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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2013 #22 **June 14, 2013**

INSIDE:

HHS ACBTSA Discusses Future of US Blood Center System

Anyone involved in blood banking knows that US blood centers have seen a myriad of changes over the last several decades. They will likely continue as hospitals further consolidate and healthcare reform takes effect. Blood centers have experienced a marked decreased demand for red blood cells and have undertaken mergers and other alliances to increase efficiencies, while remaining competitive in the ever-changing healthcare environment.

As blood centers grapple with new business models and strive to do more with less, many experts find themselves wondering – Is the current US blood center system sustainable and designed to deliver optimal service going forward? Furthermore, it is uncertain how much more consolidation is in store for blood centers and what the landscape will look like in the next several years. The Department of Health and Human Services' Advisory Committee on Blood & Tissue Safety & Availability (ACBTSA) took on these big questions at a meeting on June 5 and 6, held at a National Institutes for Health facility in Rockville, Md.

Jay Menitove, MD, the ACBTSA committee chair, and president, CEO, and medical director of the Community Blood Center of Greater Kansas City, began the meeting, with a brief introduction of the topics to be discussed. Howard K. Koh, MD, HHS Assistant Secretary for Health, presented three main questions to be considered by the committee, listed below.

- What blood center services are considered essential to the US healthcare system?
- How do anticipated changes in healthcare (e.g. business models, economic forces, advances in medical care, patient blood management) affect blood centers and the provision of essential services?
- How should the transfusion medicine field be defined in the next decade with regard to population health, better patient outcomes, and reducing costs?

The Current Blood Center Landscape. Karen Shoos, JD, former AABB CEO and the principle investigator of PEPFAR grants and internal technical assistance at AABB, and David Green, CEO of Mississippi Valley Regional Blood Center and ABC president, began the presentations on Wednesday with an overview of the current blood center landscape, as well as the challenges faced and drivers for

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OUR SPACE

FABC Director of Fund Development Jodi Zand

Help us Help You

Last year, America's Blood Centers conducted its SEQuaLS member satisfaction survey, where ABC members could pose questions to ABC's and the Foundation for America's Blood Centers' (FABC) staff. One member asked, "Is there a way to make more grants available to member centers?" To provide the short answer – yes, the FABC is working to provide more useful grants to ABC members, but let's start at the beginning.

As most of you know, grants are awarded to ABC's member blood centers through the FABC, which was initially founded in 1997 as a vehicle to accept financial contributions from sponsors and suppliers to fund ABC programs that benefit the membership, like the popular *My Blood, Your Blood*. The FABC sought to provide additional value to ABC members without raising dues. In 2002, the Foundation began awarding small grants to ABC members, while also funding ABC National Initiatives.

In recent years, the number and monetary value of grants given to ABC members has increased. Meanwhile, the FABC continues to fund certain ABC programs with a national scope. The recent "member-focused" grants have included the redesign of the recently launched AmericasBlood.org and the future redesign of the ABC members' website, as well as the ABC Specialty Workshop Scholarship Program, which provides 26 scholarships to ABC members to supplement costs for attendance at an ABC Specialty Workshop.

However, it goes without saying, that the more money we raise, the more grants we can give to members. The FABC board recently began a strategic planning process, led by Board Chair Francine Décary, MD, PhD, MBA, and Board Member Roy Roper, focused on increasing our funding and diversifying the sources from which we solicit funds, while also working to ensure that our grant programs benefit *all* ABC members.

I encourage all members to apply for a grant when we issue the Request for Proposals later this fall. Meanwhile, the FABC will keep exploring ways to increase revenues so that we can award more grants that benefit the ABC membership. It is also timely to recognize the industry suppliers that have continued to support the FABC despite the financial squeeze felt during these tough economic times. We are grateful for their support and we hope to continue counting on them.

I would, however, not be doing my job if I failed to mention that we need you to support the FABC! Whether it is attending an event like the annual gala or *Links for Life* Golf Tournament, or sharing information about the FABC with friends and colleagues, or making a financial contribution, your support *does* matter. Even a small donation can go a long way in increasing the dollars we have to give back to our members and the blood community!

Jodi M Zand

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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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Sustainability of US Blood Center System (continued from page 1)

change. Ms. Shoos offered AABB's perspective on these challenges, while Mr. Green offered the ABC viewpoint.

Several forces are causing shifts within blood banking, said Ms. Shoos, including the trend toward patient blood management, as hospitals seek to reduce unnecessary transfusions, improve patient care, and cut costs. Both patient blood management and the development of new therapies that replace blood-intensive therapies have lead to a decline in blood use, said Ms. Shoos. Economic pressures have reduced the number of surgeries in the US, and thus blood use, while the impending "baby boomer bulge," the increase in people over the age of 65, may increase blood use over the next several years.

Another driving force shaping blood banking has been the accelerated movement of hospitals to align with large healthcare systems and to integrate with doctors and other providers in accountable care organizations (ACOs), said Mr. Green. "This is really the end of the independent hospital. More and more hospital systems are seeking to have just one blood supplier," he added. This trend has led blood centers to consolidate as well, and Mr. Green suggested that further consolidation will occur because most blood centers are not currently suited to support large healthcare systems with hospitals throughout the country.

