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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2014 #20 **May 30, 2014**

INSIDE:

Survey: Most Patients, Physicians View Transfusion as Risky

Despite major advances in transfusion safety, the results of a recent survey conducted at the University of Alabama at Birmingham (UAB) show that 20 percent of patients and at least 27 percent of their anesthesiologists or surgeons perceive transfusion as being very often or always risky. The study and an accompanying editorial call on physicians to help patients take a more active role in their transfusion care.

Furthermore, the survey results, published in the June issue of *Anesthesia Analgesia,* show that patients and physicians differ in their perceptions about transfusion-related risk and complications. Thomas R. Vetter, MD, MPH, and colleagues of the UAB Department of Anesthesiology, found that patients and physicians often misunderstand the actual level of risk associated with various transfusion-related adverse events, suggesting both groups would benefit from education on adverse transfusion complications and the benefits of transfusion.

Patients have begun to take a more active role in their health care over the last several years with the rising adoption of "patient-centered care," in which the patient partners with the physician to make clinical decisions that are responsive to the individual patient's preferences, needs, and values. Providing patient-centered care in the realm of transfusion medicine requires that clinicians understand their patient's perceptions of transfusion and be capable of educating patients about transfusion to make a shared decision about this treatment, write Vetter and colleagues.

To investigate the factors associated with surgical patients' perceptions of blood transfusion, the researchers surveyed a cross-section of patients and physicians about their transfusion-related knowledge and attitude. They were asked to rate their perceptions of overall transfusion risk and of five specific transfusion-related adverse events: transfusion related-adverse reaction, fever, dyspnea (difficulty breathing), HIV/AIDS/hepatitis, and medical error. Dyspnea was used as a proxy for adverse events like transfusion related acute lung injury [TRALI] and transfusion associated circulatory overload [TACO]).

The researchers received responses from 294 patients and 73 physicians, and found that 20 percent of patients perceived blood transfusion as "very often" or "always" risky. Perceptions of risk varied by certain patient characteristics. African American race and having a high school or less level of education were associated with greater perceived overall risk, as well as greater concern about

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OUR SPACE

Celso Bianco, MD, ISBT's President-Elect

The Catchphrase Patient Blood Management has Been Hijacked!

Appropriate transfusion is good for patients. Blood transfusion saves lives every day. However, benefits of transfusion are not included among the data collected by patient blood management (PBM) and hemovigilance programs. We need to develop indicators and count successes of transfusions therapy.

In the early days, blood was scarce because of limited storage and preservation technologies. Blood bankers were the only professionals recommending sparing use of blood products, while physicians encouraged transfusions that made their patients get better and feel better.

AIDS shattered our view of transfusion safety, prompted randomized trials that provided evidence supporting a conservative approach to blood use and the birth of hemovigilance in France and Serious Hazards of Transfusion (SHOT) in the UK, programs that quantified recognizable risks. Together with AABB, the Centers for Disease Control and Prevention developed the National Healthcare Safety Network Hemovigilance Module to collect data on transfusion-associated adverse events.

Observational studies and clinical trials continue to examine adverse outcomes. In the US, fear spurred "bloodless medicine," previously reserved for patients who rejected transfusions because of religious convictions. Professional societies have prepared restrictive guidelines for transfusion of blood components. Informed consent forms for patients emphasize potential risks and barely address potential benefits; a survey at the University of Alabama at Birmingham reviewed on the front page of today's *Newsletter* concludes that "a sizable percentage of patients still perceive transfusion as having significant associated risk."

Obviously, lower use means lower costs for hospitals and lower costs encourage adoption of blood utilization measures. Hospital administrators, healthcare economists, and consultants are happy since PBM is a physician-supported activity. Unfortunately, they are counting only adverse events, not lives saved or improved outcomes. The only outcomes reported by adverse event databases are suboptimal ones and the foregone conclusion that blood is bad. The only conclusion that can be extracted from Food and Drug Administration reports on transfusion-associated fatalities is that "blood still kills."

Tragically, adverse events based observational and clinical trial data encourage restrictive transfusion policies, and the popular yardstick for success of PBM for transfusing physicians and administrators is a reduction in the number of transfused products (the low hanging fruit), not data on transfusion-associated benefits for patients, which are difficult to collect. It is sad that many of the recommendations for use of blood as a therapeutic resource and some PBM guidelines focus on what SHOULD NOT be done, rather than what SHOULD be done. Appropriate transfusion is good for patients! We urgently need to identify, develop, and incorporate true measures of transfusion success in PBM and hemovigilance programs to provide a balanced view of transfusion medicine.

– *Celso Bianco* celso@txmedicine.com

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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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Perceptions of Transfusion (continued from page 1)

allergic reaction, fever, and dyspnea. Having a high school or less level of education was significantly associated with a greater concern about HIV/AIDS and medical error.

