



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2013 #28

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The *ABC Newsletter* will not be published on Aug. 9 because ABC staff will be attending the ABC Interim Meeting in Milwaukee, Wis. next week. The next issue will be published on Aug. 16. We hope to see you in Milwaukee!

Legislators Urge HHS to Reevaluate MSM Deferral Policy

Today, US Rep. Mike Quigley (D-Ill.), US Sens. Tammy Baldwin (D-Wis.) and Elizabeth Warren (D-Mass.), and US Rep. Barbara Lee (D-Calif.) sent a letter to the Department of Health and Human Services Secretary Kathleen Sebelius requesting information on the ongoing efforts by HHS to reevaluate the Food and Drug Administration’s permanent blood donor deferral of men who have sex with men (MSM). The bipartisan letter, signed by an additional 82 members of the US Congress, states that the legislators “look forward ... to ending this outdated policy and moving forward with securing the nation’s blood supply in a scientifically sound manner.”

FDA instituted the lifetime MSM blood donor deferral policy following the AIDS epidemic to protect the blood supply from transfusion-transmitted diseases, based upon the higher incidence and prevalence of HIV in MSM. However, “since the beginning of the HIV/AIDS epidemic more than 30 years ago, the scientific community’s understanding of the virus has changed dramatically,” says the legislators’ letter. “We have seen vast advances in blood screening technology, blood donation policy changes in other countries allowing MSM to donate, and opposition from our nation’s blood banks who have called the current ban ‘medically and scientifically unwarranted.’”

The letter comes shortly after the American Medical Association (AMA) adopted a resolution opposing the lifetime MSM deferral in favor of rational, scientifically-based deferral periods that are fairly and consistently applied to all blood donors (see *ABC Newsletter*, 6/21/13) (available at <http://bit.ly/1ceyBC1>). The members of Congress supporting this letter to HHS said they “feel that AMA’s recent vote in opposition to the current policy provides even greater impetus for HHS to move swiftly with its research and revision of the current ban.”

In 2010, the HHS Advisory Committee on Blood Safety and Availability found the current MSM deferral to be “suboptimal,” and several studies have since been initiated to assess the risks of MSM donation and the impact that new deferral

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OUR SPACE

ABC Executive Vice President Louis Katz, MD

Three Kinds of Lies: Lies, Damned Lies, and Statistics

Two recent reports appeared separately in the *ABC Newsletter*. The Healthcare Cost and Utilization Project (HCUP) Statistical Brief, #149 from the federal Agency for Healthcare Research and Quality (<http://1.usa.gov/14QoU6H>) lists transfusion as the most frequent procedure performed in US hospitals during 2010, while the 2011 National Blood Collection and Utilization Survey (NBCUS) (www.hhs.gov/ash/bloodsafety/nbcus/) shows significant decreases in blood transfusions since 2008. I have received inquiries about the apparent discrepancy between the reports, but there is probably no conflict – they count apples and oranges.

HCUP tabulated what they could methodologically from standardized databases, while NBCUS elicited the specific information that blood bankers are most interested in. HCUP uses coding data from stays in short-term, non-Federal, general, and other hospitals, and should be quite accurate, provided that those institutions are coding and reporting appropriately. These data represent aggregation of ICD-9-CM codes for all autologous (including perioperative salvage) and allogeneic components, plus volume expanders and coagulation concentrates (undoubtedly resulting in inflation of transfusion rates) using HCUP Clinical Classification Software (CCS) to collapse the data into “meaningful groupings.” Transfusion was reported during 91 stays/10,000 population during 2010, an increase of 126 percent since 1997. The authors cannot tell us how many allogeneic units are transfused during each episode. The data are therefore not useful in judging the volume of transfusion in the US. The comparator year (two years before TRICC was published) is ancient history in the context of blood management. The comparison also misses the peak of red blood cell (RBC) transfusion in the mid-2000s. Whether the patient populations from the two time frames are comparable is another confounder.

When these data were distributed, blood bankers were skeptical, being acutely aware of declining RBC and plasma use in our own systems during recent years. By contrast, NBCUS shows an 8.2 percent drop in RBC transfusions since 2008. While generally unpublished, it is hardly anecdotal to note that for many ABC members, the decline is greater than 8.2 percent and accelerating. Also, based on trends at hospitals served by Mississippi Valley Regional Blood Center and discussions with my colleagues, I suspect single-unit RBC transfusion (an anathema during training to those of us of a certain age) has caught on as the default strategy in many facilities. Anyway, it is possible that the population frequency at which inpatients are transfused is higher now than in the (medically remote) past, but the number of units to which they are exposed is falling – probably a good thing for patients. It is also a good thing for us to understand the two reports to articulate clearly the “state-of-the-art” in blood use to our varied constituencies.

lkatz@americasblood.org ♦

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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Congress Letter to HHS on MSM Deferral (continued from page 1)

policies may have on the blood supply. There are three ongoing HHS-supported studies investigating this issue. A Retrovirus Donor Epidemiology Study-II (REDS-II) and the Donor History Questionnaire study are scheduled to report results in October 2013. The Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) study will be completed in 2014. In March 2012, HHS also released for public comment a request for information (RFI) on the design of a new pilot study to assess the feasibility and safety of new criteria for MSM blood donation.

