NOTED

The Armed Services Blood Program (ASBP) held its workshop on Oct. 25 at the AABB Annual Meeting in Philadelphia, during which speakers shared developments affecting the ASBP, military-civilian collaborations, and advancements in blood support for overseas contingency

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BRIEFLY NOTED (continued from page 11)

operations. During the workshop, America's Blood Centers CEO Christine Zambricki, DNAP, CRNA, FAAN, spoke on the panel about military-civilian collaborations, and ABC's director of Regulatory Services, Ruth Sylvester, was honored with ASBP's Lifetime Achievement Award. The workshop opened with an introduction by Navy Capt. Roland L. Fahie, director of the ASBP, who discussed some of the challenges facing the ASBP and advancements in the safety and availability of blood products provided by the military blood program. He encouraged the audience to spread the word about the ASBP and its mission. "You are the ASBP," said Capt. Fahie. Next, keynote speaker Stacy Fidler took the stage to share her personal story about how the ASBP touched her life by providing life-saving blood products to her US Marine son Mark. While Mark was deployed in Afghanistan he was severely injured in an explosion, leading to the loss of his legs and numerous surgeries. On that first day alone, Mark required 120 units of blood. Ms. Fidler was shocked to find that much of the blood came from the US military blood program. She concluded her heart-felt story telling the audience, "When you give blood – you give life." Next, a panel of blood organization leaders discussed how civilian blood collection organizations work to help support the military blood program in a session on "Military-Civilian Collaborations," moderated by Capt. Fahie. Speaking on the panel was Dr. Zambricki, representing ABC; E. Mary O'Neill, MD, vice president of Patient Services at the American Red Cross; and Nina Salamon, executive vice president of Blood Centers of America. Dr. Zambricki and Dr. O'Neill discussed Memorandum of Understanding (MOU) agreements that allow civilian blood centers to collect blood on military bases, highlighting how helpful this is to blood centers. Dr. Zambricki also explained how ABC's member centers help to support the military blood program in support of contingency and wartime operations – points that were reiterated by Dr. O'Neill and Ms. Salamon. Dr. Zambricki and Ms. Salamon shared how member blood center, Mississippi Blood Services in Jackson recently created a "Military Memorial Garden" to honor individuals serving in the US Army, Marines, Navy, Air Force, and Coast Guard. Next, a panel spoke about the "Future of Blood Support for Overseas Contingency Operations." Panelists discussed current challenges in providing blood overseas – including the short shelf-life of platelets and difficulty transporting this product overseas. They also explored future developments, such as the implementation of cold platelet additive solution (PAS) platelets, pathogen reduction technology in whole blood and platelets, and wider use of tranexamic acid. The workshop concluded with the presentation of the ASBP Lifetime Achievement Award to retired Air Force Lt. Col. Ruth Sylvester, ABC's director of Regulatory Services, and retired Navy Cmdr. Jerry Holmberg, PhD (see *ABC Newsletter*, 10/24/14). Dr. Zambricki presented Lt. Col. Sylvester with flowers to congratulate her on this accomplishment, on behalf of ABC.

A cloud-based online system currently being developed by Puget Sound Blood Center (PSBC) and New York Blood Center (NYBC) may improve patient safety by enabling hospitals to more easily locate and request antigen negative blood units with extended typing from blood centers for patients with antibody problems and uncommon blood types, according to an educational session at the AABB Annual Meeting last week. Connie Westhoff, PhD, SBB, director of Immunohematology and Genomics at NYBC, and Meghan Delaney, DO, MPH, medical director of Red Cell Genomics at PSBC, led the session, with Dr. Delaney describing NYBC and PSBC's efforts to develop an open and real-time online system for sharing uncommon donor red blood cell (RBC) units throughout the US. The project to develop this system is being supported by a grant from the Foundation for America's Blood Centers (FABC). Dr. Westhoff began the session by highlighting the growing movement to prevent alloimmunization, particularly for the chronically transfused, by providing antigen-matched blood for these patients. All RBC transfusions are matched to the patient's ABO and RhD blood type, but there are more than 300 RBC antigens, some of which can cause patients to experience an adverse immune response following transfusion. This reaction – alloimmunization – occurs in about 3 to 5 percent of transfused

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BRIEFLY NOTED (continued from page 12)

