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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2013 #8 **March 1, 2013**

INSIDE:

AdvaMed, Eucomed, and ABO Release White Paper Supporting Harmonization of Blood Device Medical Technology

AdvaMed, Eucomed, and the Alliance of Blood Operators (ABO) released today a white paper supporting the regulatory harmonization of blood devices globally. The paper is titled, "The Value of Harmonization Efforts in Blood Device Medical Technology: Impact of Managed Convergence on Innovation and the Public Health."

In close collaboration with ABO, AdvaMed, which represents US medical device manufacturers, and Eucomed, the European medical technology industry association, have worked together with blood regulators and blood establishments in joint efforts to support the harmonization of blood devices. ABO is an international network of non-profit blood services, which seeks to develop well-researched positions on prioritized global issues and to facilitate horizontal learning across its membership in order to identify and promote good practice.

"ABO is very pleased at reaching this important milestone in our long journey towards assuring patients and donors that blood operators have global access to the safest and most effective tests and medical devices used in blood collection and processing," said Jennifer Williams, ABO chair and chief executive of the Australian Red Cross Blood Service. "ABO is looking forward to continuing to work closely with industry and regulators to achieve this important goal."

About eight years ago, the founding members of ABO (America's Blood Centers, the Australian Red Cross Blood Service, Canadian Blood Services, European Blood Alliance, and the UK's NHS Blood and Transplant) met to determine the burgeoning organization's top priorities. When the Food and Drug Administration and Health Canada asked ABO to name its greatest regulatory priority, the group agreed that the major goal was achieving faster and cheaper access to safety improvements in the devices and tests used in the blood community to collect and process blood, said ABC CEO Jim MacPherson.

"We knew from the manufacturers that country-by-country approval was one of the biggest costs and, therefore, the biggest obstacle to that goal," added Mr. MacPherson. "We also knew that the pharmaceutical industry had already solved this problem through agreements with regulators (under the International Conference on Harmonization) on what data the regulators collectively wanted to see in order to obtain individual approval in each country."

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OUR SPACE

ABC CEO Jim MacPherson

The Future of ABC

Through the SEQuaLS customer satisfaction survey, I received many questions about the future of ABC, especially given my planned retirement in 2015. Having been its chief executive for nearly 27 years, this is perhaps the most important question. First, ABC's mission has not changed in 51 years: to help blood centers serve their communities. So as long as community blood centers exist, the role for ABC is to help them do their job better. To be sure, "community" and "blood centers" are being redefined within healthcare. Accountable Care Organizations are all about local patients, but hospitals are consolidating like never before into regional and national systems. That leaves blood centers needing to retain a local focus while having broader geographic leverage.

ABC's current focus, as always, is within its four core values. Those are, in ascending importance: innovation, data, education, and advocacy ("IDEA"). Those values have been relevant during ABC's existence, and likely will remain so, if in different forms, over the next two to three decades. Whether it is science and medicine or advocacy and marketing, ABC's current efforts zero in on the changes in healthcare and hospitals, and the threats and opportunities that lie therein. In my 41 years in blood banking, I have never seen such a focus on customers.

With our future being redefined, the ABC Board of Directors is looking at all options for the organization's future. That includes possible restructuring and mergers with complementary organizations. As a young man of 37 and with a staff of two, I had to worry about only 26 members that provided about one-quarter of the US blood supply. Today, that staff is still small (less than 20) and serves members in two countries with multiple global links. Just within the last five years, we have increased our daily member contacts from in the hundreds to now in the thousands. Think about that: ABC touches thousands of people within our member blood centers daily and many more thousands globally at least weekly. All those touches are to help you do your job better.

It is impossible to truly replace any leader who has spent decades learning while shaping an organization, but I am confident that a good successor will be found to fill my position – there is no other option. ABC may be reshaped to retain its remarkable influence, but at its core it will always strive to help its members serve their community.

Jmacpherson@americasblood.org *Visit Jim on Facebook: www.facebook.com/JimMacPhersonABC.*

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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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Blood Device Harmonization (continued from page 1)

The white paper discusses some of the collaborative efforts that are already underway between blood establishments, regulators, and the medical device organizations. For example, in June 2011, blood establishments from around the world, the European Commission, Competent Authorities from France and Portugal, FDA, EBA, and medical technology industry representatives met to discuss the potential risk of use-error of medical devices used for apheresis donors and patients and to discuss a harmonized solution for apheresis connectors applicable at an international level.

The death of a donor in France in 2009 caused by misconnection of anticoagulant in place of saline, drew attention to this safety issue. For several years, Eucomed, ABC, EBA, and ABO have been leading efforts to improve connector safety, focusing on developing an engineered solution to prevent use-error and subsequent donor and patient injury from occurring during apheresis blood collections or therapeutic plasma exchange. In parallel to efforts for an engineered solution, work at the International Organization for Standardization level are underway for two standards on connections regarding a reservoir connector for citrate anticoagulant solutions.

Getting the medical technology community, blood organizations in various countries, and now the regulators on board with harmonization of blood devices has not been easy and has taken many years, according to Mr. MacPherson. He notes that International Medical Device Regulators Forum (IMDRF) recently agreed that the apheresis connector issue is a possible future work item for the organization. IMDRF was formed in 2012 to develop common processes for device harmonization.

"These ongoing collaborative efforts are an extraordinary example of how patient safety and innovation can be both maximized to achieve regulatory harmonization in order to promote timely, safe, and optimal patient care ... Through convergence, collaborative efforts can best streamline the movement of devices from product conception to needed access to critical blood technologies around the globe," states the white paper. (*Editor's Note*: In Europe, the term "convergence" is generally used in this context instead of "harmonization.")