While the Congress members applaud HHS for supporting this research, they are concerned that progress has been too slow and the agency has not been forthcoming enough with information. They request updates from HHS on the ongoing studies and the new pilot study design.

In response to a request from staffers of Sens. Baldwin and Warren, ABC asked its member centers to contact their elected officials and request that they support the letter to HHS. Several ABC members reached out to their Congress members asking that they stand behind this request for information on the status of HHS's MSM deferral policy studies.

ABC, AABB, and the American Red Cross have long supported changing the current MSM deferral to a one-year deferral (joint statement available at <http://bit.ly/18N8wGc>). The organizations strongly support the use of rational, scientifically-based deferral periods that are applied fairly and consistently among blood donors who engage in similar risk activities. The organizations also support the ongoing work of HHS and the National Institutes of Health to evaluate deferral policies and potential risks to the blood supply.

ABC thanks all of its member centers who contacted their elected officials to bolster support for the letter to HHS. The press release, letter, and a full list of Congress members who signed on can be viewed at <http://1.usa.gov/1cvICJP>. ♦

Letters from ABC Specialty Workshop Scholarship Recipients

Earlier this year, America's Blood Centers launched the ABC Specialty Workshop Scholarships Program, made possible by a grant from the Foundation for America's Blood Centers. This program provides 28 scholarships to professionals from ABC's member blood centers to supplement the costs for attendance at an ABC Specialty Workshop this fiscal year.

ABC held the Technical/Lab and Quality Directors Workshops from May 7 to 8 in Atlanta, Ga. Below are excerpts from letters to the editor from ABC members who received an ABC Specialty Workshop Scholarship to attend the Technical/Lab and Quality Directors Workshops.

"As a scholarship recipient for ABC's Technical/Lab Directors and Quality Workshop, I was elated to hear that I would be attending my first ABC Workshop ... The ability to network and exchange ideas with other leaders in the industry was invaluable and is now an added tool in my quality work belt that I can call upon when needed. In fact, I have reached out to a number of quality professionals since my return ... I would like to personally thank ABC and the FABC for giving individuals, like myself, the ability to attend specialty workshops we would not otherwise be able to attend." – **Robert W. Harper II, director of Quality Assurance, Suncoast Communities Blood Bank, Inc.**

(continued on page 4)

Letters from ABC Scholarship Recipients (continued from page 3)

“I would like to thank ABC and the FABC for the opportunity I was provided to attend the Technical/Lab and Quality Directors Workshops with the assistance of the ABC Specialty Workshop Scholarship. Without this assistance, I would have been unable to attend ... As a director in quality assurance/regulatory for many years, we have struggled with changes in moving from a compliance-focused organization to a quality-focused culture. Speakers Eva Quinley and Tracy Sipma provided us with greater information to help us take the steps towards a quality culture that is more collaborative with a focus on accountability, goal alignment, and process excellence.

The roundtables provided a great mechanism to get the technical directors and quality personnel to intermingle and brainstorm together on topics that are a challenge to both areas ... The workshops provided me with tools to develop improvements within our own processes and to learn from others.” – Tina Chanez, MB, MT(ASCP), director of Regulatory, Mississippi Valley Regional Blood Center.

“ ... The valuable learning experience and knowledge platform that this forum provided allowed myself and others who attended the ability to leverage what we learned to strengthen not just the trust in our operations that regulating entities expect, but also what our donors and patients deserve. As a quality professional in this dynamic industry, the opportunity to tap into this endless source of information allows me to stay on top of and benchmark what is and what is not working well in blood banking to drive best practices not only for my organization, but also for the blood community as it continues to evolve. An opportunity that facilitates bringing together experts and experienced individuals to map out the future is priceless

... On a personal take-away from the events at the workshop, it allowed me to acquire knowledge that will help me to grow professionally as well as validated the knowledge I have gained thus far.” – Rob Ventura, director of Quality, Institute for Transfusion Medicine.