patients but is much more common among the chronically transfused. Alloimmunized patients require antigen-negative RBCs and while some hospitals type the blood on their shelves for common antigens, it can be difficult to find blood that is negative for multiple combinations of antigens (uncommon antigens). Dr. Westhoff explained that antigen matching patient with donor for more than ABO and RhD types is operationally difficult and costly, and that donor centers are best positioned to provide antigen testing on donor units. This is why NYBC and PSBC have been working on the "Uncommon Donors in the Cloud" project. Alyssa Ziman, MD, medical director of Transfusion Medicine at UCLA Health, discussed RBC selection for patients with warm autoantibodies. Patients with warm-reactive autoantibodies may require chronic transfusion and therefore are prone to alloantibody formation. The presence of both auto- and alloantibodies present challenges to a transfusion service regarding the performance of immunohematology testing and RBC unit selection. Several studies have suggested a benefit to providing prophylactically-matched units that are antigen-negative to prevent production of alloantibodies. She described some challenges in providing these types of units and various strategies to ensure that patients with warm autoantibodies receive properly matched blood. She highlighted that a computer-based system, like the one being developed by PSBC and NYBC, would be helpful to more quickly and efficiently identify such blood units. Stella T. Chou, MD, of The Children's Hospital of Philadelphia, reviewed why components with uncommon blood types are necessary in the treatment of sickle cell disease (SCD). Because patients with sickle cell disease generally require life-long, regular RBC transfusions, alloimmunization is common, with many patients forming multiple antibodies. Furthermore, increased levels of antigen matching reduces alloimmunization in these patients; she recommended that an extended pre-transfusion RBC phenotype be obtained for all individuals with SCD. Since access to antigen-matched units can be challenging for patients with multiple alloantibodies, the Uncommon Donors in the Cloud project will be helpful to provide quicker access to these RBCs. Next, Dr. Delaney provided an overview of the Uncommon Donors in the Cloud Project. The current methods for finding uncommon blood types relies on manual, ad-hoc requests via phone or fax, which may cause a delay in getting the needed blood to the patient. And in some cases, the requests cannot be accommodated. The program under development by PSBC and NYBC will close some of these gaps using a real-time online system, called "Blood Connect." It allows the requesting hospital to post an RBC need that is then broadcast to potential suppliers. The system allows suppliers to respond to requests and to post their inventory of available extended-typed blood products. Dr. Delaney showed the audience several examples of the Blood Connect dashboard and unit request system. Feasibility testing is underway, and Dr. Delaney encouraged interested blood centers to sign up for the Blood Connect mailing list to stay updated as to the system's projected launch in 2015. Those interested in learning more about Blood Connect may contact meghand@psbc.org or cwesthoff@nybloodcenter.org. ♦

REGULATORY NEWS

The Centers for Disease Control and Prevention recently updated its malaria information and prophylaxis recommendations for Algeria, Argentina, Costa Rica, Ecuador, Guatemala, Mexico, and Sri Lanka. The updated recommendations can be viewed at http://1.usa.gov/1vR33r3. (Source: CDC What's New update, 10/30/14)

The Food and Drug Administration announced on Oct. 23 that it had approved Obizur [Antihemophilic Factor (Recombinant), Porcine Sequence] for the treatment of bleeding episodes in adults with acquired hemophilia A (acquired Factor VIII [FVIII deficiency). Obizur contains a recombinant analogue of porcine (pig) FVIII, which is similar enough to human FVIII to lead to effective clotting, but

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REGULATORY NEWS (continued from page 13)

less likely to be affected by the antibodies against human FVIII that are present in people with hemophilia A. The drug received orphan drug designation by the FDA because it is intended for use in the treatment of a rare disease or condition. Obizur is manufactured by Baxter Healthcare Corp., in Westlake Village, Calif. The package insert and FDA approval documents can be found at http://1.usa.gov/1xaPeaa. (Source: FDA press release, 10/24/14)

GLOBAL NEWS

AABB and the Asian Association for Transfusion Medicine (AATM) announced on Oct. 22 that they have signed a memorandum of understanding (MoU) aimed at promoting common goals in transfusion medicine and cellular therapies. The collaboration – headed by a joint leadership team – will increase adoption and dissemination of blood and cellular therapies standards in Asia as well as accreditation programs in these disciplines, according to an AABB press release. Among the joint efforts, the team intends to offer online education and training programs and will consider presenting wet workshops to advance patient and donor care and safety. The leadership team also may provide additional educational programs, including fellowships for young professionals. "As the emphasis on global medical practices intensifies, we look forward to establishing a strong inter-organizational relationship with the Asian Association for Transfusion Medicine that will help spread the adoption of standards for transfusion medicine and cellular therapies, as well as sound accreditation practices, in their member countries," said Miriam A. Markowitz, M.Sc., AABB CEO. "This collaboration will act as a needed enhancement to transfusion medicine to ensure safety for all patients," said AATM President Farrukh Hasan, MD. "There is growing interest in transfusion medicine, and this MoU is a wonderful step forward." The Secretary General of AATM, Nabajyoti Choudhury, MD, added, "This MoU will open a new opportunity for collaboration amongst transfusion medicine professionals from Asia. Such an agreement addresses the need for safe blood components and products across our region." The term of the MoU is three years and may extend to other areas of mutual interest and benefit, according to the AABB press release. (Source: AABB press release, 10/22/14)

INFECTIOUS DISEASE UPDATES

EBOLA

Attendees at the AABB Annual Meeting in Philadelphia last week filed into a packed room for a hot topic session on "Ebola and Transfusion Medicine." The session covered the basics about the virus; infection prevention and control; the unlikely probability of transfusion-transmission; the handling of specimens from unknown and suspected Ebola patients; transfusion therapy for patients; and the role of convalescent plasma in treatment. Speakers included ABC Chief Medical Officer Louis Katz, MD; Scott Koepsell, MD, PhD, of the University of Nebraska Medical Center; Anne Winkler, MD, of Emory University; Beth Shaz, MD, of New York Blood Center; and Aaron Tobian, MD, PhD, of Johns Hopkins University. Dr. Katz noted in his presentation that an AABB working group is working to produce and disseminate template documents for participation by collection facilities in investigational new drug (IND) and investigational device exemption (IDE) studies of convalescent plasma used to treat Ebola patients. The group is discussing with the FDA the best way to implement an "umbrella" multicenter IDE protocol, in lieu of repeated individual emergency IND protocols. The presentation slides from the AABB session can be found at http://bit.ly/1zySjUJ. The Oct. 24 *ABC Newsletter* provides more information and resources on Ebola virus.