The paper goes on to detail key benefits that harmonization can achieve including: promoting new technologies and facilitating access to safe and effective devices and technologies; promoting the use of internationally recognized standards; streamlining regulatory requirements to best meet regulatory needs and meet global demands; and leveraging collaboration of collective stakeholders to meet public health needs.

"Eucomed is very supportive of the concept of managed convergence which is taking the apheresis safety connector project as an initial project to engage collaboration between regulators, blood establishments, and manufacturers," said Ruth Foster, chair of Eucomed's Blood Safety Group.

The paper's authors emphasize that harmonization efforts must be housed in a forum where industry, regulators, and blood establishments can work together in a collaborative and responsive manner. "We are committed to ongoing collaborative work to support blood device regulatory convergence and lending assistance/technical experts to facilitate work in this area. Joint dialogue and cooperation between key stakeholders is a vital step in blood device harmonization efforts," said the paper.

"As an active member and supporter of AdvaMed and Eucomed, we are enthused about the progress made on the Value of Harmonization Efforts in the Blood Device Medical Technology," said David Perez, president of Terumo BCT and chair of the AdvaMed Blood Sector Group. "I believe these efforts

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Blood Device Harmonization (continued from page 3)

will accelerate access to medical device technologies that will not only improve blood and donor safety but also improve the lives of the patients we all ultimately serve. This has been an impressive, collaborative effort between the suppliers of AdvaMed and Eucomed, ABO members, and regulators."

The paper notes that achieving a unique leur apheresis connection to prevent mixing up saline-citrate and anticoagulant is an ideal first collaborative project. However, the larger objective would be harnessing the public health mission of global regulators to collaborate across stakeholders to promote global harmonization. "Such collaboration could yield better standardization of clinical trials for all participating countries, while respecting the approval processes of participating countries." The paper suggests that a project group could develop a summary technical document for device clinical submissions.

AdvaMed and Eucomed commend the collaborative work of ABO and its partners stating, "Our organizations express our continued commitment to the important area of blood device technology and the critical importance of regulatory harmonization efforts to help meet needs today and face emerging issues of the future surrounding critically needed blood technologies and their role in the public health."

The white paper can be accessed at http://bit.ly/XLbh3F. ♦

NHSBT: One-Year MSM Deferral Does Not Significantly Increase HIV Risk

A study from NHS Blood and Transplant (NHSBT), the blood service of England and Wales, suggests that allowing men who have sex with men (MSM) to donate blood after a 12-month deferral period does not significantly increase the risk of transfusion-transmitted HIV, as compared to a lifetime deferral. Perhaps more importantly, a shorter deferral time, perceived by many as scientifically rational and more fair, could improve compliance and actually decrease the risk of transfusion-transmitted HIV by up to 29 percent.

The study, led by Katy Davison and colleagues of NHSBT, was published on Feb. 9 in *Vox Sanguinis.* The UK Department of Health's Advisory Committee on the Safety of Blood, Tissue and Organs (SaBTO) has already recommended reducing the lifetime deferral on donating by MSM to 12-months; this recommendation was implemented in November 2011 in England, Wales, and Scotland (see *ABC Newsletter*, 9/9/11).

The report estimates the risk of transfusion-transmitted HIV in England and Wales during 2005 to 2007 under a permanent exclusion of MSM, and compares it with the estimated risk under a 12-month deferral. The findings confirm previous research suggesting that the donors' compliance with MSM deferral has more bearing on transfusion-transmitted HIV risk than does the length of the deferral period.

Methods. A previous study estimated the HIV transfusion-transmission risk when changing from a permanent exclusion of MSM to a five-year deferral in England and Wales during 2005-2007, and concluded that the five-year deferral would have a negligible effect on blood safety. The same methods were used in this study to calculate the HIV risk under a 12-month MSM deferral. HIV incidence and prevalence were calculated among blood donors, and surveillance and survey-based data used to estimate the HIV infection status of 15- to 44-year-old MSM in England and Wales during 2006, the midyear of the assessment. They then estimated HIV transfusion risk under several sets of assumptions regarding deferral compliance and HIV incidence.

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MSM Deferral and HIV Risk (continued from page 4)

Results. Assuming equal compliance with a 12-month vs. lifetime deferral, a 12-month deferral would lead to one extra-HIV infectious donation every 455 years. Poorer compliance among MSM with the deferral would be expected to increase the estimated risk, and improved compliance could decrease risk.

Discussion. The researchers conclude that there is only a negligible increase in HIV risk when moving from a permanent exclusion to a 12-month MSM deferral, if incidence and compliance with deferral are unchanged. However, they note that the true magnitude of this change is dictated by HIV incidence and prevalence among newly eligible MSM blood donors, but is more heavily dependent upon their compliance with the deferral period. While it is estimated that transfusion-transmitted HIV risk could increase if compliance decreases, other studies have indicated a high compliance with 12-month deferral. A Swedish analysis has suggested a one-year deferral to be optimal based on increased compliance with the donor criterion.

"The modelling outlined in this article demonstrates what we suggested in our 2010 *Transfusion* report – that the compliance rate, rather than the deferral duration itself, is the most influential factor on overall risk of HIV transmission," said Clive Seed, PhD, senior blood safety analyst at the Australian Red Cross Blood Service, who was not involved in the NHSBT study. "Critically, this analysis suggests that a risk reduction can be accomplished under a shortened deferral, conditional on the deferral duration comfortably exceeding the window period. Specifically for a 12-month deferral duration, under scenario B.iv. where compliance improves from 95 to 97.5 percent, the overall HIV transmission risk declines by 19 percent."