The results showed that anesthesiologists and surgeons perceive transfusion risk to be greater than do their surgical patients – with 27 percent reporting it is very often or always risky. However, the authors also found that the physicians' reported levels of concern about the five specific transfusion-associated adverse outcomes were lower than their patients, suggesting physicians may have other significant concerns not represented in this is survey.

Both physicians and patients displayed knowledge gaps regarding adverse transfusion events, as both groups overestimated the risk of transfusion-related fever, allergic reaction, or hemolytic transfusion reactions. Patients reported a greater level of concern about HIV/AIDS or hepatitis and perceived that these reactions occurred more frequently than did their physicians.

The authors suggest that for patients to take an active role in their care and knowledgably sign consent forms regarding transfusion, they must be presented with current data on transfusion risks. They noted that future research should investigate whether offering this information reduces patients' perceptions and concerns about transfusion risk and improves their transfusion-related knowledge and satisfaction with their health care. They also suggest that physicians should undergo appropriate training about patient-centered decision-making, including that regarding transfusion. Educational brochures about transfusion could also help to increase a patient's preoperative knowledge about this treatment with minimal cost, write the authors.

"Understanding patients' perceptions of blood transfusion and, ultimately, identifying demographic groups with specific concerns will better enable healthcare professionals to address patient-specific risk during the informed consent process," conclude Vetter and colleagues. "Therefore, physicians will be able to inform their patients of all available alternative therapies, and to recommend blood management in accordance with the individual patient's values, beliefs, and fears or concerns."

Paloma Toledo, MD, MPH, of the Institute for Public Health and Medicine at Northwestern University, agrees with the study authors that some type of evidence-based decision aide, like a brochure, would be helpful in allowing patients to make informed, value-based decisions about transfusion.

"At a minimum, if such a decision aide was developed for blood transfusions, patients and physicians would be sharing the same knowledge, and this would hopefully result in patients making truly informed decisions about blood transfusion therapy, bringing us one step closer to high-quality, patient-centered care," writes Dr. Toledo.

Citations: Vetter TR, *et al*. Perceptions about blood transfusion: a survey of surgical patients and their anesthesiologists and surgeons. Anesth Analg. 2014 June;118(6):1301-8.

Toledo P, *et al*. Shared decision-making and blood transfusions: is it time to share more? Anesth Analg. 2014 June;118(6):1151-3.

ABC Reminds Blood Centers to Participate in Disaster Preparedness Activities

Last year saw its share of disasters and emergencies that impacted healthcare organizations and 2014 began with an unusually harsh winter in many parts of the country. With spring being ushered in by severe weather and hurricane season just around the corner, America's Blood Centers remins blood centers to update and practice their disaster plans.

ABC sent a disaster preparedness update to its member blood centers in the midst of Hurricane Preparedness Week, sponsored by the Occupational Safety and Health Administration (OSHA) and the National Oceanic and Atmospheric Association (NOAA), which is recognized from May 25 to May 31. The update provided several helpful resources for blood centers to use in updating their disaster plans (ABC members can access the update at http://bit.ly/1tqMDF2).

"Now is a good time to review your disaster plans, update them, and communicate those changes to staff through education, training, and disaster drills. Additionally, if you haven't already done so, you should establish dialogue with your local Emergency Management Agencies (EMA) so they know and understand the role that blood and your organization play in a disaster," said Ruth Sylvester, ABC's director of Regulatory Services, who also handles disaster response.

ABC and Blood Centers of America (BCA), which work together for disaster response purposes, have already conducted an annual review of the blood center Disaster Response Plan. The Hub and Spoke list, which is a system used to determine how blood would be delivered during an emergency that impacts the blood supply, has been revised to accommodate recent membership changes. ABC members can read more about these changes in MCN 14-056 at http://bit.ly/1tqMDF2 and can access the Hub and Spoke plan at any time at http://bit.ly/SUqpQz.

"Knowing who to contact when disaster strikes is key to providing the necessary assistance," said Wendy Trivisonno, vice president of Biologic Sourcing and Business Development at BCA. To ensure that contact information is up-to-date, blood centers should complete an online survey, available in the MCN at http://bit.ly/1tqMDF2. This information should be updated any time that a change in staff occurs.

One helpful disaster preparedness tool provided by the Centers for Disease Control and Prevention is the Clinical Outreach and Communication Activity (COCA), which offers current information for clinicians about emerging health threats during emergencies and disasters, including terrorism. A recent COCA update provided links to recordings and slides from a webinar held on Nov. 14, 2013 titled, "Assessing Risk and Strengthening Community-Wide Preparedness" (http://1.usa.gov/TX2XDa). This webinar reviews several tools available to perform all-hazards risk assessment, as required in the Centers for Medicare and Medicaid (CMS) rule noted below, and provides links to helpful resources that blood centers may find useful.