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INFECTIOUS DISEASE UPDATES (continued from page 14)

DENGUE, CHIKUNGUNYA, WEST NILE VIRUS, AND HEPATITIS E VIRUS

Three transfusion medicine experts provided updates on the current status of dengue, chikungunya, West Nile virus (WNV), and hepatitis E virus (HEV) during the Transfusion Transmitted Diseases (TTD)-I session at the AABB Annual Meeting in Philadelphia last week. First, Susan L. Stramer, PhD, from the American Red Cross (ARC), discussed dengue and chikungunya virus. Dr. Stramer reviewed blood donor *in vitro* dengue screening data from Puerto Rico from 2010 to 2013, which found a rate of one confirmed positive test result for every 573 donors screened. With this relatively high rate, comparable to that found for WNV in the US, it remains unclear why there have been only four clusters of transfusion-transmitted dengue despite high viremic levels in donors. It is likely that cases are missed, but also that the degree of illness caused when transmission does occur may be less than anticipated. Dr. Stramer provided data on the 2005 to 2007 chikungunya outbreak in La Reunion Island in the Indian Ocean, the 2006 experience in Italy, and the expanding outbreak in the Caribbean with more than 750,000 cases reported, including 11 locally transmitted cases in Florida. She also touched on mitigation measures including deferral for potential autochthonous exposures in Puerto Rico, pathogen inactivation, nucleic acid testing (NAT), and donor travel deferrals. Roger Y. Dodd, PhD, who recently retired from ARC, discussed WNV, noting that while there have been no new developments in transfusion safety aspects relating to WNV, transfusion-transmissions remain exceptionally unusual, testing algorithms continue to evolve, and the spread of the disease requires close monitoring. Harvey Alter, MD, from the National Institutes of Health, wrapped up the session with a presentation on HEV, the most common cause of acute hepatitis worldwide. HEV is responsible for 20 million incident infections, 3 million acute case, and 700,000 fatalities each year. While there have been very few documented cases of transfusion-transmitted HEV, concern has risen over this pathogen in the blood community. While HEV was once thought to be acute, self-limiting, and occurring only in the developing world – it has appreciable incidence in the developed world. Furthermore, HEV can cause persistent infection in immunosuppressed patients and cause cirrhosis in those chronically infected. Dr. Alter referenced a retrospective prevalence and transmission study published earlier this year of 225,000 donors in England that revealed 79 (1 in 2848) HEV RNA positive donors. Of the 43 patients who received components from those donors, 18 (42 percent) became infected with HEV. Dr. Alter concluded by posing the question "Should blood donors be screened for HEV RNA?" Many questions remain to be answered before donor screening could be implemented, such as the duration of asymptomatic viremia in donors, the minimal infectious dose, how often that dose is exceeded in healthy donors, and the performance and regulatory status of donor screening assays. He added that answers may lie in large, prospective studies, but such studies are difficult and costly. (Source: AABB.org Annual Meeting 2014 coverage, 10/26/14; AABB Annual Meeting session (9102-S-HEM)

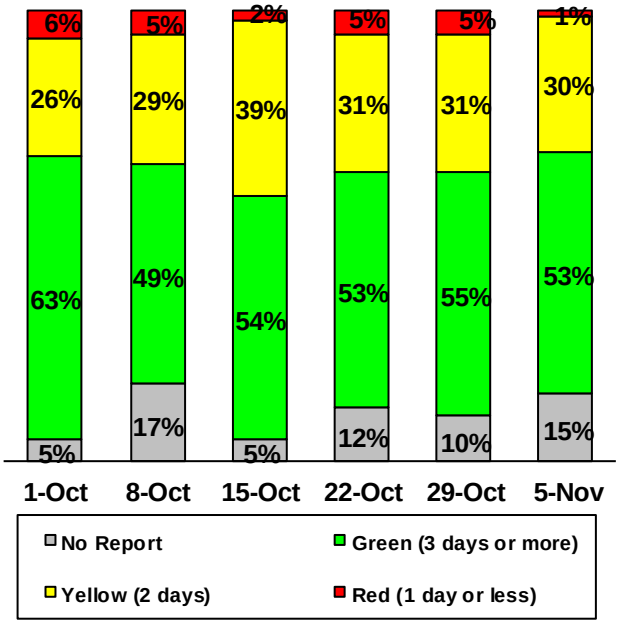
SPORADIC CREUTZFELDT-JAKOB DISEASE

The American Red Cross (ARC) and the Centers for Disease Control and Prevention reported in an abstract at the AABB Annual Meeting in Philadelphia on 20 years of sporadic Creutzfeldt-Jakob Disease (sCJD) lookback. In 1995, ARC and CDC initiated a lookback study to assess the risk of transfusion-transmitted sCJD, reported Deanna Flynn, MPH, of ARC, and colleagues. They have identified 54 sCJD blood donors who have been linked to 666 enrolled transfusion recipients. There have been no cases of sCJD among the recipients. "The results of this ongoing lookback study continue to show no evidence of transfusion transmission of sCJD," concluded the authors. "Along with other epidemiological studies and in contrast to variant sCJD, these data support the conclusion that the risk, if any, of transmission of sCJD by blood products is extremely rare."