Dr. Seed refers to a previous study that he and colleagues at the Australian Red Cross Blood Service and the Kirby Institute conducted and published in July 2010, showing that adopting the 12-month MSM deferral in Australia did not lead to a significantly increased recipient risk of HIV.

The authors of the current NHSBT study also note that more advanced donor screening tests for HIV have significantly improved blood safety and decreased the risk of transfusion-transmitted HIV. Other countries have followed in the footsteps of the UK and Australia, often citing improved donor screening as an important reason to implement a fixed-period MSM deferral instead of lifetime exclusion. Canadian Blood Services (CBS), for example, submitted a plan to Health Canada in December 2012 to lift the lifetime MSM ban in favor of a five- to- 10-year deferral (*ABC Newsletter*, 12/7/12).

The US Food and Drug Administration requires the lifetime deferral for MSM, while many other risk deferrals are limited to one year. This stringent position is based on the higher incidence and prevalence of HIV in MSM and on concerns that MSM represent a population that may be at higher risk for other putative blood transmissible agents. Ongoing studies commissioned by the Department of Health and Human Services are exploring whether the MSM deferral policy can be changed to permit certain low-risk gay men to donate without compromising the safety of the blood supply. America's Blood Centers, the American Red Cross, and AABB have long advocated a reduction of the lifetime ban to a 12-month deferral.

Citations: Davison KL, *et al*. The risk of transfusion-transmitted HIV from blood donations of men who have sex with men, 12 months after last sex with man: 2005-2007 estimates from England and Wales. Vox Sang. 2013 Feb 9. [Epub ahead of print]

(continued on page 6)

MSM Deferral and HIV Risk (continued from page 7)

Seed CR, *et al*. No evidence of a significantly increased risk of transfusion-transmitted human immunodeficiency virus infection in Australia subsequent to implementing 12-month deferral for men who have had sex with men. Transfusion. 2010 Dec;50(12):2722-30.

Socialstyrelsen (National Board of Health and Welfare, Sweden). Summary of analyses on selection criteria for blood donors and requirements for methods of testing. Unit for Communicable Disease Prevention and Control, 2009.

Q&A with ABC's *Human Resources Department*

America's Blood Centers' Staff Answers your Questions

America's Blood Centers recently conducted its SEQuaLS assessment, a customer service survey that solicits feedback from member blood centers on ABC's activities. Through this assessment, members were able to pose questions to the ABC staff. Each ABC department will respond to these questions through this weekly Q&A column in the Newsletter.

Q: I am an HR leader new to the industry. What advice or counsel would you give me to ensure that I am getting the most value from ABC?

A: Sign up for America's Blood Centers Human Resources (HR) Forum and Listserv. Each resource is available to all staff of ABC member blood centers. If you would like to be added or to ensure that you are currently a member of the HR Forum and/or Listserv, please e-mail Lolita Hampton at lhampton@americasblood.org.

HR Forum members receive e-mail updates about the current programs and projects of ABC's HR Steering Committee such as: the biennial Human Resources & Employee Training/Development Workshop (scheduled for May 2014); HR Forum surveys (e.g., benefits and compensation); and the HR Forum Webinar Series. This quarterly series of webinars explores hot topics affecting human resources in blood banking. For more information and to access archives of previous webinars, please visit: http://members.americasblood.org/go.cfm?do=Page.View&pid=127.

In addition, HR Forum members have access to a wealth of information through ABC's HR Listserv, which at present has more than 170 subscribers. The Listserv allows you to exchange ideas on HR issues and stay current with your peers in the blood center community. Also, you can search the archives for previous discussion topics and documents. More information regarding the Listserv is available at: http://members.americasblood.org/go.cfm?do=Page.View&pid=126.

Health Agencies Decry Sequester Cuts, Saying Americans at Greater Risk

When the sequestration ax falls today (March 1), the Department of Health and Human Services says it will have to forgo providing thousands of vaccinations to children and cancel more than 2,000 food safety inspections as well as 4 million "Meals on Wheels" to needy seniors. Up to 373,000 mentally ill adults and emotionally disturbed children also may go untreated, Bill Hall, a spokesman for HHS, told Maggie Fox of NBC News this week.

The only programs completely exempt from the cuts are Medicaid, the Children's Health Insurance Program, and Social Security. Everything else that HHS oversees – from food and drug safety, to biomedical research, to infectious disease surveillance, will see 5 percent across-the-board cuts.

The Centers for Disease Control and Prevention says its $6 billion budget will shrink by an estimated $350 million over the next seven months. The cuts will force the agency to cancel plans to hire 2,000 disease control specialists. Among the myriad program cuts the agency will also be forced to make is a reduction in the number of measles vaccinations for children abroad, which will mean that more cases of the infectious disease will find their way into the US, said CDC Director Thomas R. Frieden, MD, MPH, in remarks this week to *CQ HealthBeat* Editor John Reichard.

The funding decrease will mean that the CDC will detect other infectious diseases more slowly, which will lead to more deaths during the next flu outbreak, he said. "More than two-thirds of our budget goes to boots-on-the-ground work at the state and local level to find and stop outbreaks and other health threats." Dr. Frieden said that the cuts come as the agency has slashed $100 million in administrative costs in the past few years.

The National Institutes of Health faces $1.5 billion in cuts to its $31 billion budget. NIH Director Francis Collins, MD, speaking at a press conference last week with Sen. Barbara Mikulski (D-Md.) at the agency's headquarters, said that the sequester cuts will delay clinical trials, cut thousands of jobs, and jeopardize the training of a generation of young scientists. Dr. Collins said that each of NIH's 27 institutes and centers face a 5.1 percent cut, meaning that researchers investigating cancer, heart disease and blood diseases, such as diabetes, will all face the same pain. So far, however, NIH does not expect to furlough researchers or other staffers.