Mr. Green explained that there are several possible business models that may help blood centers adapt to these shifts within healthcare, such as the mega-center model, which would include just five to eight national programs, or a model based off of the railroad industry, which would include about five to eight large national processors partnering with more than 100 small, local programs.

While rapid change in blood banking has been alarming to many, both Mr. Green and Ms. Shoos highlighted emerging opportunities for blood centers. For example, blood centers are "uniquely suited to handle cellular therapy products and personalized medicine," said Ms. Shoos. Blood centers can remain relevant by forming "value-added partnerships with hospitals," offering transfusion medicine and blood management expertise, said Mr. Green. Ms. Shoos added that blood centers must downsize infrastructure and rationalize capacity, become better integrated into healthcare delivery systems, and attract new leaders who will embrace the challenges ahead.

Blood Collection and Transfusion Trends. Barbee Whitaker, PhD, director of AABB's Center of Data and Special Programs, offered insight into exactly how blood use has shifted since 2008, presenting the unpublished results of the HHS 2011 National Blood Collection and Utilization Survey (NCBUS), conducted by AABB. The survey includes responses from 131 blood centers (96.3 percent response rate), 1,342 hospitals (42.3 percent response rate), and 20 cord blood banks (28.6 percent response rate). The findings support previous assertions of downward trends in collections and transfusions. In 2011, blood banks collected 15.7 million units of whole blood (WB) and RBCs, which is 9.1 percent less than in 2008. In 2011, there were 13,684,000 allogeneic RBC transfusions, compared with 14,782,000 in 2008, a 6.4 percent decrease.

There were 199,000 WB derived platelet units transfused in 2011, a 23.6 percent decline since 2008, and 1,970,000 apheresis platelet units transfused, an 11.9 percent increase from 2008. In 2011, there were 3,882,000 units of plasma transfused, a 13.4 percent decrease. Overall, 11.6 percent fewer components were transfused from 2008. As other presenters suggested, the overall trend toward decreasing blood use may be due to the increase in patient blood management programs, which 30 percent of respondents indicated having in place at their hospitals.

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Sustainability of US Blood Center System (continued from page 3)

A presentation on Thursday by Richard Benjamin, MD, PhD, chief medical officer of Biomedical Services at the American Red Cross (ARC), reflected many of the trends seen in the recent NBCUS data that Ms. Whitaker presented. Data from ARC and Blood Centers of America show a continuation in the downward trend of RBC collection and transfusion, with a 4 to 6 percent further decline in 2012. He cited many of the same drivers causing this trend that Ms. Shoos and Mr. Green discussed in their presentations. Dr. Benjamin predicted that despite the increase in people over the age of 65 over the next couple of years, the downward trend in RBC distribution is likely to continue as economic factors and trends toward patient blood management become dominant forces driving RBC demand.

However, Dr. Benjamin noted that it is difficult to make any assertions regarding the blood supply and demand with certainty because the US lacks a robust system to track blood component use in hospitals to assess the demand. He emphasized that this situation "places blood centers in a financially precarious position and perpetuates cycles of supply and demand imbalances leading to shortages and waste."

In his presentation on ARC's perspective on the blood center environment, Chris Hrouda, ARC executive vice president, provided a candid view of the US blood system's future. He reviewed the numerous drivers of change mentioned by previous speakers, noting that if blood centers are really going to achieve financial stability, "the next phase has to be to drive out industry-wide redundant capacity," including redundancies in testing/distribution capacity, surveillance and research and development, collections capacity, physical plant capacity, and workforce. While there has been consolidation, it has not been enough to effectively eliminate redundancy, said Mr. Hrouda. He added that these exigencies will likely have a profound impact on blood banking, such as less investment in overall quality improvements, slowing of testing advances and product innovation, more risk introduced into the system, and reduction in surveillance capabilities.

He concluded that possible solutions include: consolidating the industry into a small number of providers; moving to a national blood supply model; or the federal government setting a price floor for core products. "Regardless, we must identify the right model to maintain appropriate investments in the safety of the blood supply," said Mr. Hrouda.

Blood and Tissue Center Perspectives. Meeting attendees had the opportunity to hear from blood and tissue centers that are engaging in new ways to stay competitive and relevant in the evolving healthcare environment. Jackie Fredrick, president and CEO of the Centers for Transfusion and Transplant Medicine (CTTM) and BloodCenter of Wisconsin, gave a talk titled "Pathway to the Future – Pluralistic and Innovative Models for Blood Centers." She noted that to remain relevant, blood centers must maintain both the foundational goal of maintaining a safe and adequate blood supply, but also must achieve goals to sustain the center, such as expanding the center's size and scale, diversifying and redefining the center's mission to provide healthcare solutions, and investing in future requirements of healthcare technology, expertise, and product/service development.