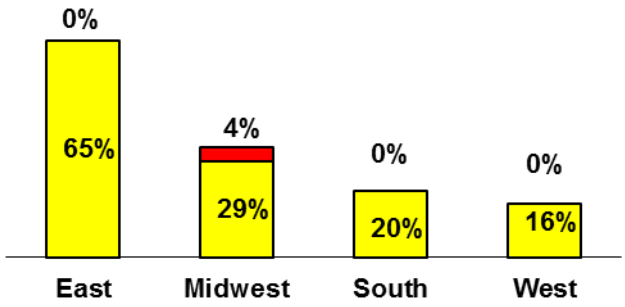
Citation: Flynn D, *et al*. Twenty years of the Creutzfeldt-Jakob Disease look-back study: no evidence of transfusion transmission. Transfusion 2014:54 Supplement: 28A

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, November 5, 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

The Blood Center, headquartered in New Orleans, La. and serving south Louisiana and Mississippi, is joining nine other independent blood centers in the Alliance for Community Transfusion Services (ACTS). A hybrid collaboration of independent blood centers throughout Texas, Oklahoma, Florida and Louisiana, ACTS members aim to collaborate in their approach to strengthening relationships between community blood programs and local hospitals. "We look forward to collaborating with other strong, community-centered blood centers in the Alliance to help improve our own operations," said Billy Weales, president and CEO of The Blood Center. "Pooling resources and ideas through ACTS will strengthen our resilience in facing the intensifying challenges in our industry." The Alliance's philosophy is that excellent service to local hospitals must be cost-effective in today's climate of dynamic change in the healthcare industry. "The industry's push toward increased access to care while reducing costs means that community blood centers must be adaptable and efficient in services offered. In the ever-evolving healthcare industry, The Blood Center strives to remain on the leading edge of technology and services. Partnering in ACTS is another tool to help The Blood Center maintain its mission to the community," stated a press release from The Blood Center. (Source: The Blood Center press release, 11/3/14)

THE BLOOD CENTER
Serving you for life!

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MEMBER NEWS (continued from page 16)

Fred Hamilton, of the Breast Cancer Eradication Initiative, presents Lifeblood President and CEO Susan Berry-Buckley with a check supporting breast cancer awareness efforts.

Lifeblood, headquartered in Memphis, Tenn., received a $4,500-check on Oct. 24 from the Breast Cancer Eradication Initiative (BCEI) for its efforts in raising breast cancer awareness in the mid-south region, the blood center announced in a recent press release. This marks the fifth consecutive year that Lifeblood has received the grant to support the purchase of breast cancer awareness shirts for blood donors in spring 2015. Access to a safe and sufficient blood supply is important for cancer patients, who often use blood products during their treatments. A longtime supporter of Lifeblood, BCEI organizes the Pink Ribbon Open, an LPGA Pro-Am golf event that will take place in April 2015. Proceeds from the golf tournament fund breast cancer research, education, and treatment. (Source: Lifeblood press release, 10/24/14)

BloodCenter of Wisconsin's Diagnostic Laboratories announced in an Oct. 30 press release the availability of a comprehensive cancer mutation HemOnc Panel, using next generation sequencing technology. The next generation sequencing (NGS) panel developed by BloodCenter of Wisconsin is designed to detect variants in 30 genes that are either prognostic or diagnostic for 10 different myeloid hematologic malignancies. Genetic profiling of hematologic malignancies through NGS is transformative technology for cancer diagnostics and patient care. "NGS technology is revolutionizing how genetic information is utilized for optimal cancer patient care," said Matthew Anderson, MD, PhD, medical director for BloodCenter of Wisconsin's Diagnostic Laboratories. "With NGS we can sequence millions of fragments of tumor DNA simultaneously, providing more comprehensive information to physicians more rapidly, at a lower cost." BloodCenter's NGS HemeOnc panel interrogates more regions of the genome, focusing on targets that are relevant to particular cancers. "Using NGS technology, BloodCenter can use one assay to detect the genetic changes in 30 gene targets that may be present in a patient's tumor," said D.P. Dash, PhD, director of BloodCenter of Wisconsin's Molecular Oncology Laboratory. "Our primary focus is on hematologic malignancies such as acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), and myeloproliferative neoplasms (MPN). The panel provides oncologists and pathologists comprehensive information that can support diagnosis, prognosis and risk stratification, and may support the use of targeted therapy." As part of the diagnostic report, BloodCenter of Wisconsin will also provide additional clinical data which can assist physicians in providing more personalized patient treatment. The enhanced report includes information on Food and Drug Administration approved therapies and relevant clinical trials that can be critical for optimal patient care, said BloodCenter in a press release. "Physicians need that information to more efficiently manage their patients," said Dr. Anderson. "From a physician's perspective, it is a tremendous value to have not only the mutational status of the tumor, but all the relevant clinical data contained in a single report." More information about the HemOnc Panel can be found at http://prn.to/1xb6Mmq. (Source: BloodCenter of Wisconsin press release, 10/30/14)

PEOPLE

Lynne Uhl, MD, division chief of the Department of Laboratory and Transfusion Medicine at Beth Israel Deaconess Medical Center in Boston, officially became the 2014-2015 AABB president during the closing session at the AABB Annual Meeting last week. Dr. Uhl took the reins from Graham Sher, MD, PhD,

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CEO of Canadian Blood Services, who served as AABB president from 2013 to 2014. Dr. Uhl emphasized hemovigilance as an important goal of the association in 2015. She has years of experience in hemovigilance in her current position at Beth Israel Deaconess Medical Center, an early member of the AABB Center for Patient Safety. AABB also welcomed the newly approved 2014-2015 board of director members, including:

- President-Elect: **Donna Regan, MT(ASCP)SBB**, director of the St. Louis Cord Blood Bank and Cellular Therapy Laboratory at SSM Cardinal Glennon Children's Medical Center;
- Vice President: **Zbigniew Szczepiorkowski, MD, PhD, FCAP**, associate professor of pathology and of medicine at Geisel School of Medicine at Dartmouth;
- At-Large Director 2: **Susan Roseff, MD,** chair of the Division of Clinical Pathology and medical director of Apheresis at the Virginia Commonwealth University Health System;
- At-Large Director 4: **Susan Johnson, MSTM MT, (ASCP)SBB**, director of the clinical education program at BloodCenter of Wisconsin;
- At-Large Director 6: **Jeannie Callum, MD, FRCPC**, director of transfusion medicine and tissue banks at Sunnybrook Health Sciences Center in Toronto;
- At-Large Director 8: **E. Mary O'Neill, MD,** vice president for the American Red Cross Patient Services; and
- At-Large Director 10: **Steven Frank, MD**, an anesthesiologist at The Johns Hopkins University School of Medicine.

AABB members can find more information about the new president and board of directors at http://bit.ly/1z4cE13. (Source: AABB website, 11/6/14)

Trudell Green was recently named laboratory operations manager at Blood Bank of Delmarva (BBD). In her new position, she will oversee the operations of the component preparation lab, testing/processing lab, and distribution. Ms. Green is a registered medical technologist with a Specialist in Blood Banking. She has held various positions at two other blood banks including executive director of Central Texas Regional Blood and Tissue Center in Austin and, more recently, technical director of lab services at Miller-Keystone Blood Center in Bethlehem, Pa. In addition to blood banking, Ms. Green also has experience with national sales, marketing, and quality compliance in the blood industry. She served as a US Peace Corps volunteer in South Africa, working as a capacity development specialist for a non-governmental organization called Nqutu AIDS Committee from 2010 to 2012. Ms. Green has a BA in microbiology with a minor in chemistry, as well as a BS in medical technology from the University of Texas. (Source: Blood Bank of Delmarva press release, 10/31/14) ♦

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.

Q&A with ASBP Lifetime Achievement Award Winner Jerry Holmberg

Retired Navy Cmdr. Jerry Holmberg, PhD, director of Scientific Affairs at Grifols, was recently honored with the Armed Service's Blood Program's (ASBP) 2014 Lifetime Achievement Award (see *ABC Newsletter*, 10/24/14). Dr. Holmberg was recognized for this achievement alongside fellow award recipient retired Air Force Lt. Col. Ruth Sylvester during the AABB Annual Meeting last week (see page 8). Dr. Holmberg has more than 43 years of experience in all areas of laboratory medicine with a concentration on blood bank operations, research, education, and policy.

The *ABC Newsletter* conducted an interview with Dr. Holmberg to gain his unique perspective on how the blood banking industry has changed during his 43 years of service and what the future may hold.

What drew you to the military blood service?

Dr. Holmberg: I had been involved with laboratory medicine for years before entering the military blood service. In fact, I started working in the lab when I was 16 years old, and there was always an interest there. A lot of people don't realize, I taught for six years at a university before entering the military. I worked with an Army colonel who talked to me about the advancements going on in Navy medicine, and I felt there was really an opportunity to advance my education through the military blood service. I realized the realm of opportunities' in blood banking.

What have been some of the greatest advancements you've seen over the course of your career?

Dr. Holmberg: I've seen numerous advancements in the layers of safety in place to protect the blood supply. For instance, when I started in the field, the only two [blood safety] tests required were for hepatitis and syphilis, as well as ABO and Rh blood type screening. Of course, going through the AIDS epidemic in the early '80s really crystalized the concern about protecting the blood supply from emerging infectious diseases. Any of us who lived through that period of time really want to make sure that we never see that happen again.

We are constantly asking ourselves, "How do we maintain the safety of the blood supply? How do we make sure we're doing everything that we can?" With the AIDS epidemic came not only screening the blood supply but also screening of active duty service members to make sure they weren't transmitting infectious diseases. I saw the implementation of total force testing as well as screening of the blood supply. I've been able to see the influence that blood banking has on public health …

What types of advancements have you seen in terms of donor health and donor relations?

Dr. Holmberg: Globally, we've done a lot with communicating with the donor, informing the donor, and encouraging the younger generation to donate blood … As all of us get older, we rely on the younger generation and it's really important for that generation to see that they do have a community responsibility.

Looking back at your career thus far in blood banking, of what accomplishments are you proudest?

Dr. Holmberg: I hope that people appreciate the coordination efforts that I've made to bring people and organizations together for the advancement of science. Personally, I take pride in some of the research

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I've done on frozen red cells and platelets, as well as my work in biovigilance and hemovigilance. One thing that I wish I could have done more with is with hemovigilance, but I think that it is started down the right path and it will continue. I see hemovigilance blossoming around the world. If we want to maintain the safety of the blood supply we have to have an active hemovigilance system.

What do you feel are the greatest challenges facing the blood industry in general?

Dr. Holmberg: The biggest challenge is trying to find an agent that could be used for pathogen reduction of red blood cells. We need to find an agent that would be gentle enough on the red blood cell membrane, but effective enough to reduce pathogens for whole blood treatment.

Along those lines, what industry development(s) do you think will have the greatest impact on blood safety moving forward?