NIH has not had a budget increase in a decade, meaning that its budget has already been eroded by annual inflation. Carol Greider, a Nobel prize winner who chairs the Department of Molecular Biology and Genetics at Johns Hopkins University in Baltimore, said at the press conference that the number of NIH grants she has received has dropped from four to two in the past couple of years, and she has had to cut her staff of trainee assistants by at least half.

Automatic cuts will impact the Centers for Medicare and Medicaid Services, but the agency has not yet detailed the impact or said which programs will be most affected.

Congress has not yet approved the federal government's fiscal year 2013 budget; NIH, like other federal agencies, has been operating under a continuing resolution since Oct. 1, a stop-gap measure that runs out on March 27.

Many Republican lawmakers discounted the potential impact of the cuts. "We are talking about less than 3 percent of the annual federal budget," said Louisiana Gov. Bobby Jindal on Monday at a briefing. "For them to suggest that this will result in a hollowing out of the military, interruptions in food inspections, and result in folks not getting critical healthcare services is, again, preposterous." (Sources: *CQ Healthbeat News*, 2/24/13; *Science Insider*, 2/21/13; NBC News, 2/26/13) ♦

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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 Legislative Day Breakfast to Feature Red Cross Public Policy Official

Blood center professionals will get a chance to learn a few things from an accomplished government relations and public policy veteran at the Legislative Day Breakfast on Tuesday, March 19, during America's Blood Centers Annual Meeting.

Cherae Bishop, senior vice president, Government Relations, at the American Red Cross, will discuss her experiences and lessons-learned on Capitol Hill and relate her personal story. Ms. Bishop joined the American Red Cross, National Headquarters in 2008 as the senior director of Legislative Affairs. In 2012, she was promoted to her new role, capping 15 years of experience in government relations, legislative affairs, and public policy.

Prior to joining the American Red Cross, Ms. Bishop provided legislative and strategic advice and counsel to Volunteers of America, Inc. (VOA) as the non-profit's vice president of Legislative Affairs and Public Policy. She led the organization's legislative efforts in the areas of homelessness, elder care, and veterans' issues. Her work led VOA's Veterans Collaborative to receive a $130 million authorization from Congress for community-based, faith-based, and public organizations to offer transitional housing or service centers for homeless veterans.

Ms. Bishop also served as manager of Constituency Relations for Altria, Corporate Services, Inc., the parent company of Phillip Morris, Inc., Phillip Morris International, and Kraft Foods, Inc.

She also served as the manager of Government Affairs with the forest and paper industry company, Weyerhaeuser Co., from 2001 to 2004. She played a key role in securing $2 million in federal funding for Washington States Forests and Fish Plan, which improves aquatic systems and promotes viable forests. Ms. Bishop has also held key positions at the American Forest and Paper Association and the National Association of Manufacturers.

A native of Hamden, Conn., Ms. Bishop received a Bachelor of Arts degree from Wesleyan University in Middletown, Conn., and a Juris Doctor degree from the American University Washington College of Law in Washington, DC.

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

RESEARCH IN BRIEF

A study published this month in *JAMA Surgery* shows that an a thawed plasma protocol for the emergency department expedited transfusion of plasma to severely injured patients. The study was conducted by Radwan and colleagues at the University of Texas Health Science Center in Houston. Hemorrhage is the leading cause of death within the first hour of arrival to a trauma center and one of the leading overall causes of death in trauma patients. Past studies have shown that in severely injured patients who are coagulopathic and thrombocytopenic, higher ratios of plasma and platelets are associated with reduced mortality. To achieve higher plasma-red blood cell (RBC) ratios and to deliver plasma more quickly, many healthcare facilities have implemented massive transfusion protocols, which often involve keeping thawed plasma (TP) in the hospital blood bank or in the emergency department (ED), rather than having to retrieve and thaw frozen plasma products in the blood bank. The University of Texas Health Science Center has kept TP in its blood bank for 20 years, and on Feb. 1, 2010, the hospital began placing TP in the ED (TP-ED) for quicker delivery to severely injured patients. Using the Trauma Registry of the American College of Surgeons Database, the researchers evaluated all adult trauma patients admitted from June 1, 2009 through Aug. 31, 2010, who arrived directly from the scene, were at the institution's highest level of trauma alert activation, and received at least one unit of RBCs and one unit of plasma in the first six hours of admission. A TP protocol was initiated by giving four units of AB plasma to patients in the ED. Patients were divided into two groups: those admitted before (TP-BB) and eight months after implementing the TP location change (TP-ED). The primary outcome was the time to first unit of plasma, and the secondary outcomes included 24-hour blood use and 24-hour and 30-day mortality. A total of 294 patients met the study criteria. The TP-ED patients had a shorter time to first plasma treatment (89 vs. 43 minutes). The TP-ED protocol was associated with a reduction in 24-hour transfusion of RBCs, plasma, and platelets. Multivariate logistic regression identified TP-ED as an independent predictor of decreased 30-day mortality. "We demonstrated that implementation of TP-ED protocol expedites transfusion of plasma to severely injured patients. This approach is associated with a reduction in overall blood products used and a 60 percent decreased odds in 30-day mortality," conclude the authors. In an accompanying commentary, Jonathan R. Hiatt, MD, noted, however that the beneficial effect of TP-ED protocol on mortality must be interpreted with some caution as the multivariable model did not include the Glasgow Coma scale score or volume of transfusion in the first six hours. Dr. Hiatt also noted that while increased transfusion ratios are generally recognized as beneficial, exact ratios of plasma and platelets are debated and may be different depending on the presence of traumatic brain injury. He added that the study highlights the value of ongoing quality improvement programs. While the improved timeliness of plasma availability is not surprising, the substantial change in the mortality endpoint is difficult, in a retrospective study, to reconcile with the administration of the first thawed plasma in 43 minutes vs. 89 in the control; that observation must be reproduced in appropriate trials controlled for unrecognized confounding variables.