Ms. Fredrick used BloodCenter of Wisconsin and its parent organization, CTTM, as an example of how blood centers can diversify their services to remain successful and profitable. For instance, BloodCenter of Wisconsin provides transfusion medicine services, hematology and transplantation solutions, diagnostic reference lab and medical consultation, and conducts research through the Blood Research Institute. She added that to continue offering value-added services to hospitals, blood centers will need HHS and FDA to invest in innovation, provide a regulatory path to promote innovation, and create a framework for value/outcomes-based care.

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Sustainability of US Blood Center System (continued from page 4)

Similarly to BloodCenter of Wisconsin, South Texas Blood & Tissue Center (STBTC) has diversified its services, which was highlighted in a presentation by Linda Myers, CEO of STBTC and chief operating officer of QualTex Laboratories. She discussed the many services offered by STBTC and its affiliates, including testing services, blood services, support services, and provision of tissue, cord blood, and peripheral blood stem cells (PBSCs). She emphasized that blood and tissue centers like STBTC should move toward cellular therapies and regenerative medicine.

On Thursday, the audience heard from another blood center finding creative ways to generate profit, Puget Sound Blood Center (PSBC). Jim AuBuchon, MD, president and CEO of PSBC, gave a talk called "Blood Center Sustainability: Knowing the Customer." He used PSBC's story to illustrate the numerous business opportunities for blood centers – infectious disease testing, cord blood banking, donor recruitment, donor testing and processing, transfusion services, patient services, biomedical research, postgraduate education, and providing plasma derivatives, and hemophilia care. The new blood center business model involves selling less at a reduced price and developing new services at a reduced margin, said Mr. AuBuchon.

Hospital Perspective. Joe Rutledge, MD, of Seattle Children's Hospital, provided the hospital perspective in a presentation called "Lab in a Lab Model." He discussed the advantages of partnering with PSBC to form its own transfusion medicine service.

Also offering a hospital perspective was S. Gerald Sandler, MD, medical director of the Blood Bank at Georgetown University Hospital. Dr. Sandler discussed the potential impact of pathogen inactivation, specifically Octaplas, a solvent-detergent-treated plasma product. Dr. Sandler feels that when Octapharma informs clinicians about the availability of Octaplas, they will either use fresh frozen plasma less restrictively because it is safer, or will feel that the product is too expensive and avoid use. Dr. Sandler concluded that the phase-in of this product would likely be slow because of surcharge and would best be distributed by blood centers, rather than pharmacies.

Committee Discussion. Following the presentations on Thursday, the Committee held open discussion. Committee Chair Dr. Menitove said that due to the rapidity of change in the healthcare industry and in blood banking, he feels that another meeting should be held, before the committee's scheduled December meeting, to lay out some concrete recommendations regarding the US blood center system. Harvey Klein, MD, chief of the NIH Clinical Center's Department of Transfusion Medicine, added that considerable change and consolidation is inevitable for blood banks. The real question, he added, is whether the blood community will play an active role in deciding its fate, or whether it will just allow the market to determine the future of the US blood center system.

Other members of the committee agreed that while the blood supply is not under any immediate threat, possible solutions to the current challenges should be discussed sooner rather than later. Dr. Menitove and James Berger, HHS senior advisor for blood policy, agreed to convene a small group of experts to formulate more specific recommendations to be discussed at the ACBTSA's December meeting. This meeting of experts will be open to the public and will be announced in the Federal Register.

The webcast from this most recent meeting can be viewed at www.hhs.gov/ash/bloodsafety/ by clicking on the "View the live webcast" link.

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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. ♦

The FABC's 4th Annual *Links for Life* Golf Tournament Headed to California

The Foundation for America's Blood Centers (FABC) announced this week that the 4th Annual *Links for Life* Golf Tournament will be held in conjunction with the 2014 ABC Annual Meeting in Palm Springs, Calif. on March 22. The event, sponsored by LifeStream and Blood Systems, will be held with support from HemoCue at the Desert Willow Golf Club.

The Links for Life Golf Tournament is an annual fundraising event that supports the FABC and raises awareness of the need for voluntary blood donors. The FABC funds programs carried out by ABC members that improve the availability, quality, and safety of blood. ABC blood center executives, representatives from blood-related medical technology companies, and even pro golfers came out to support the FABC's life-saving mission at last year's event, which raised $42,000 (see *ABC Newsletter*, 10/26/13).

The Desert Willow Golf Club was named one of the Top 50 Public Courses by *Golf World Magazine* in 2010, and one of the best places to play in 2008 and 2000 by *Golf Digest*. Once again, the Institute for Transfusion Medicine (ITxM) will sponsor two PGA Tour players to attend the event. Last year, D.A. Points and Rod Pampling golfed alongside ABC executives and other blood community leaders.

As at past tournaments, one CEO or other executive from each ABC member blood center will be able to golf free of charge. With this year's tournament set in beautiful Palm Springs, ABC encourages spouses and family members to register, as they will be offered a discounted rate. All golfers will receive a goodie bag including a hat, golf towel, engraved nametag, and divot tool, as well as the use of a GPS device on the golf course. Golfers will also enjoy breakfast, lunch, and an awards banquet after completing the tournament.