Dr. Holmberg: I believe the blood supply is safe in the US. We have a very safe blood supply, and so now the question is "How do we maintain that safety?" In light of all the emerging infectious diseases at our doorstep – Babesia, chikungunya, dengue virus, hepatitis E virus … I think that pathogen reduction offers a hope for future improvements in blood safety. Perhaps in the future, we won't have to be chasing the next emerging infectious disease, but rather could eliminate these risks with pathogen reduction.

You have been very active in working on blood safety issues abroad through the US President's Emergency Plan for AIDS Relief (PEPFAR). What motivates you to stay active in global blood safety?

Dr. Holmberg: Personally, I feel that I've been blessed with so much and I have a responsibility to give back. When I first began working with PEPFAR in Zambia, I was working in an orphanage, and each one of these children were orphans of HIV. … Just being around the children of Africa and realizing that there was a responsibility, a global responsibility that all of us have, just really stimulated me and has kept me focused on this work over the years. And having my own grandchildren, I'm also realizing that my children and grandchildren could be patients at some point. It really has influenced me to ensure the safety of the blood supply, no matter where you go in this world, is adequate. It's just realizing how much we owe back that makes me really feel a sense of global commitment.

MEETINGS

Dec. 2-3 **FDA Blood Products Advisory Committee Meeting, Silver Spring, Md.**

The Food and Drug Administration will hold a meeting of its Blood Products Advisory Committee (BPAC) from Dec. 2 to 3 at its White Oak Campus in Silver Spring, Md. On Dec. 2, BPAC will hear scientific data regarding the current blood donor deferral policy for men who have sex with men (MSM), including an update from the HHS Advisory Committee on Blood and Tissue and Availability (ACBTSA). There will also be presentations on the emergence of chikungunya virus in the Western Hemisphere and its implications for blood safety, as well as on the first survey of the Rapid Donor Surveillance project on Middle Eastern Respiratory Syndrome coronavirus. On Dec. 3, the committee will discuss the appropriate classification for blood establishment computer

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MEETINGS (continued from page 21)

software and accessories. The meeting will be available via webcast. More information is available in the Federal Register notice at http://1.usa.gov/1snaq8G.

March 20 **International Blood Safety Forum, Washington, D.C.**

Global Healing will hold the International Blood Safety Forum in conjunction with America's Blood Centers' Annual Meeting at the Ritz Carlton, Pentagon City on March 20. Participants will learn about the ways various national blood systems overcome seemingly insurmountable challenges on a daily basis to provide reliable, safe blood to patients. Stay tuned for more details! For more information, e-mail contact@globalhealing.org. ♦

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

Director of Hospital Services. Michigan Blood is looking for a Director of Hospital Services to join our management team and lead statewide efforts to provide remarkable service to our 40 plus hospital partners across the state. We are a growing blood center with more than fifty years of service to Michigan communities that rely upon more than 100,000 voluntary blood donations annually to serve those partners. This position is responsible for the operational functions of blood products inventory management, component processing, order preparation and fulfillment, and courier services. Through a team of laboratory supervisors and professionals, you will develop and execute strategies to lead a team that will enhance our services through those processes. This position requires a bachelor's degree. Master's degree preferred. Five to 10 years of laboratory, GMP or related experience required. Healthcare business leadership experience preferred. Experience working with FDA and EU agencies is desired. We offer a competitive salary and benefit plan. If you want to be part of a lifesaving organization with a dynamic mission, please apply via our website: www.miblood.org. EOE

Business Development Manager. LifeStream, a blood center located in Southern California, serving 80 hospitals with 200,000 blood products annually, is searching for a Business Development Manager. Under broad direction: assists in the formulation and implementation of corporate strategic and business development programs to ensure the best use of LifeStream's resources in accord with objectives for growth and profitability; develops and implements the organization's sales strategies; handles special projects as assigned by the VP/Business Development. The candidate must have a four-year bachelor's degree (BA or BS). Advance degree desired. Minimum five years' experience in healthcare, pharmaceutical, medical products or blood center setting. Must have exceptional interpersonal communicative skills developed and cultivated through extensive customer sales or service experience. Current California driver's license. Please visit www.LStream.org to view the full job description and position responsibilities. LifeStream has an excellent compensation & benefits plan. For further information and to apply online please visit: www.LStream.org. Or fax cover letter, resume and salary history to (909) 386-6813. Must pass pre-employment background check, drug screen and physical exam. LifeStream is an Equal Opportunity Employer, M/F/D/V. Job Number: IN-4193265708

Hospital Relations Manager. LifeStream, a blood center located in Southern California, serving 80 hospitals with 200,000 blood products annually, is searching for a Hospital Relations Manager. Serves as a technical resource for customer transfusion services: answering questions, providing training, and other support related to LifeStream's products and services. Also is a primary customer service contact, working to improve services,

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resolve any service issues, and build stronger relationships with customers. Promotes LifeStream programs. Ensures excellent service is provided to hospitals and other customers. The candidate must have a four-year bachelor's degree (BA or BS) in biological sciences or medical related discipline, with MT (ASCP) or equivalent. SBB desirable. Minimum four years' experience in Blood Banking or five years in hospital laboratory with transfusion service experience, (or equivalent). Must have exceptional interpersonal communicative skills developed and cultivated through extensive managerial and customer service experience. MT (ASCP) or equivalent is required. California CLS license not required. Current California driver's license required. LifeStream has an excellent compensation & benefits plan. For further information and to apply online please visit: www.LStream.org. Or fax cover letter, resume and salary history to (909) 386-6813. LifeStream is an Equal Opportunity Employer, M/F/D/V. Job Number: IN-4193265212