Citations: Radwan ZA, *et al*. An emergency department thawed plasma protocol for severely injured patients. JAMA Surg. 2013 Feb 1;148(2):170-5.

Hiatt JR, *et al*. Stopping the bleeding: comment on "an emergency department thawed plasma protocol for severely injured patients." JAMA Surg. 2013 Feb 1;148(2):175-6.

A study, published in *Nature Medicine*, suggests that an antidepressant used since the 1960s may help treat sickle cell disease. Sickle cell disease is caused by an abnormal type of hemoglobin, which causes red blood cells (RBCs) to assume abnormal crescent shapes. This can lead RBCs to block small blood vessels and impairing blood flow, thus causing acute pain crises, severe bacterial infections, and necrosis

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RESEARCH IN BRIEF (continued from page 9)

(tissue death). It is known that enhancing fetal hemoglobin production can mitigate symptoms of sickle cell disease, but the body stops producing fetal hemoglobin after infancy. Lihong Shi *et al* from the University of Michigan found that the enzyme lysine-specific demethalyse 1 (LSD1) acts as a barrier to fetal hemoglobin production. In *ex vivo* experiments, tranylcypromine (TCP), a Food and Drug Administration-approved antidepressant, inhibited LSD1, allowing fetal hemoglobin production to increase. "This is the first time that fetal hemoglobin synthesis was re-activated both in human blood cells and in mice to such a high level using a drug, and it demonstrates that once you understand the basic biological mechanism underlying a disease, you can develop drugs to treat it," said James D. Engel, PhD, an author of the study. A clinical trial is being planned for adult patients with sickle cell disease. Andrew Campbell, MD, who has worked with Dr. Engel, finds this research exciting, but cautions that future clinical research is necessary to determine if the results in mice and cultured human red cell precursors will translate into humans for TCP or other drugs that inactivate LSD1. (Source: University of Michigan press release, 2/19/13)

Citation: Engel JD, *et al*. Lysine-specific demethylase 1 is a therapeutic target for fetal hemoglobin induction. Nat Med. 2013 Feb 17. [Epub ahead of print]

A study in *Blood* provides insight into the nature, incidence, and risk factors for developing an autoimmune disease after cord blood transplantation. The retrospective study was conducted by EUCOCORD and the European Group for Blood and Marrow Transplantation Autoimmune Disease Working Party. All centers reporting to EUCOCORD were invited to participate and were asked for follow-up on all patients who received cord blood transplantations before Jan. 1, 2009; they identified all those who had developed an autoimmune disease after a cord blood transplant. In the cohort of more than 700 patients, over 6 percent developed an autoimmune disease from five weeks to 10 years after transplant. Most were organ-specific autoimmune diseases, such as cytopenias followed by autoimmune diseases of the thyroid and a few cases of miscellaneous multisystematic autoimmune disease. Autoimmune hemolytic anemia and immune thrombocytopenia were observed most commonly, and must be considered in any patient at any time after a cord blood transplant as a possible reason for cytopenia. Patients transplanted for nonmalignant disease were at increased risk for developing post-transplantation autoimmune diseases. In patients not responding to initial treatment with steroids, rituximab may be an effective treatment option, said the authors. They suggest that both clinical and mechanistic aspects of new autoimmune diseases occurring after hematopoietic stem cell transplantation should be researched further.

Citation: Daikeler T, *et al*. New autoimmune diseases after cord blood transplantation: a retrospective study of EUCOCORD and the Autoimmune Disease Working Party of the European Group for Blood and Marrow Transplantation. Blood. 2013 Feb. 7;121(6):1059-64.

BRIEFLY NOTED

***The New York Times* recently published an article featuring a successful bloodless lung transplant in a Jehovah's Witness patient, highlighting improved bloodless surgery methods.** The article tells the story of Rebecca S. Tomczak, a Jehovah's Witness from Augusta Ga., who was told last April that a lung transplant could save her from a fatal lung condition. Jehovah's Witnesses believe that Christians cannot consume blood, which includes transfusion. Ms. Tomczak had difficulty finding a hospital that would perform a bloodless lung transplant, but eventually found Scott A. Scheinin, MD, at The Metho-

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BRIEFLY NOTED (continued from page 10)

dist Hospital in Houston, who uses various blood management techniques and conducts bloodless surgeries. Ms. Tomczak's case would be the 11th bloodless lung transplant attempted at Methodist over three years. None of the 10 patients who proceeded Ms. Tomczak, including two who had double-lung transplants, had problems related to surgical blood loss or postoperative anemia. Recent studies have shown that Jehovah's Witness patients who undergo bloodless surgery typically do not do any worse than patients who receive blood. For example, one study published in July 2012 in the *Archives of Internal Medicine* showed that patients who refused blood transfusions during cardiac surgery were not necessarily at greater risk of surgical complications or long-term mortality when compared with cardiac patients who had blood transfusions (see *ABC Newsletter*, 7/13/12). Some Witnesses choose to accept blood fractions like clotting factors, as well as synthetic proteins that stimulate red cell production. Others will also accept the use of mechanical cell salvage techniques, which re-infuse the patient with blood lost during the surgery; the church does not view this as a transfusion since the blood remains in a continuous circuit with the body. Some doctors, like Dr. Scheinin, believe that these bloodless surgery techniques can and should be applied to other patients in the interest of conserving blood and avoiding unnecessary transfusion. While Dr. Scheinin notes that some studies have shown possibly deleterious effects of transfusion, most large randomized controlled trials comparing conservative vs. liberal transfusion strategies suggest largely equivalent outcomes among the two groups. Bloodless surgery techniques are valuable to patients who refuse blood, but the true value to patients who will accept blood are unknown. *The New York Times* article is available at http://nyti.ms/XJc458. (Source: *The New York Times*, 2/24/13)