Sponsorship opportunities will be available in the form of a number of joint packages to support the annual meeting and golf tournament, as well as to sponsor each individually. More information about the tournament will be released in the coming months! Questions regarding the tournament can be directed to Jodi Zand at jzand@americasblood.org. ♦

RESEARCH IN BRIEF

Research published in the *American Journal of Cardiology* on June 1 shows that patients who experience a decrease in platelet count following transcatheter aortic valve replacement (TAVR) are at increased risk of adverse events. Pascal Lim, MD, PhD, of the University Hospital Henri Mondor in Cretil, France, and colleagues retrospectively studied 144 consecutive patients with severe symptomatic aortic stenosis who received the CoreValve device between December 2007 and July 2011. Blood platelet count was measured at baseline and every day after the TAVR until discharge. Outcomes were defined according to Valve Academic Research Consortium. Before undergoing TAVR, the blood platelet count averaged 216 x 10^9/L $\pm$ 67 x 10^9/L. All but one patient experienced a decrease in platelet count post-procedure. The platelet count decreased an average of 34 $\pm$ 15 percent. The decrease in platelet count was associated with a higher rate of prosthesis migration, longer x-ray and procedural times, and larger contrast amounts. In-hospital major adverse cardiovascular events were observed more frequently in patients with severe platelet count decreases. Also, the percentage of blood platelet count decrease was the only predictor of in-hospital major adverse cardiovascular event, write the authors. They conclude that a decrease in platelet count is common following TAVR, and its severity is associated with poor outcomes.

Citation: Gallet R, *et al*. Effect of transcatheter (via femoral artery) aortic valve implantation on the platelet count and its consequences. Am J Cardiol. 2013 Jun 1;111(11):1619-24. ♦

AABB Publishes Agenda for TRALI Public Workshop

AABB published the agenda for the upcoming public workshop titled "Current Perspectives on TRALI Risk Reduction," to be held on July 8 at the Marriott North Bethesda Conference Center in Bethesda, Md. The agenda is available at http://bit.ly/1a8zDwQ. More details about the workshop can be found at www.aabb.org/events/conference/Pages/conf.aspx.

BRIEFLY NOTED

An article published on June 7 in *Science* discusses the impact of removing limitations on the number of Food and Drug Administration advisory committee members with conflicts of interest (COI). In 2012, the FDA Safety and Innovation Act (FDASIA) was signed into law, including provisions that change FDA advisory committee financial COI requirements. Waivers may be granted for experts with financial COIs to serve on FDA's advisory committees if the COI is unlikely to affect the integrity of the services, the need for the individual's service outweighs the potential for a COI, or if the individual will provide essential expertise. Certain provisions of the FDASIA remove caps on the number of waivers permitted by the 2007 FDA Amendments Act (FDAAA). Under FDAAA, 11.5 percent of advisory committee members may be granted COI waivers. FDA was also directed to recruit non-conflicted experts from academic institutions, professional societies, and patient and consumer groups. The new COI requirements in the FDASIA remove the COI waiver cap, and does not specify that FDA must recruit members from "consumer" or "patient safety" organizations. Also, selection criteria changed from including both expertise and financial disclosures to simply requiring "the most expert advice." Finally, under FDASIA, the Annual Report on FDA Advisory Committee Vacancies and Public Disclosures must now include the number of nominees who did not participate because of disqualifying COI. Those in favor of removing COI caps refer to data showing that COIs may not actually affect voting patterns and that committee members with COIs may have higher expertise. Also, a 2007 FDA study concluded that "the ability to create a conflict-free panel is speculative," arguing that it is more difficult to find highly qualified non-conflicted members, and that doing so would have negative impacts on FDA. However, proponents of keeping the COI limits in place argue that financial COIs compromise the scientific integrity of the FDA's advisory committees, and that specific cases have shown COIs may influence the advisory committees' decisions. Those in favor of the COI caps also note that vacancies on the advisory committees are declining under the old rules, while FDA's productivity is increasing. Furthermore, there are non-conflicted experts out there. A 2009 study showed that 47.2 percent of academic life science researchers declared no relationship with the industry. The authors conclude that as discussions begin regarding the 2017 reauthorization of FDASIA, "Increased engagement of the scientific and medical communities is crucial to ensure a strong and effective FDA advisory system." The article is available

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BRIEFLY NOTED (continued from page 8)

to *Science* subscribers or for purchase at www.sciencemag.org/content/340/6137/1172.summary.

Citation: Wood SF, Mador JK. Science and regulation. Uncapping conflict of interest? Science 2013 June 7;340(6137): 1172-3. ♦

REGULATORY NEWS

The Food and Drug Administration issued a safety communication on June 10 titled "New boxed warning for thrombosis related to human immune globulin products." FDA recently analyzed data that strengthened an association between the use of intravenous, subcutaneous, and intramuscular human immune globulin products and the risk of thrombosis. FDA writes that "additional caution regarding the use of these products is warranted." FDA is requiring manufacturers to add information about risk and mitigation of thrombosis to the current boxed warning labels of these products. "A retrospective analysis of data from a large health claims-related database, as well as continued post-marketing adverse event reports of thrombosis, have strengthened evidence for an association between use of these products and risk of thrombosis," said FDA in the communication. More detailed information is available at http://1.usa.gov/12Jr0bL. (Source: FDA safety communication, 6/10/13)