The American Meteorological Society recently published a study titled, "A Prescription for the 21st Century: Improving Resilience to High-Impact Weather for Healthcare Facilities and Services" (http://bit.ly/1rK2vBw). The report, which came out of a workshop held to gather information that would improve resilience for healthcare facilities, focuses on enhancing resilience through risk management.

CMS published a proposed rule on Dec. 27, 2013 titled, "Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers." The proposed rule would revise the Conditions of Participation and establish national emergency preparedness requirements for providers and suppliers that participate in Medicare and Medicaid. While this proposed rule does not apply to most

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Disaster Preparedness (continued from page 4)

ABC members directly, it will apply to the hospitals they serve. Blood centers should anticipate increased planning by hospitals and encourage that they include blood suppliers in their plans. The well-researched proposed rule provides many helpful references and resources that ABC member centers may find useful (http://1.usa.gov/1iu6LFn).

"Disaster plans and planning should be a continual process that is done at least annually to ensure plans are up-to-date and organization leaders and staff are aware of and ready to respond when disaster strikes," said Ms. Sylvester. "As with any plan, a key to success is exercising that plan. Participating in local, regional, or national EMA exercises is one way to test a plan as well as to insert your organization into the local emergency response activities. Another is to conduct table-top exercises within your own organization. When conducting in-house exercises, consider inviting local EMA officials and representatives from your local hospitals as a way of solidifying the relationships necessary when disaster strikes. We are also available to assist anyone with exercise planning."

ABC members can find more information and disaster preparedness resources at http://bit.ly/1gE13kx.

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SAVE THE DATE

America's Blood Centers Information Technology Workshop

Indianapolis, IN – September 16-17, 2014
Hosted by indiana BLOOD CENTER

Negotiated hotel room rate: $159 + tax
http://bit.ly/omni_indianapolis

2014 Workshop Fees (early bird/regular)
2-day registration: $390/$445

Scholarship opportunities available to ABC members to cover the cost of registration fees and help with travel expenses. Application form and details will be made available once registration opens.

"The Indiana Blood Center is looking forward to welcoming ABC members to Indianapolis for the Information Technology Workshop. We anticipate a vibrant dialogue, exchange of ideas and discussions on the time tested best practices used by our member centers. This will be an excellent opportunity to mingle with your peers, meet new people and prepare for the rigors of the changes bound to hit the information technology world. We look forward to seeing you in Indianapolis this Fall."

– Byron Buhner
President and CEO, Indiana Blood Center

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

Indianapolis International Airport (IND) is served by most major US airlines and offers non-stop service to 34 destinations; check *www.indianapolisairport.com* for more information.

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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.

ABC Welcomes Visitors in Washington

America's Blood Centers' board of directors met for two days in Washington, D.C., last week to continue discussions regarding ABC's strategic plan and progress on its strategic initiatives. The board of directors and officers were also able to visit the recently renovated ABC offices on May 22 for a reception with the ABC staff (pictured above).

Last week, AABB CEO Miriam A. Markowitz (second from right) and Theresa Wiegmann, JD, director of Public Policy and special counsel at AABB (right), met with America's Blood Centers' CEO Christine Zambricki, DNAP, CRNA, FAAN (second from left), at the ABC offices in Washington, D.C. to discuss the two organizations' mutual interests. They are joined above by Bill Coenen, ABC's chief financial officer.

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.