A military trial program initiated in Afghanistan this past summer allowing medical evacuation helicopters to carry blood and medics to administer in-flight transfusions is already saving lives, reported Stars and Stripes, an independent news source for the US military community. Previously, only specialized Air Force "Pedro" rescue helicopters could carry blood, meaning that most wounded troops could not get transfusions until arriving at a hospital. "Most of the people we see who die, it's really because they don't have blood in their body," Army Capt. Deanna Klesney, a flight surgeon who is overseeing the training, told Stars and Stripes. "A lot of people die en route." The article notes that roadside bombs remain the biggest killer of US troops, and many injured in such attacks suffer amputations and other injuries that can result in rapid blood loss. Under the new program, medics have administered transfusions on nearly 90 flights and the program has saved lives, said Capt. Klesney in the article. She notes that getting blood to these injured troops even 15 or 30 minutes sooner can make a difference. Flight medics must complete an intensive two-to-three day training course to get certified to administer in-flight transfusions. They must do hands-on testing, in full body armor, to make sure they can perform the procedures in flight conditions. Statistics being collected on the program show that so far, nearly 62 percent of in-flight transfusion recipients tracked have survived, a high rate considering the patients receiving transfusions are generally the most severely wounded. Currently, units in regional commands south and southwest Afghanistan are able to administer in-flight transfusions, but eventually the program is expected to be implemented throughout Afghanistan. The Stars and Stripes article can be accessed at http://1.usa.gov/UMgpq8. (This article information was used with permission from Stars and Stripes) ♦

REGULATORY NEWS

The Food and Drug Administration published this week an updated draft guidance on syphilis testing of blood donors. This draft guidance is titled "Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis." This version replaces the June 2003 draft guidance titled "Revised Recommendations for Donor and

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REGULATORY NEWS (continued from page 11)

Product Management Based on Screening Testing." The guidance recommends identifying donors with a history of syphilis through questioning, and deferring donors who have had or been treated for syphilis or gonorrhea in the past 12 months. FDA also recommends in the draft guidance testing donors using either a nontreponemal or treponemal test approved by FDA for the purposes of donor screening. FDA recommends deferring donors who test repeatedly reactive on screening tests and provides guidance on donor reentry based upon test results. The draft guidance is open for comments until May 28. ABC will be submitting comments and encourages the membership both to submit their own comments and to share with ABC any concerns or questions for inclusion in ABC's comments. The draft guidance is available at http://1.usa.gov/13opbQ0. (Source: FDA Draft Guidance for Industry, 2/25/13)

The Food and Drug Administration issued this week its final Guidance for Industry titled "Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma." In this guidance, FDA recognizes the standard full-length and abbreviated donor history questionnaires (DHQs) and accompanying materials prepared by the Plasma Protein Therapeutics Association (PPTA). The current PPTA documents are version 1.22 dated September 2012 referenced in this guidance. In the guidance, FDA "acknowledges day of collection" to include responses to questions within 24 hours of the time of collection. FDA recommends that the Abbreviated PPTA DHQ be used with the Full-Length PPTA DHQ. These DHQs may be administered either by establishment staff or self-administered with follow-up by staff. FDA notes that the PPTA DHQs have questions relating to cancer, organ, tissue, and bone marrow transplant, as well as bone or skin graft, and pregnancy. FDA does not require donors to be screened for these conditions. The guidance provides recommendations for reporting implementation of the PPTA DHQ. If an establishment implements this DHQ with minor modifications of format or more restrictive selection criteria, the notice can be made in the establishment's annual report. Other changes would be considered major and would require a Prior Approval Supplement. The guidance and DHQs can be accessed at http://1.usa.gov/Xj6UPc. (Source: FDA Guidance for Industry, 2/25/13) ♦

INFECTIOUS DISEASE UPDATES

HIV

The US Institute of Medicine (IOM) recently released a 700-page report evaluating the 10-year-old US program that provides HIV treatment and prevention in dozens of developing countries – the President's Emergency Plan for AIDS Relief (PEPFAR). The program, launched in 2003 under then-President George W. Bush as an emergency response to the global AIDS epidemic, has spent more than $38 billion between 2004 and 2011. The IOM report, "Evaluation of PEPFAR," suggests PEPFAR needs to begin shifting to host-country ownership of the program, and needs to increase its emphasis on HIV prevention, particularly through sexual transmission. The report was required by Congress in 2008 when it last authorized PEPFAR, a measure that expires at the end of the 2013 fiscal year. To compile the report, IOM drew on a variety of data sources, including financial data, program monitoring indicators and clinical data, extensive document review, and primary data collection through more than 400 semi-structured interviews with a range of stakeholders in 13 PEPFAR partner countries. The report outlines key challenges for the future. "Even with PEPFAR's contribution to the substantial scale-up of HIV services in countries with restricted resources and infrastructure, the most profound challenge is simply the unmet need. In the future, it will be crucial for PEPFAR to work effectively with partner countries and global stakeholders to ensure that hard-fought gains are sustained and to continue to make progress against the

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INFECTIOUS DISEASE UPDATES (continued from page 12)