AABB's sixth edition of Standards for Cellular Therapy Services is now available for purchase online in the AABB Marketplace. The publication includes new standards that address clinical activities such as patient consent, patient care, and preparation for administration. The revised standards also offer expanded non-hematopoietic content addressing elements of novel cellular therapies and a restructured "process Control" chapter. This edition also includes revisions to assist in the international application of the standards. The new edition of standards becomes effective on July 1. The summary of changes can be accessed at http://bit.ly/13F7sC3, and the new standards can be purchased at http://bit.ly/141rYMh. (Source: AABB Weekly Report, 6/7/13)

Cellphire Inc. announced in a press release this week that the Food and Drug Administration has granted approval of an exploratory Investigational New Drug (IND) application for Thrombosomes, a lyophilized human platelet derived infusible hemostatic agent. Application of this technology to human platelets has resulted in the development of Thrombosomes, a potential treatment for uncontrolled hemorrhage. Thrombosomes are derived from human platelets and lyophilized to a dry powder that can be stored at room temperature for extended periods and prepared for infusion by the addition of sterile water. The trial, permitted under the FDA IND, is an escalating dose safety trial designed to demonstrate the safety of sub-clinical doses in health subjects. "IND approval for this first-in-human safety trial is a major milestone for Cellphire and Thrombosomes, demonstrating the safety of sub-clinical doses will pave the way for a Phase 1 IND application allowing human safety trials at clinical dose levels and future efficacy studies in thrombocytopenic or surgical patients. We are very pleased that the FDA has reviewed our data and agrees that we have shown appropriate consistency in manufacturing and safety in healthy animals to take this first-in-humans step", said Michael Fitzpatrick PhD, president and director of Clinical Research and Development for Cellphire, and previous chief operating officer of America's Blood Centers. More information is available at www.cellphire.com. (Source: Cellphire press release, 6/10/13)

The Food and Drug Administration has released a draft guidance titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices – Draft Guidance for Industry and Food and Drug Administration Staff." America's Blood Centers' staff is currently reviewing the document and more details will be provided in next week's *ABC Newsletter*. The document is available at http://1.usa.gov/140wCKv. (Source: FDA draft guidance, 6/13/13) ♦

GLOBAL NEWS

The World Health Organization and blood services around the world are celebrating World Blood Donor Day today, June 14, which raises awareness of the need for safe blood and blood products. This day also acts as a thank-you to voluntary, unpaid blood donors for their life-saving gift. With the slogan "Give the gift of life: donate blood," this year's campaign, the 10th anniversary of World Blood Donor Day, will focus on the value of donated blood to the patient, not only in saving life, but also in helping people live longer and more productive lives. America's Blood Centers has partnered once again with Nexcare Bandages from 3M on the 5th annual *give* campaign in celebration of World Blood Donor Day. Through this alliance, Nexcare Bandages provides resources to participating ABC blood centers, including a supply of limited-edition *give* bandages for donors and an extensive media relations campaign. See next week's *ABC Newsletter* for coverage of activities and promotions run by ABC's member blood centers to celebrate World Blood Donor Day. (Source: WHO website, 6/13/13) ♦

INFECTIOUS DISEASE UPDATES

HIV

New research by scientists at the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIAID), reveals the mechanism by which HIV kills immune cells, reported NIH in a June 5 press release. The research was published in *Nature* on June 5. This finding has implications for preserving the immune system of HIV-infected individuals, according to NIH. HIV replicates inside immune cells called CD4+ T cells through complex processes that include inserting its genes into cellular DNA. The researchers, led by Arik A. Cooper, PhD, staff scientists at the Virology Lab of the NIAID Vaccine Research Center, discovered that during this integration step, a cellular enzyme called DNA-dependent protein kinase (DNA-PK) becomes activated. DNA-PK normally coordinates the repair of simultaneous breaks in both strands of molecules that compromise DNA. As HIV integrates its genes into cellular DNA, single-stranded breaks occur where viral and cellular DNA meet. The scientists discovered that the DNA breaks occurring during HIV integration activate DNA-PK, which then performs an unusually destructive role: eliciting a signal that causes the CD4+ T cell to die. The cells that succumb to this death signal are the very ones mobilized to fight the infection. According to the scientists, these new findings suggest that treating HIV-infected individuals with drugs that block early steps of viral replication – up to and including activation of DNA-PK integration – not only can prevent viral replication, but may improve CD4+ T cell survival and immune function. The findings also may shed light on how reservoirs of resisting HIV-infected cells develop and may aid efforts to eliminate these sites of persistent infection. (Source: NIH press release, 6/5/13)

Citation: Cooper A, *et al*. HIV-1 causes CD4 cell death through DNA-dependent protein kinase during viral integration. Nature. 2013 June5. [Epub ahead or print]