RESEARCH IN BRIEF

Research published from the Sanquin Blood Supply Foundation, the blood supplier of the Netherlands, questions the efficacy and cost-effectiveness of autologous blood salvage devices and erythropoietin used to reduce blood transfusion in surgical patients. Patient blood management, which seeks to promote the appropriate use of blood products, may include the use of red blood cell (RBC) transfusion alternatives to reduce the use of blood products during surgery. Erythropoietin and perioperative cell salvage are two techniques used to reduce blood use during surgery, however, both are costly and many studies supporting their efficacy have been small and underpowered. Cynthia So-Osman, MD, PhD, have published the results of two large randomized trials that investigated the cost effectiveness and efficacy in reducing transfusions of these two techniques for elective total hip- and knee-replacement surgery. In one study, they evaluated the use of erythropoietin, cell salvage, and/or postoperative drain reinfusion devices on allogeneic RBC transfusion, while using a restrictive transfusion threshold. In a factorial design, the adult patients with hemoglobin levels of 10 to 13 g/dL were randomized to erythropoietin or not, and subsequently for autologous reinfusion by cell salvage or postoperative drain reinfusion devices or for no blood salvage device. They analyzed mean allogeneic intra- and postoperative RBC use and the transfusion rate, as well as cost-effectiveness, in 2,442 patients. With erythropoietin, mean RBC use was 0.50 units per patient and the transfusion rate was 16 percent, while without erythropoietin, 0.71 units per patient were transfused and the transfusion rate was 26 percent. Erythropoietin resulted in a non-significant 29 percent mean RBC reduction and 50 percent reduction of transfused patients. Erythropoietin increased costs by €785 (≈ $1,068.70) per patient – or €7,300 (≈ $9,938.22) per avoided transfusion. With autologous reinfusion, mean allogeneic RBC use was 0.65 units per patient and the transfusion rate was 19 percent with erythropoietin and 0.76 units per patient and 29 percent without erythropoietin. Compared with controls, autologous blood reinfusion did not result in RBC reduction and increased costs by €537 (≈ $731.07) per patient. The authors conclude that erythropoietin with a restrictive transfusion policy contributed to a reduction in RBC transfusion, but at an unacceptable cost. "No clinically relevant decrease in RBC transfusion was found by using autologous blood salvage or DRAIN [postoperative drain reinfusion devices], which consequently only increased costs," they added. In a second study, the researchers conducted a randomized study on the integrated use of RBC, cell saver, and/or postoperative reinfusion devices and allogeneic RBC use, with a restrictive transfusion threshold. Patients were randomized to autologous reinfusion by cell saver or DRAIN, or no blood salvage. They analyzed the mean intra- and post-operative RBC use and the transfusion rate and cost-effectiveness. In 1,759 total hip- and knee-replacement patients, the mean RBC use was 0.19 RBC units per patient in the salvage group and 0.22 in the control group. The transfusion rate was 7.7 percent in the autologous group compared with 8.3 percent in the control group. No difference in RBC use was found between the cell saver and DRAIN groups, while the cost increased by €298 (≈ $401.61) per patient. They conclude that "intra- and postoperative blood salvage devices were not effective as transfusion alternatives" and the "use of these devices did not reduce RBC use and increased costs."

Citations: So-Osman C, *et al*. Patient blood management in elective total hip- and knee-replacement surgery (Part 1): a randomized controlled trial on erythropoietin and blood salvage as transfusion alternatives using a restrictive transfusion policy in erythropoietin-eligible patients. Anesthesiology. 2014 April;120(4):839-51.

So-Osman C, *et al*. Patient blood management in elective total hip- and knee-replacement surgery (Part 2): a randomized controlled trial on blood salvage as transfusion alternative using a restrictive transfusion policy in patients with a preoperative hemoglobin above 13 g/dl. Anesthesiology. 2014 April; 120(4):852-60.

RESEARCH IN BRIEF (continued on page 8)

RESEARCH IN BRIEF (continued from page 7)

An analysis in *Transfusion* of blood product recalls in the US during 2010 suggests while recalling blood products is sometimes necessary to interdict potentially harmful blood units, it is unclear whether the recall system makes a contribution to the quality of the nation's blood supply organizations. Since the 1980s, stricter quality control measures have been implemented among blood suppliers to ensure that blood products are provided without defects, with the Food and Drug Administration increasing its focus on current Good Manufacturing Practices. There is no general agreement on the effectiveness of this new approach to quality and no single measure has been recognized as an appropriate metric to gauge the impact of this approach. To investigate the efficacy of quality control measures, researchers led by Jeffrey McCullough, MD, analyzed recalls of all blood products for 2010, available publicly on the FDA website, and categorized the reason for the recall, the organization producing the recalled products, and the FDA district in which the blood was recalled. During 2010, there were 2,466 recalls involving 8,278 blood products. None of the recalls was considered to have a reasonable probability of causing serious adverse health consequences or death (FDA Class I). The most common reasons for recalls were donation and donor qualification (73 percent) and product quality control (14 percent). The FDA class of recalls varied by recall reason, month of the year, FDA district, number of units of blood collected per FDA district, and number of units collected by the blood center. The number of recalls per 100,000 units of blood and the reason for the recall varied by FDA district and blood centers collecting smaller numbers of units had higher rates of recalls. The two largest blood collection organizations – the American Red Cross and Blood Systems – had fewer recalls per 100,000 units collected and fewer Class II recalls, suggesting that larger organizations may operate at a higher level of quality, but that assumes that recalls are an indication of quality. "What a remarkable observation – during the entire year of 2010, not a single blood product was recalled because it was thought to represent a serious adverse health consequence or potential death to a patient," wrote the authors. Additionally, 21 percent of the recalls were Class III, which are not likely to cause adverse health consequences, suggesting that the "nation's blood supply system operates at a very high level of quality and safety," said the authors. "The recall system serves a valuable purpose, but it is not clear that the recall system currently makes a contribution to the quality of the nation's blood supply organizations. Continuous assessment of recalls might be a valuable contribution," they conclude.