HIV pandemic in the face of a weak global economy and many competing demands for resources for health development," wrote Robert E. Black, the PEPFAR report's authoring committee chairman, in a commentary in *The Lancet*. Many of the challenges noted in the report focus on ensuring sustainability of the PEPFAR programs within the countries' own health systems. The report also addresses the blood safety initiatives of PEPFAR noting that "Blood safety is a critical element of a comprehensive approach to HIV prevention." In 2003, WHO estimated that 5-10 percent of HIV infection were acquired through transfusion-related transmission. Blood and medical injection safety have been components of PEPFAR's prevention efforts since the program's inception in 2003, and its primary type of activity around blood safety is the provision of technical assistance and capacity building. Despite some challenges, PEPFAR participants identified blood safety work as a PEPFAR success in several countries. Interviewees also described how capacity in the national blood safety system had been built with PEPFAR support. "The IOM PEPFAR recommendations resonate with all organizations that provide technical assistance in blood safety," said AABB CEO Karen Shoos, JD, the principal investigator for AABB's PEPFAR projects. "For the last nine years, AABB, in keeping with its Quality Systems approach, has focused its PEPFAR technical assistance on developing *sustainable* blood programs. This goal requires that we assist countries in their adoption of national laws, policies, and regulations, the development of in-country talent, and the implementation of effective quality management and national procurement systems, all based on the blood needs of the country and supported by appropriate clinical use guidelines. Sustainability, however, also requires that countries now plan for decreasing external funding through integration of the blood program into their national health systems and securing adequate and ongoing government funding. Important to our mission in this arena is ensuring that blood safety continues to be an important PEPFAR priority." (*Editor's Note*: Ms. Shoos will receive America's Blood Centers' Thomas F. Zuck Lifetime Achievement Award in March for her work with PEPFAR.) The IOM report can be accessed at www.nap.edu/catalog.php?record_id=18256. (Source: Nature News Blog, 2/20/13; "Evaluation of PEPFAR," 2/20/13)

Citations: Black RE. The future of the US response to global HIV/AIDS. Lancet. 2013 Feb 20. [Epub ahead of print] ♦

MEMBER NEWS

Bonfils Blood Center held its first-ever benefit concert, Give LIVE, on Feb. 14, featuring Denver, Colo.'s DeVotchKa, a four-piece multi-instrumental and vocal ensemble that is most known for composing the score to the film *Little Miss Sunshine*. The group was also nominated for a 2006 Grammy Award for Best Compilation Soundtrack. Bonfils was able to raise nearly $130,000 through sponsorships, ticket sales, and general gifts, making Give LIVE one of the blood center's largest fundraising events to date. More than 1,500 guests took part in this evening, which included a pre-concert VIP party for sponsors and VIP ticket holders, as well as an exclusive meet-and-greet with the band.

DeVotchKa plays at Bonfils Blood Center's Give LIVE benefit concert on Feb. 14.

DeVotchKa played for nearly two hours, singing many of their most popular songs. Bonfils raises funds year-round for blood donor and patient safety, community and donor outreach, mobile blood drive support, and much more.

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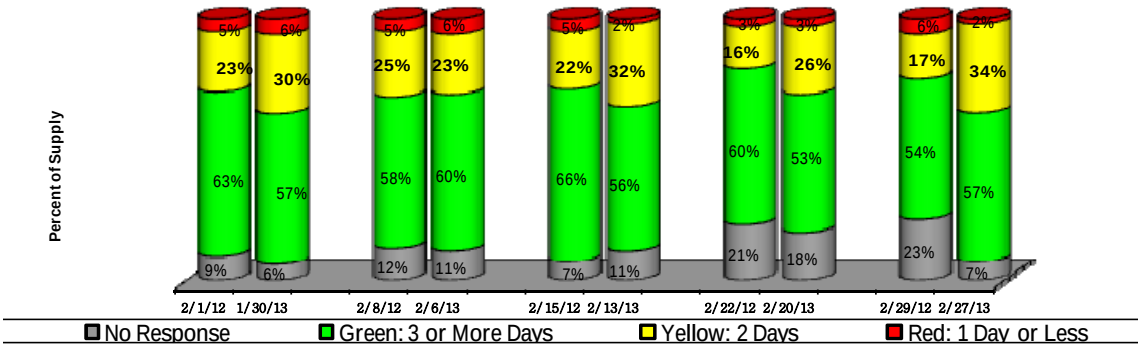
MEMBER NEWS (continued from page 13)

Proceeds from Give LIVE will help Bonfils fund these projects and initiatives throughout 2013. (Source: Bonfils Blood Center press release, 2/21/13) ♦

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



The order of the bars is (from top to bottom), red, yellow, green, and no response

COMPANY NEWS

Quest Diagnostics, a provider of diagnostic information services, reported in a press release on Monday that it has signed a definitive agreement to sell its HemoCue diagnostic products business to Radiometer Medical ApS for about $300 million. HemoCue develops, produces, and markets hemoglobin, glucose and other point-of-care testing systems worldwide. "The HemoCue divestiture, along with our sale of OralDNA in December 2012, demonstrates our commitment to refocus our business on diagnostic information services," said Steve Rusckowski, president and CEO of Quest Diagnostics, in the press release. "We plan to use the proceeds to repurchase approximately $300 million of Quest Diagnostics shares as part of our stock buyback program." The transaction is expected to be completed in March. (Source: Quest Diagnostics press release, 2/25/13) ♦

MEETINGS

April 10-11 **FDA Public Workshop: Application of Advances in Nucleic Acid and Protein Based Detection, Bethesda, Md.**