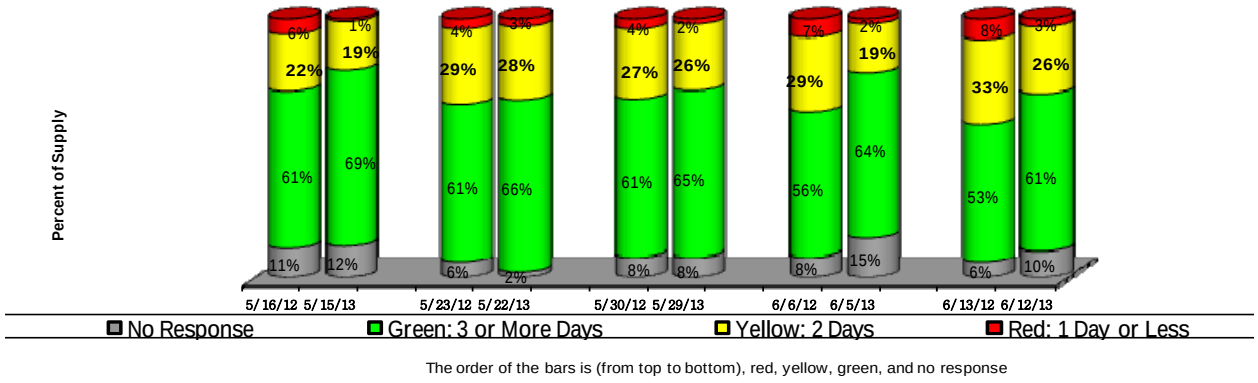
INFECTIOUS DISEASE UPDATES (continued on page 11)

INFECTIOUS DISEASE UPDATES (continued from page 10)

MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS

The Centers for Disease Control and Prevention published in its June 14 *Morbidity and Mortality Weekly Report* (MMWR) an update regarding severe respiratory illness associated with the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), formerly known as novel coronavirus. It was first reported to cause human infection in September 2012 in the area of the Arabian Peninsula. Continued reports of cases outside the region raise concern about its spread to other geographic areas. There is currently no evidence to suggest that MERS-CoV poses a threat to the blood supply. AABB's Transfusion Transmitted Diseases Committee continues to monitor the situation. CDC's MMWR is available at http://1.usa.gov/160Fhhf. (Source: CDC MMWR, 6/14/13)

STOPLIGHT®: Status of the ABC Blood Supply, 2012 vs. 2013



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MEMBER NEWS

Community Blood Center of the Carolinas (CBCC) announced in a recent press release that it is kicking off a whole blood and platelet donation campaign to help ensure an adequate blood supply during the summer months. Donors who give whole blood two times at one of CBCC's five donor centers between June 1 and Sept. 30 will be entered into the "Grilling Hot Summer" drawing for a Weber Genesis E310 gas grill. Donors will also receive a free T-shirt upon their first donation. Those who donate platelets three times during the months of June and July at any of CBCC's five donor centers will receive coolers. "During the summer months, blood donations drop significantly while the need for blood never decreases," said Martin Grable, CBCC president and CEO. "Summertime donors help prevent these serious shortages. We appreciate our summer whole blood and platelet donors and encourage the community to support local patients through regular donation." (Source: CBCC press release, 6/10/13)

MEMBER NEWS (continued on page 12)

MEMBER NEWS (continued from page 11)

San Diego Blood Bank held its 5th Annual Bandit Blood Drive on June 8 at the San Diego Harley Davidson, leading the center to collect 113 pints of blood. Blood drive attendees enjoyed a free barbeque, live bands, and "Chopper the Biker Dog," (pictured right) the successor of the motorcycle-riding dog, Bandit. Second Chance Rescue, an organization that helps find homes for displaced pets, was also represented at the event. Special guests at the blood drive included actor/musician Mickey Jones, Marine David Smith, who depended on life-saving blood transfusions after suffering a traumatic injury, and local radio station personalities. (Source: San Diego Blood Bank press release, 6/5/13)

BloodCenter of Wisconsin will host a two-day "gemba visit" to discuss how lean thinking can help deliver high quality, cost effective healthcare, BloodCenter announced in a press release this week. More than 40 Healthcare Value Network (HVN) (www.createvalue.org/delivery/hvn/) leaders from around the country will gather at BloodCenter from June 26 to 27 for the event titled "Transforming Continuous Improvement Culture in Healthcare at BloodCenter of Wisconsin." The event will involve structured learning and interaction at a variety of worksites at BloodCenter's downtown Milwaukee headquarters to see lean projects in action. Gemba is a Japanese term for the place where the work is actually performed and value is provided. The HVN unites healthcare leaders from across North America who share a commitment to providing high-quality, cost-effective care through the application of lean concepts. BloodCenter is the only HVN member in the Milwaukee area."As adults we learn from each other, not by sitting in front of PowerPoint presentations in a conference room. The light bulb goes on when we get to see the real work in the ICU, the clinic, the ER, or the laboratory," said John Toussaint, MD, CEO ThedaCare Center for Healthcare Value. "As a peer-to-peer learner, you are a student going to see, and a teacher when others come to see your work. That's the magic of the Healthcare Value Network, and we are pleased to see and support the important work that the BloodCenter of Wisconsin is accomplishing as a Network member." Visitors at BloodCenter's "gemba visit" will include leaders from renowned HVN healthcare organizations such as ThedaCare, Christie Clinic, and UCLA Medical Center. Visitors at the event will discuss improvements in patient care with BloodCenter physicians; see how BloodCenter is collaborating with its hospital partners through medical direction, patient blood management, and a variety of services to provide greater value and advance patient care; and see how BloodCenter is implementing continuous improvement systems across its Blood Services and Diagnostic Labs areas, as well as in its corporate services. (Source: BloodCenter of Wisconsin press release, 6/11/13)