Citation: McCullough J, *et al*. Blood product recalls in the US. Transfusion. 2014 May 27. [Epub ahead of print]. ♦

BRIEFLY NOTED

In a letter to the editor of *The New York Times* (NYT), the American Hospital Association (AHA) takes issue with a May 17 news analysis on executive compensation in health care, which criticized the "big bucks" paid to CEOs in the healthcare industry. In the original news analysis, Elisabeth Rosenthal noted that an NYT survey showed insurance company CEOs make $584,000 on average, with hospital CEOs making about $386,000 on average. "The proliferation of high earners in the medical business and administration ranks adds to the United States' $2.7 trillion healthcare bill and stands in stark contrast with other developed countries, where top-ranked hospitals have only skeleton administrative staffs and where healthcare workers are generally paid less. And many experts say it's bad value for healthcare dollars," wrote Ms. Rosenthal. In response to this analysis, AHA President and CEO Rich Umbdenstock wrote "Management experts say running an American hospital is among the most complex and demanding jobs in any community. Hospital CEOs must keep their doors open 24/7, even in

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BRIEFLY NOTED (continued from page 8)

disasters, in a constantly shifting local, state, and federal regulatory environment; negotiate with dozens of payers; and manage the largest and best educated staff in the community. These executives are committed to upgrading the quality of care, while lowering costs and improving the health of the community. Their compensation is subject to a rigorous process prescribed by the IRS for those that are tax-exempt organizations. We take particular issue with a quote suggesting that doctors may be the only ones who want to do well by their patients. Every hospital leader goes into the field to help patients. The trust we place in our hospitals' ability to deliver care relies on the success of the committed people who lead caregiver teams that anchor every community's healthcare safety net." The letter can be found at http://nyti.ms/1oOyKAl. (Sources: The New York Times, 5/17/14, 5/25/14)

REGULATORY NEWS

AABB has released a proposed interim standard for its 29th edition of Standards for Blood Banks and Transfusion Services for public comment. The proposed interim revision to Standard 5.6.7.1 would allow units collected from men undergoing testosterone therapy to be used for allogeneic transfusion, provided that the program receives a variance from the Food and Drug Administration. The standard will be available for comment until June 22 at http://bit.ly/1oyYVgB. Comments must be submitted to standards@aabb.org. (Source: AABB Weekly Report, 5/23/14)

Food and Drug Administration staff from the Center for Biologics Evaluation and Research (CBER) met with AABB's FDA Liaison committee to discuss topics of mutual concern regarding donor and patient safety. The committee includes representatives from America's Blood Centers, AABB, the Advanced Medical Technology Association, the American Red Cross, the American Society for Apheresis, the Armed Services Blood Program, and the College of American Pathologists. Discussion focused on a range of issues including:

- FDA variances allowing the collection of red blood cells (RBCs) from individuals on testosterone;
- Barriers to using plasma collected by apheresis and labeled as fresh frozen plasma (FFP) or plasma frozen within 24 hours after phlebotomy (PF24) for further manufacturing; and
- Assistance to establishments seeking licensure of apheresis cryoprecipitated antihemophilic factor.

AABB's Bacterial Contamination Work Group provided information about extending the maximum storage for apheresis platelets. Attendees also received updates from the association's Transfusion Transmitted Disease Committee on Chikungunya virus. During this meeting, CBER staff presented information about a recent reorganization of FDA's Office for Blood Research and Review (OBRR), involving divisions that manage regulatory submissions from blood establishments. The agency's Division of Blood Applications (DBA) is now called the Division of Blood Components and Devices. Regulatory Project Management staff (i.e., consumer safety officers) who previously reported through DBA to OBRR, now report directly to OBRR. The Division of Hematology has also been restructured into two divisions – the Division of Hematology Clinical Review and the Division of Hematology Research and Review. OBRR's new phone number is (240) 402-8360. A full summary of the meeting is available on AABB's website at http://bit.ly/1nHqVg5. (Source: AABB Weekly Report, 5/23/14)

REGULATORY NEWS (continued on page 10)

REGULATORY NEWS (continued from page 9)

The Food and Drug Administration announced in the Federal Register on May 23 that it plans to allocate as much as $37.5 million to an initiative intended to improve the quality of clinical trials. FDA plans to grant the Duke Translational Medicine Institute $7.5 million per year for as many as five years in hopes that the "clinical trial enterprise" can be improved to better provide regulators and the industry with data to drive decision-making. The funding will go toward helping the Clinical Trials Transformation Initiative (CTTI) increase the quality and efficiency of clinical trials, stated FDA in the announcement. CTTI, which is based out of Duke University, includes nearly every major government healthcare agency, pharmaceutical company, and trade organization as members, as well as several medical device manufacturers and academic medical centers. The group's stated goal is to "identify and promote practices that will increase the efficiency of clinical trials," which it does by identifying specific problems, and then establishing projects to study the issue and propose solutions, reported online news source, Regulatory Focus. More broadly, CTTI seeks to find solutions to common problems, which any one company or entity would ordinarily find prohibitively expensive. "The opportunity for meaningful interaction with a broad set of stakeholders committed to improving the clinical trial enterprise and also the ability to rapidly gather data to address emerging issues offer significant value to the clinical trial enterprise," wrote FDA in the Federal Register. More information can be found in the Federal Register notice at http://1.usa.gov/1gFnfee. (Sources: Regulatory Focus, 5/22/14; Federal Register, 5/23/14) ♦