Executive Director Donor Relations. The Institute for Transfusion Medicine (ITxM) is proud to be an integrated blood center servicing multiple states. The Executive Director Donor Relations can be based in Pittsburgh, PA, Chicago, IL, or Richmond, VA. The Executive Director Donor Relations is responsible for the management direction of the Donor Relations Department to ensure that departmental activities support the achievement of organizational goals and that the department policies and procedures are in compliance with regulatory agencies, in accordance with current good manufacturing practices and safety guidelines. The Institute for Transfusion Medicine offers a competitive salary, commission plan, and benefits package. Apply online at: www.itxm.org. *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

Regional Director, Oregon and Southwest Washington Blood Program (OSWBP). The Oregon and Southwest Washington Blood Program, an extension of Puget Sound Blood Center, is proud to be the local, independent blood center for the region. Through our partnerships, we have a far-reaching, long-term presence throughout the Northwest. Every day we work to save lives through research, innovation, education, and excellence in blood, medical and laboratory services. We have served donors and patients in partnership with our community for 70 years. Requirements include: bachelors' degree business management, organizational development, health sciences, public relations or equivalent combination of education and relevant experience (MBA preferred); blood banking experience highly desirable, seven years' experience and demonstrated success in community outreach, development or multi-location healthcare management; outstanding written, verbal, interpersonal, facilitation, negotiation and conflict resolution skills. More information at www.psbc.org. Qualified applicants send resumes to humanresources@psbc.org Attention: Job #7414ABC. Puget Sound Blood Center is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law.

Manager, Blood Collections Operations - Job #7416. For more than 70 years, Puget Sound Blood Center has had a far-reaching presence throughout the Puget Sound Region. We have proudly served donors and patients in partnership with our community. Based in beautiful Seattle, Wash., we are seeking a dynamic, experienced leader to join our Blood Collections department, taking responsibility for the team that provides Quality, Training, Process Improvement and Operational support to the team that provides the core function of our mission. Requirements include: bachelor's degree in Health Science related field; or equivalent combination of education and work experience. Registered Nurse License (Washington State) preferred; three to five years supervisory/management experience with proficiency in technical, leadership and team building skills required, previous blood banking experience preferred. More information at www.psbc.org. Qualified applicants send resumes to humanresources@psbc.org Attention: Job #7416ABC. Puget Sound Blood Center is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law.

Program QA Coordinator (Medical Services (Medical Apheresis) Department). Gulf Coast Regional Blood Center has a great opportunity for an experienced Program Quality Assurance Coordinator in its Medical Services area. The position reports directly to the Medical Director and manages all aspects of the quality and

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compliance activities related to the National Marrow Donor Program Donor and Apheresis Centers and Medical Apheresis programs. This is an excellent position for someone interested in using project management skills in a regulated healthcare work environment. Requirements for this job are bachelor's degree (preferably in healthcare) from an accredited college or university and a minimum of three years' experience in compliance or coordination of organ or other tissue transplant programs or equivalent combination of education and experience. Apply at www.giveblood.org today! The Blood Center is an Equal Opportunity Employer. Qualified applicants for positions are considered without regard to race, color, religion, sex, national origin, age, disability, status as protected veteran or other characteristics protected by law.

Medical Director. BloodCenter of Wisconsin is currently seeking a physician to join their growing Hematology service of the Medical Sciences Institute. This position is based in Milwaukee, WI. In direct partnership with the Directors of the Platelet and Neutrophil Immunology Laboratory and Hemostasis Laboratory, this position provides clinical and scientific direction to include case review, clinical consultation, and associated assay development. We will rely on you to work effectively with the Medical Director and VP of Diagnostic Laboratories and the Scientific Director of the Platelet and Neutrophil Immunology Laboratory to define research and development priorities, validate and implement new assays, and to provide leadership and management to the laboratory. This position actively participates in the activities of the Medical Sciences Institute. BloodCenter offers a competitive salary, commission plan, and benefits package. Learn more and apply online at www.bcw.edu. Equal Opportunity Employer of Minorities, Females, Protected Veterans, and Individuals with Disabilities.

Director of Product Management. Be a part of a dynamic and forward thinking blood center in this changing healthcare environment! This position is based in Milwaukee, WI. This position is responsible for the integration of manufacturing, inventory management, and distribution and customer service operation. This key role also assures that the manufacturing and distribution processes for blood products are performed in compliance with regulatory and organizational requirements. We will rely on you to assure customer satisfaction, operational/cost effectiveness, and quality results. The ideal candidate will have a bachelor's degree, a minimum of five years of current management experience in a regulated environment to include operational, logistical, financial and human resource responsibilities. Successful candidates will have the ability and desire to learn the basic science encompassed within the operations coupled with skills and ability in inventory management, distribution, and customer service. 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.