PEOPLE

Brian Custer, PhD, associate investigator at Blood Systems Research Institute (BSRI), was recently appointed to the Department of Health and Human Services' Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). The committee provides advice to the secretary and assistant secretary for health regarding public health safety related to the availability of blood products; public health, ethical and legal issues related to transfusion medicine; and any implications that environmental and economic factors have on the safety and availability of blood and tissue. Dr. Custer received his

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bachelor's degree in biology from the University of Oregon and his Masters of Public Health in epidemiology and a PhD in pharmaceutical outcomes research and policy from the University of Washington. He is an adjunct associate professor of Laboratory Medicine for the University of California, San Francisco, and has been with BSRI since 2003. His research areas include blood donor behavior and transfusion epidemiology. "The ACBTSA is a committee with a wide-ranging portfolio. In this time where there is increased competition coupled with decreased blood utilization, reduced resources for transfusion medicine research, and new challenges resulting from healthcare reform, I am very pleased to have the opportunity to serve on ACBTSA. Blood providers face major challenges and serving on this committee will provide me the opportunity to contribute to efforts to ensure both the safety and stability of blood and tissue supplies in the US during what promises to be a pivotal period for all blood centers," said Dr. Custer. (*Editor's Note*: See page 1 for coverage of the most recent ACBTSA meeting.) (Source: Blood Systems press release, 6/10/13)

Matthew Anderson, MD, PhD, recently joined the BloodCenter of Wisconsin as the medical director of Diagnostic Laboratories. In this role, Dr. Anderson will focus on enabling new models of patient care through advances in laboratory medicine and genomics. He will work with Diagnostic Laboratory directors to define research and development priorities, leading external clinical collaborations and clinical/translational research from a physician perspective. Dr. Anderson will also serve as medical director for the Histocompatibility Laboratory. "Dr. Anderson's medical and scientific expertise will be a great addition to the team. His demonstrated leadership and progressive perspective in molecular pathology and genomics will accelerate advances being made in the area of personalized medicine by our world-renowned laboratory experts," said Ilke Panzer, senior vice president of Diagnostic Laboratories. BloodCenter's Diagnostic Laboratories help physicians provide clinical care to patients worldwide, fostering better understanding and treatment options for patients with difficult-to-diagnose diseases. In addition, the laboratories collaborate with other institutions and companies to bring new treatment options to patient care. "I am excited to be joining the team at the BloodCenter of Wisconsin. As a leader in diagnostics, transfusion medicine, and basic research, BloodCenter is a unique environment to develop novel solutions for improved patient care," said Dr. Anderson. Prior to joining BloodCenter, Dr. Anderson served as an assistant professor in the Department of Pathology at the Stanford University School of Medicine, and as the assistant director of the Stanford Histocompatibility, Immunogenetics, and Disease Profiling Laboratory. Dr. Anderson is a graduate of the Medical Scientist Training Program at the Medical College of Wisconsin. He completed his residency and fellowship training at the Stanford University Medical Center, and is board certified in anatomic pathology and molecular genetic pathology. (Source: BloodCenter of Wisconsin press release, 6/10/13)

MEETINGS

July 30-31 **FDA Workshop: Battery-Powered Medical Devices Workshop: Challenges and Opportunities, Silver Spring, Md.**

The Food and Drug Administration will hold a public workshop titled "Battery-Powered Medical Devices: Challenges and Opportunities" on July 30 to 31 from 8 a.m. to 5 p.m. at FDA's White Oak Campus in Silver Spring, Md. The purpose of this workshop is to create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and

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reliability of these devices. More information is available in the Federal Register notice at www.gpo.gov/fdsys/pkg/FR-2013-06-05/html/2013-13244.htm.

Contact: Iacovos Kyprianou, Center for Devices and Radiological Health, FDA, 10903 New Hampshire Ave. Bldg. 66, Rm. 3609, Silver Spring, MD 20993. E-mail: iacovos.kyprianou@fda.hhs.gov.

Oct. 21-22 **AdvaMed Workshop: 501(K) Submissions, Arlington, Va.**

AdvaMed will hold a 501(K) Submissions Workshop on Oct. 21-22 at the Sheraton Crystal City in Arlington, Va. This interactive workshop will include insight from industry experts and key personnel from FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). Early bird registration is currently ongoing. More information and registration details are available at www.advamedmtli.org/go.cfm?do=Wercs.Show&WID=208.

Contact: skinchen@advamed.org (for group discounts).