GLOBAL NEWS

The South African National Blood Service (SANBS) recently changed its blood donor deferral policy for men who have sex with men (MSM), reported the *International Business Times* on May 21. Prior to the new policy, MSM were only permitted to donate blood to the SANBS if they had been celibate for six months or longer. Following implementation of the new regulation, anyone who has a new sexual partner will be deferred from donating blood for six months, and anyone who has multiple partners will be unable to donate blood. Both criteria are irrespective of the prospective donor's sexual orientation. "It took us a while because we didn't have local facts that warranted changing our policy, although we knew South Africa was different from other countries in terms of risk of HIV," Vanessa Raju, SANBS communications manager, told the International Business Times. "The policy wasn't meant to be discriminatory, but it was seen as such. We then worked closely with the Department of Health and other organizations to reassess the situation," she added. Blood services in several countries around the world have changed their policies regarding MSM, often lifting permanent deferrals in favor of fixed-period deferrals. The *International Business Times* article is available at http://bit.ly/Slk8Nu. (Source: International Business Times, 5/21/14)

The US, Canada, and Mexico recently adopted a set of principles to help strengthen information sharing during health-related emergencies, announced a May 20 press release from the US Department of Health and Human Services. Specifically, these nations adopted a set of principles and guidelines on how the three countries' governments will share in advance public information and communications products during health emergencies of mutual interest. HHS Secretary Kathleen Sebelius, Canada's Minister of Health Rona Ambrose, and Mexico's Secretary of Health Mercedes Juan López signed a Declaration of Intent, formally adopting the principles, at a meeting during the 67th World Health Assembly in Geneva, Switzerland. The declaration calls on the three countries to:

- Share public communications plans, statements, and other communications related to health emergencies with each other prior to their public release;

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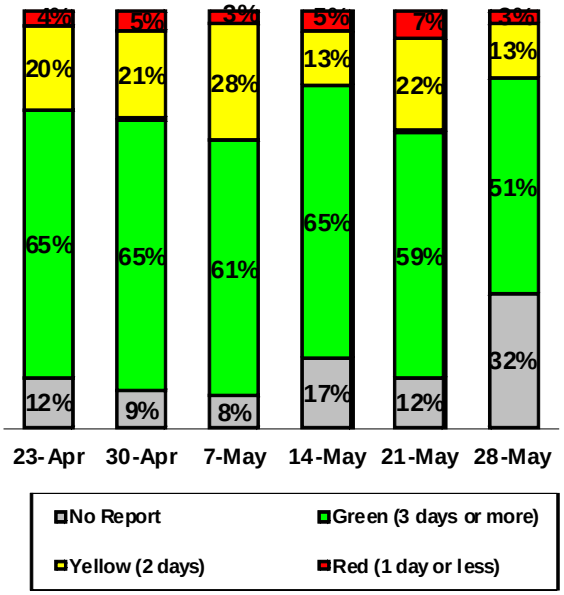
GLOBAL NEWS (continued from page 10)

- Apprise other appropriate authorities, depending on the type of health emergency, within their respective governments when the declaration is invoked;
- Conduct an annual short communications exercise to improve joint coordination; and
- Hold recurrent meetings, as they may mutually determine, to review and propose amendments to the Declaration of Intent.

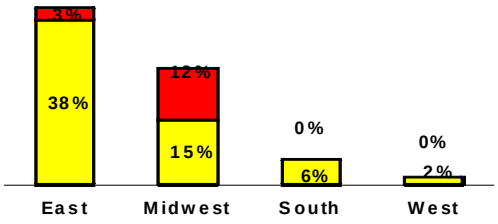
"The US, Canada, and Mexico have had a long and close relationship in supporting and improving our collective ability to respond to public health events and emergencies of mutual interest when they arise," said Sec. Sebelius. "This declaration reinforces our joint efforts to strengthen our national capabilities to communicate effectively with our respective populations." More information and a link to the full declaration can be found in the HHS press release at http://1.usa.gov/1vAAcdq. (Source: HHS press release, 5/20/14)