The Food and Drug Administration will hold a public workshop titled "Application of Advances in Nucleic Acid and Protein Based Detection – Methods to Multiplex Detection of Transfusion-Transmissible Agents and Blood Cell Antigens in Blood Donations." It will be held on April 10 from 8 a.m. to 5:30 p.m. and April 11 from 8 a.m. to 5 p.m. in the Natcher Conference Center at the National Institutes of Health in Bethesda, Md. Registration is free, but early registration before April 1 is recommended to secure a spot. More information is available at http://1.usa.gov/15Ui2Xn. ♦

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:

Assistant Medical Director. LifeStream, a $53M healthcare organization providing blood services to more than 80 hospitals in Southern California, is searching for an Assistant Medical Director. This position provides leadership and direction for the medical programs needed to support all laboratories, product management, hospital relations, donor collections, donor counseling, national marrow donor activities, and quality departments. Requirements: medical degree and board certification by a board registry recognized by the American Board of Medical Specialties. Meet eligibility requirements to obtain appointments to the medical staff of hospitals served by the center. Completion of primary medical internship and residency with minimum one year medical practice (transfusion medicine) or fellowship preferred. Valid license (or eligibility) to practice medicine in the state of California. Must be available to work on-call two weeks per month. Must pass pre-employment background check, drug screen, and physical exam. Apply online: www.LStream.org. LifeStream is an Equal Opportunity Employer, M/F/D/V.

Cord Blood Laboratory Manager. The Puget Sound Blood Center is seeking an experienced leader to manage our laboratory operations and oversee the development and coordination of protocols and procedures. The Manager is responsible for quality control, technical audits, and developing strategies for implementing new methodology, products, and services. This opportunity involves interaction with other medical organizations and supervision of laboratory personnel. The requirements for this position include: baccalaureate degree in medical technology or equivalent certification, two years' experience in cellular therapy, or related, two years' experience at the manager level; outstanding communication skills, knowledge cellular therapy standards, including cGMP and cGTP; familiarity with QA, cryopreservation, microbiology, sterile technique and safe handling of potentially infectious human blood/tissues. To apply, send application materials via email HumanResources@psbc.org or fax (866) 286-8495 with reference number 6917. Should you have a disability that requires assistance and/or reasonable accommodation with the application process, contact the HR department at humanresources@psbc.org, or at (206) 292-6500, or at 921 Terry Avenue, Seattle, WA 98104. Puget Sound Blood Center is an Affirmative Action / Equal Opportunity Employer.

Quality Assurance Regulatory Affairs Manager (Lifeblood, Memphis, Tenn.). The QA Regulatory Affairs Manager works under the supervision of the director of QA and the vice president, QA. Responsibilities include: review of procedures, processes and validation documentation to assure that current practices meet or exceed regulatory guidelines and industry standards, hosting external auditors/inspectors to include preparation of audit reports and response to audit findings as needed, performing internal audits, as assigned, assisting with management of licenses and certificates, reviewing/completing error reports and corrective/preventative actions, as assigned, managing staff. Minimum qualifications include: Bachelor of Science in related field or associate degree with commensurate experience, at least five years of management experience required, at least five years blood banking experience and/or operations in regulated industry, regulatory experience required, working knowledge of regulatory and accreditation standards including FDA, OSHA, and CLIA, and previous auditing and/or technical writing experience preferred. For more information or to apply, please visit http://lifeblood.iapplicants.com/.

Director, Quality Assurance (Virginia Blood Services). The Quality Assurance Director is responsible for assuring compliance to the ITxM Quality Plan and regulatory compliance for the Virginia region. Assist in the development and implementation of changes within the quality unit. Leads QA meetings. Provide quality presence for operational changes. Standardize QA processes between Pittsburgh, Chicago and Virginia. Assist and monitor the annual review of SOPs. Supervise staff. Bachelor of Science or Arts is required with a master's degree highly desirable. ASQ certification also highly desirable. Ten plus years progressive experience required with five years in a QA role in an FDA/cGMP regulated environment essential. Experience in a blood center setting is highly preferred. Progressive supervisory experience is required. Interested candidates can read a complete job description and apply online at

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POSITIONS (continued from page 15)

www.vablood.org. Virginia Blood Services is an equal opportunity and affirmative action employer.

Director of Donor Services. Michigan Blood, a growing and healthy organization, is looking for a dynamic person to join our management team and lead our statewide donor services efforts and staff. This position will oversee a department with 170+ employees and responsibilities include staffing, training, performance management, financial management, and continuous process improvement. The ideal candidate will demonstrate remarkable leadership, customer and technical services so that the donor's life-saving donation can best meet all of our hospital partner demands. Previous senior management experience is required. We offer a competitive salary and an exceptional benefit plan. If you want to be part of a growing organization and make a life-saving difference, please apply via our website: www.miblood.org.

Laboratory Technician #611/Laboratory Technologist #612. Inland Northwest Blood Center, located in the beautiful Pacific Northwest, is seeking a full-time Laboratory Technician or Laboratory Technologist to join our committed team of professionals in performing serologic investigations and routine/emergency immunohematology. Position is scheduled night shift (11:00 a.m. – 7:30 p.m.). Experience in laboratory work/blood banking desirable; ability to lift up to 25 pounds frequently/up to 50 pounds occasionally; and Laboratory Technician: *MLT(ASCP) or equivalent training and licensure; Laboratory Technologist: Bachelor of Science degree and certification as *MT (ASCP) or equivalent. *Current students of an accredited program who will obtain licensure within six months may also apply. Complete position description available upon request (800) 423-0151, Ext. 4247. Competitive compensation/benefits package; applicants must send/fax a completed INBC Application, Attn: Human Resources, INBC, 210 W Cataldo Ave, Spokane, WA 99201; FAX (509) 232-4530; position open until filled. Applications are available on our website at www.inbcsaves.org. EEO/AA