Senior Manager Transfusion Services (Westchester, New York). At New York Blood Center, one of the most comprehensive blood centers in the world, our focus is on cultivating excellence by merging cutting-edge innovation with diligent customer service, groundbreaking research, and comprehensive program and service development. Reporting to the Senior VP/Chief Medical Officer, you will oversee our strategic expansion goals and the overall operations/administration for our Transfusion Services laboratories located in Elmsford, NY. Responsibilities include: Ensuring compliance with FDA, NYSDOH, CAP, AABB, Joint Commission (TJC), preparing performance improvement plans, developing schedules and monitoring work to staff, implementing productivity standards, training clinical pathology residents, hematology fellows and NYBC fellows, initiating, coordinating and enforcing systems, policies and procedures and participating in hospital contract negotiations. Qualified candidates must have a BS in Medical Technology, MT (ASCP) or equivalent, NYS Clinical Laboratory License, 10 plus years of clinical laboratory experience, three years management experience within a clinical laboratory environment. The ability to develop/manage budgets, familiarity with AABB standards, NYSDOH regulations, CAP guidelines and JCAHO requirements, and Transfusion Service Departmental SOPs. Superior leadership, communication, and PC skills are required. MBA/MPH/SBB preferred. We offer a competitive compensation package and dynamic work atmosphere. Apply online at: http://bit.ly/1omJl9v. EOE AA M/F/Vet/Disability

Reference Laboratory Technologist. Mississippi Valley Regional Blood Center (MVRBC) has an exciting opportunity in our St. Louis, MO facility for a Reference Laboratory Technologist to work in our Reference Department performing antibody testing, antigen typing, and providing consultation to hospital staff as needed. This position is full time with a working schedule of Monday through Friday 3:00 pm to 11:00 pm, including on-call rotation for weekends and holidays. Candidates will possess MT/MLS certification with ASCP or equivalent. SBB a plus, but not required. Ideally, candidates will have three years of blood banking experience in the past five years. Interested candidates may visit www.illinoisdiversity.com/j/8857831 to apply. EOE: M,W,V,D

Donor Relations Consultant. Mississippi Valley Regional Blood Center has an exciting opportunity for a Donor Relations Consultant to develop strong relations with community organizations for hosting mobile blood

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drives. The ideal candidate will have strong communication and organizational skills, a demonstrated ability to obtain measurable goals, solid customer service experience, previous business to business experience, and the ambition to motivate others. This position requires an individual who is confident in public speaking; media relations experience is a plus. This is a full-time position working Monday through Friday with occasional evenings and weekends. A bachelor's degree or equivalent combination of experience and education is required; preferred studies include business, communications, marketing, or sales. Must possess a valid driver's license, be insurable by MVRBC's insurance carrier, and be willing to drive within the MVRBC service area. Interested candidates may visit www.illinoisdiversity.com/j/8601040 to apply. EOE: M,W,V,D

Manager/Director, IRL & Molecular Laboratory. The San Diego Blood Bank is a progressive company with outstanding service and leadership in the blood banking industry. Synergies between SDBB, the community, the biotechnology industry and academic institutions allow us to save lives with quality blood services, innovative clinical research, new technologies, and health & wellness. With proactive and aggressive new approaches to core business, research, and sophisticated technology, SDBB is where you want to be! Immediate opening: Manager/Director, IRL & Molecular Laboratory. Responsibilities include: Investigation of complex red cell antibody problems and molecular determination of red blood cell antigens for hospital laboratories, testing and consultation to hospitals with patients refractory to platelets, implementation of new molecular technology and testing platforms and collaborative partnership with biotech researchers. Candidate Qualifications: BS or Master's degree, MT, SBB - (ASCP), CA CLS license (or eligible) and three to five years IRL and management experience. To apply or learn more visit: http://bit.ly/1sQmXF5 or call (619) 400-8271.

IRL & Molecular Med Tech (Night shift). The San Diego Blood Bank (SDBB) is a progressive company with outstanding service and leadership in the blood banking industry. Synergies between SDBB, the community, biotechnology industry and academic institutions allow us to save lives with quality blood services, innovative clinical research, new technologies, and health & wellness. With proactive and aggressive new approaches to core business, research, and sophisticated technology, SDBB is where you want to be! Immediate opening: Night shift - IRL & Molecular Med Tech. Responsibilities include: Investigation of complex red cell antibody problems, molecular determination of red cell antigens for hospital laboratories, testing and consultation to hospitals with patients refractory to platelets, implementation of new molecular technology and testing platforms and collaborative partnership with biotech researchers. Candidate Qualifications: BS or Master's degree, MT, SBB - (ASCP), CA CLS or CIS license (or eligible), and three to five years IRL experience. To apply or learn more visit: http://bit.ly/1waJA7p or call (619) 400-8271.

Blood Center Laboratory & Production Manager. LifeServe Blood Center is seeking senior level candidates to oversee operations of our Hospital Services department. This position is responsible for oversight, development, and implementation of lab functions, such as testing, product management, manufacturing and distribution. This position is responsible for the direct management of a team focused on customer service, testing and distribution. Primary responsibilities: Streamline operations, create/meet department budget, drive performance to meet department and quality metrics, develop/implement process improvement initiatives, and comply with all employee training and accreditation requirements. Education/Experience: Bachelor's degree in Business Administration, Biology or related field, MT, MLS or MLT preferred, two to three years of management experience required in production environment, blood banking or laboratory setting preferred, and experience in lean manufacturing or six sigma highly recommended. Other Requirements: Employment offers - contingent on the successful completion of pre-employment, post offer drug testing and background checks. LifeServe is fully committed to EEO. All applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, age, sexual orientation, gender identification, genetic information, marital status, pregnancy, disability, veteran status or any other legally protected status. Interested applicants should visit our website, www.lifeservebloodcenter.org to apply. Click "Join our Team".