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

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, May 28, 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 Community Blood Center of the Carolinas (CBCC) recently presented the Ronald McDonald House of Charlotte (RMH Charlotte) with a check for $5,961 from its Third Annual "Pint for a Night" campaign. During the campaign, CBCC gave a financial contribution to RMH Charlotte for every blood donation made in March and April. "We are very grateful for the generous gift from the Community Blood Center of the Carolinas and for all the blood donors participating in 'Pint for a Night'," Mona Johnson-Gibson, executive director of RMH of Charlotte, said in a CBCC press release. "The generosity of everyone involved is a win-win for patients in our local hospitals and our Ronald McDonald House families." CBCC President and CEO Martin Grable added, "Supporting organizations like the Ronald McDonald House of Charlotte is core to our mission of strengthening the bonds of community. Many thanks to our amazing blood donors who made 'Pint for a Night' a huge success. Together, we are helping ensure hospitalized children have the blood products they need while bringing comfort to their families." (Source: CBCC press release, 5/27/14)

(Left to Right): Aly Johnson, with CBCC, presents a check for $5,961 to Jenna Westbrook and Laura-Nelle Parnell of the Ronald McDonald House of Charlotte as part of the "Pint for a Night" program.

PEOPLE

Martin Gorham and **Jeroen de Wit** were both recently honored by the European Blood Alliance as honorary presidents at a reception during an EBA board meeting held from April 10 to 11 in Madrid, Spain, reported *EBA Newsletter* #4. Both men have served as presidents of the organization. "In an organization such as EBA, much depending on the time of volunteers, the president plays a pivotal role in reaching the goals of the alliance. EBA has been lucky enough to have two consecutive presidents able to do exactly that," said the *EBA Newsletter*. Mr. Gorham grew the alliance during his years of presidency from nine to 23 countries. After Mr. Gorham's retirement from NHS Blood and Transplant, Jeroen de Wit became president in 2008. In his six years as president, Mr. de Wit further built the alliance, stabilizing EBA and adding to the organization's credibility, according to the *EBA Newsletter*. Mr. de Wit was thanked for his term as president during the reception held after the first day of the EBA board meeting. His predecessor, Mr. Gorham, gave a presentation, as did Mr. de Wit's successor, current EBA President Philippe Vandekerckhove, and EBA Executive Director Gilles Folléa. On behalf of EBA members, Willemijn Kramer, EBA secretariat, presented Mr. de Wit with a "free time guide," consisting of travel suggestions made by EBA members. (Source: EBA Newsletter #4, 5/23/14)

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:

Sales Specialist, Data Management (STRATEC Biomedical). This role will have primary responsibility in the USA for developing and substantially growing the STRATEC Data Management business (UK) in the US region. Build business plan; deliver substantial/ sustainable USA sales growth. Prepare action plans/schedules, identify targets/project the number of contacts, achieve agreed sales/profitability goals. Generate, track and follow new business leads opportunities and development of existing business relationships in North America while maximizing sales. Present and sell company products and services to current and potential clients and business to business partners. Prepare and develop presentations/proposals. Develop/maintain current product knowledge. Manage strategic accounts with potentially multiple product lines/interaction points. Identify and resolve any client concerns. Participate in development/analysis of new markets and target marketing materials to appropriate segment. Participate in seminars and trade shows as required. Donor screening, blood bank, and/or molecular market is preferred, knowledge of molecular diagnostic technology & laboratory requirements is an advantage. A strong understanding of middleware in the modern laboratory is essential. Strategic selling skills preferred. Experience with being a remote worker; ability to be self-motivated and to effectively manage multiple projects while showing strong and decisive leadership skills. To apply send resume to: m.hertz@stratec.com.

Executive Director. The European Blood Alliance (association of 25 blood services in Europe, collecting 23 million donations per year) is seeking a skilled director for fulfilling the following key objectives: representing EBA in contact with EU institutions; contributing to EBA strategy and policies; building organizational capability and capacity; supporting the membership; and managing the EBA office. The ideal candidate will demonstrate i) achievements in leadership and ability to build organizational capacity for a membership organization, and either ii) content knowledge of blood banking, or iii) a track record of networking with EU bodies with successful experience of influence, or both ii) and iii). Alert to developments in the field. Readiness to take initiative, while maintaining close liaison with Executive Board. Excellent communication skills. Sensitivity to cultural differences in Europe. Fluency in English; knowledge French and/or German advantageous. The office is located in Amsterdam. Frequent presence in Brussels and frequent travel within Europe. Appointment is for four years, with an option to extend. Starting date ASAP. Salary range: 80 – 90.000 €/year. More may be available for candidates with exceptional fit with specifications. The closing date is **June 6th**. Interview date in Amsterdam: June 25th. Further information and application: http://wp.me/p4l3nF-af.