Oct. 23 **AdvaMed Workshop: IDE Submissions, Arlington, Va.**

AdvaMed will hold an IDE Submissions Workshop on Oct. 23 at the Sheraton Crystal City in Arlington, Va. Food and Drug Administration leaders and industry experts will lead professionals through the regulatory practical guidelines governing when an investigational device exemption (IDE) is required; how to compile effective IDE applications; the rules governing clinical studies and human subject protection; institutional review boards; types of pre-investigational device exemption meetings and communications; early/expanded access, foreign studies and export; and reimbursement for investigational devices. More information and registration details can be found at http://www.advamedmtli.org/go.cfm?do=Wercs.Show&WID=210. ♦

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. 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 Recruitment. Suncoast Communities Blood Bank, located on Florida's Gulf Coast, is seeking an experienced blood donor recruitment professional to direct and manage a staff of 24 involved in both fixed site and mobile recruitment activities. Responsibilities include development and implementation of effective recruitment and retention strategies, personnel management/development and budget preparation and analysis. Bachelor's degree or equivalent in a related field plus five years management, marketing, public relations or other appropriate field; prefer at least two years donor recruitment. Please submit resume and cover letter to jobs@scbb.org. EOE, pre-employment drug testing and background checks required.

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POSITIONS (continued from page 14)

Project Manager. Blood Bank of Hawaii is seeking a Project Manager. Reporting to the President and Chief Executive Officer, the Project Manager is responsible for planning, executing, and evaluating multiple projects impacting all departments and customers. This key position builds and manages the project team, supervised by the Project Sponsor, and is responsible for budget, deadlines, quality control and stakeholder management, particularly of external stakeholders. Candidates must have change control experience and worked in a highly-regulated environment; healthcare background and familiarity with software implementation a plus. The Project Manager has full responsibility for achieving milestones, deliverables, schedule and quality of projects including improving productivity and capacity, decreased cycle time, reduced work load, rework and risk. This position also ensures SOP's and documentation are exact representations of the work process. For consideration, please apply at www.BBH.org. We offer a competitive benefits package. EOE

Manager, Transfusion Services. BloodCenter of Wisconsin seeks an experienced leader to manage our Transfusion Services team. This position is based with Children's Hospital of Wisconsin, in Milwaukee, WI. This key position is responsible for managing daily operations of pre-transfusion testing on patient samples and for providing blood and blood products to transfusion recipients in a timely and accurate manner. Also responsible for successful execution of business and strategic initiatives, managing the people and financial resources, and for ongoing and sustainable improvement in the areas of compliance, customer/employee satisfaction, and process control. Successful candidate will have strong leadership skills, effective communication skills, and strong technical skills. Position requires bachelor's degree, ASCP certification, a minimum of five years experience working in a transfusion service, and at least three years management experience. SBB preferred. We offer a competitive salary and excellent benefits. BloodCenter is a world-class institution due in part to the high caliber of its employees. Apply online at www.bcw.edu/careers. We embrace and encourage diversity in our workforce. EEO

Medical Technologist. The Blood and Tissue Center of Central Texas, located in Austin, is seeking a Medical Technologist (MT) to perform all patient testing functions and donor processing. This includes, but is not limited to, viral marker EIA testing, ABO testing, antibody screens and work-ups, antigen testing and cross-matching, as well as RPR and CMV testing. This position will accurately label blood components that are available for distribution, diligently follow all procedures for testing, maintenance, safety, and quality control, as well as assist the laboratory management to maintain adequate supplies through careful monitoring of reagent usage and placement of new reagent stock. Qualified candidates must be able to work in an area where biohazardous elements can exist. BS in Medical Technology, or equivalent, as well as ASCP or NCA Certification as a MT or Blood Bank Technologist (BB) is required. AS and certification as MLT or BB will also be considered. Must be able to work/rotate through on-call schedule – extended on-call hours may be required. Familiarity with cGMP, AABB, and FDA regulations is desired. Please visit www.inyourhands.org to apply.

Medical Director. Inland Northwest Blood Center (INBC), an affiliate of Blood Systems, Inc., is seeking a full-time Medical Director with expertise in all aspects of Transfusion Medicine, Transfusion / Quality Committee activities and Transfusion Service Management. The position works with Blood Systems' Clinical Services Team to ensure patients in hospitals served by INBC receive state-of-the-art transfusion support including support for appropriate transfusion practice. Responsibilities include provision of routine/specialized transfusion medicine, medical direction for a centralized cross-match laboratory, hospital transfusion services, blood collection, and therapeutic apheresis activities. The candidate should have experience with hospital transfusion service management. INBC serves over 35 hospitals in Eastern Washington/Northern Idaho; Spokane is a regional medical hub with a new medical school and offers advanced services to patients from four states. The region offers a high quality of life, including close proximity to seasonal outdoor activities and a mild four-season climate. Spokane's growing arts/theater community and excellent higher education choices make it a prime destination for families/working professionals alike. Candidates should be board certified/eligible in Transfusion Medicine, and board certified/eligible in AP/CP, hematology and/or oncology. Send CV to Claudia Campbell, Human Resources, INBC, 210 W Cataldo, Spokane, WA 99201; Fax: (509) 232-4530; E-mail: Claudia.Campbell@inbcsaves.org. EEO/AA