Transfusion Service Supervisor. Puget Sound Blood Center is currently seeking an evening/night transfusion service supervisor to play a crucial role in the integration and supervision of daily activities and staff at three new Transfusion Service Laboratories based at Seattle area Swedish hospitals. Requirements include: BS CLS/MT OR bachelors' degree in a chemical, physical, biological science and one year of laboratory experience in high complexity testing. MLS(ASCP), BB(ASCP), SBB(ASCP) or equivalent certification is required or certification within six months. Prior leadership experience is strongly preferred. More information at www.psbc.org. Qualified applicants send resumes to humanresources@psbc.org Attention: Job #7261ABC. EEO/AA

Donor Relations Consultant. Mississippi Valley Regional Blood Center (MVRBC), has an exciting opportunity for a donor relations consultant to develop strong relations with east central Illinois community organizations for hosting mobile blood drives at their Urbana, Ill. location. 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 weekends. A Bachelor's degree, or equivalent combination of experience and education is required to be considered; preferred studies include business, communications, or marketing. Must possess a valid driver's license, be insurable by MVRBC's insurance carrier, and be willing to drive within the MVRBC service area. We offer a competitive salary and excellent benefits including health, dental, vision, life, and

(continued on page 14)

POSITIONS (continued from page 13)

401(k). Pre-employment drug screen and background check required. MVRBC is a non-profit organization and an exclusive provider of blood products and services to more than 85 hospitals in Illinois, Iowa, Missouri, and Wisconsin. To apply visit: www.bloodcenter.org/our-people. Equal Opportunity Employer: Minorities, Women, Veterans, Disabilities.

Associate Transfusion Safety Officer. For 60-plus years BloodSource has been a recognized leader in blood banking. Our reputation is one of excellence, quality, and service. We are seeking an associate transfusion safety officer to join our Business Development team in Mather, Calif. The position will be responsible for coordinating and implementing new programs and services to support the operations of our blood management program, BloodSmart. The ideal candidate will be results-driven, thrive on challenge, have a strong commitment to customer service and be passionate about our mission. Bachelor's degree in business or science related field required, post-graduate degree, advanced blood banking certification or professional license (RN, CLS) required, knowledge of blood banking laboratory practices and transfusion medicine required, two years of blood banking management or healthcare management strongly preferred, intermediate proficiency in MS Office Word, Excel, Outlook and PowerPoint, project management experience, proven problem-solving skills, attention to detail, ability to work independently and with a team, strong verbal and written communication skills, exceptional interpersonal and customer service skills, excellent public speaking and presentation skills. Travel required for this position. Enjoy working with a collaborative and growing team in the rolling hills of Northern California. To apply, visit our website at www.bloodsource.org. EOE

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Norwood by e-mail* (mnorwood@americasblood.org) *or by fax to (202) 393-5527. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)*

2014

May 31-June 5. **3rd International Congress of the ISBT, Seoul, South Korea.** For more information please visit: www.isbtweb.org/seoul.

June 4-6. **68th Annual FABB Conference, Sarasota, Fla.** More information and a link to register can be found at www.floridaabb.com.

June 5-8. **5th International Monoclonal Antibody Workshop, New York, N.Y.** Contact: Gregory Halverson, New York Blood Center. Phone: (212) 570-3026; e-mail: ghalverson@nybloodcenter.org.

June 17-20. **Fund Development, Communications, and Donor Management Workshop, America's Blood Centers, Sacramento, Calif.** Contact: ABC Meetings Dept. Phone (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 5 Tuesday (note: new date and day). **Medical Directors Workshop, America's Blood Centers, Seattle, Wash.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 6-7 Wednesday-Thursday (note: new dates and days). **Summer Meeting, America's Blood Centers, Seattle, Wash.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 3-5. **European Conference on Donor Health and Management, the Netherlands.** More information and registration details can be found at www.ecdhm.org.

Sept. 13. **12th Annual Canadian Blood Services International Symposium - Plasma: Transfuse it, Fractionate it or Forget it?, Ontario, Canada.** Details and registration can be found at http://bit.ly/1mQfamu.

Sept. 16-17. **IT Workshop, America's Blood Centers, Indianapolis, Ind.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 23-24. **IPFA/BCA Global Symposium on the Future for Blood and Plasma Donations, Sacramento, Calif.** More information and registration details can be found at http://bit.ly/1fDqJrX.

Oct. 25-28. **AABB Annual Meeting and CTTXPO, Philadelphia, Pa.** For more information: http://bit.ly/RKAwWR.

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CALENDAR (continued from page 14)

Oct. 31-Nov. 3. **5th International Meeting on Emerging Diseases and Surveillance, Vienna, Austria.** More information can be found at http://imed.isid.org. Contact: info@isid.org.

Dec 9-10. **Supply Chain Optimization Workshop, America's Blood Centers, Austin, Texas.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

2015

Mar. 20-24. **Annual Meeting, America's Blood Centers, Washington, DC.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

May 5-7. **Technical/Lab & Quality Workshop, America's Blood Centers, Orlando, Fla.** Contact: ABC Meetings Dept. Phone (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 4. **Medical Directors Workshop, America's Blood Centers, Philadelphia, Pa.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 5-6. **Summer Meeting, America's Blood Centers, Philadelphia, Pa.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 16-17. **Financial Management Workshop, America's Blood Centers, Chicago, Ill.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.