“I would like to sincerely thank ABC and the FABC for the scholarship that allowed me to attend the 2013 Technical/Lab and Quality Directors Workshop. What I gained was an introduction to the very diverse group of attendees – from seasoned veterans to ‘newbies’ – with a huge reservoir of expertise. I did not meet one person who did not have something to offer: a contact, tip, resource, reference, or story ... The presenters introduced to me what I see as the foundation of ABC: informed, involved members who are delighted to share their knowledge and expertise with others to improve the blood banking community.” – Jean Walker, hospital services manager, Lane Blood Center.

“ ... I was very pleased to see the ABC Specialty Scholarship Program when it was announced, and appreciate the opportunity provided to me by the program ... The formal presentations were extremely valuable and interesting. Some of the highlights for me included the sessions on emerging infectious diseases, blood center approaches to Lean practices, cellular therapies in blood centers, pathogen inactivation of blood products, and metrics and benchmarking ... I always find interactions with peers at workshops and seminars highly beneficial. I find these opportunities even greater in the small group format as in this workshop. In this case, we had the opportunity to discuss the presentations and compare notes on how our centers approach these issues.” – Steve McCormick, manufacturing process specialist, Blood Systems, Inc.

“I was one of the lucky recipients of the scholarships offered for the Technical/Lab and Quality Directors Workshop. This year’s topics hit the spot. There was a great deal of information presented on the merger of blood centers and the current economic climate ... I enjoyed myself greatly and am grateful for the scholarship. I would definitely recommend attending this workshop to anyone in the blood banking industry!” – Pam Chandler, quality assurance specialist, Innovative Blood Resources. ♦

IN MEMORIAM – Herbert Perkins, 94

Herbert Perkins, MD, a teacher and mentor to many in the transfusion medicine field, passed away early Tuesday morning at 94 years old. In 1959, Dr. Perkins established the research program at Irwin Memorial Blood Bank, now Blood Centers of the Pacific. With the affiliation of Blood Centers of the Pacific with Blood Systems in 1999, the research program became Blood Systems Research Institute (BSRI). Dr. Perkins' lifetime achievements contributed profoundly to the scientific foundation of the fields of transfusion medicine and transplantation, and to the education and training of scientists, fellows, physicians, and medical technologists in these fields. His work ranged from studies in the early 1960s that established leukocyte antibodies in the etiology of febrile transfusion reactions and contributed to the understanding of blood coagulation, to work in the 1970s characterizing the human leukocyte antigen (HLA) system and the role of HLA matching in organ and bone marrow transplantation, to studies in the 1980s on prevention of transfusion-transmission of HIV and other infections, to launching the National Marrow Donor Program in the 1990s. He had remained active at Blood Centers of the Pacific and BSRI, continuing to mentor fellows and discuss research. Dr. Perkins was one of only four recipients of AABB's prestigious Fantas Award, which recognizes lifetime contributions to the fields of transfusion medicine and cellular therapy. In 2008, Blood Systems established the Herbert Perkins Scientific Lecture Award to honor Dr. Perkins as he celebrated his 90th birthday. The award sponsors a distinguished scientific speaker each year at the California Blood Bank Society Annual Meeting. Michael Busch, MD, PhD, who joined Dr. Perkins at Irwin Memorial Blood Bank in 1985 and subsequently succeeded him as director of Research at Irwin, Blood Centers of the Pacific, and now BSRI, expressed the sentiments of many of Dr. Perkins' colleagues and trainees. "I was extremely fortunate to have Herb as my mentor, colleague, and friend for 30 years. He was a wonderful scholar and human being. He lived 95 years without a wasted moment, and never said an unkind word to or about anyone. His legacy will live on in so many that he has trained and mentored," said Dr. Busch. Donations may be made in Dr. Perkins' memory to the Jewish Community Federation, FBO Herbert & Frances Perkins Fund at 121 Stuart St., San Francisco, CA, 94105. 💧



Q&A with ABC Columns Come to a Close

Over the last couple of months, the *ABC Newsletter* has published a weekly column titled "Q&A with ABC." In this column, ABC staff members answered questions posed by ABC members in the SEQuALS assessment, a customer service survey that solicits feedback from member blood centers on ABC's activities. Also during this time, certain questions were answered by ABC executives in the "Our Space" column. The ABC staff has addressed all of the questions that were plausible to answer in a Newsletter piece. Any ABC members with additional questions that were not answered through these columns may send their questions to newsletter@americasblood.org, and the inquiries will be passed to the appropriate ABC staff member(s). ABC hopes that you have found these columns useful in gaining a better understanding of our organization's activities, initiatives, and the services provided to the membership. ABC would like to thank its members who took the time to respond to the SEQuALS survey. 💧



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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 HR Committee to Hold Webinar on Managing Healthcare Reform

America's Blood Centers Human Resources Committee is inviting ABC members to attend a webinar on healthcare reform, to be held on Aug. 15 at 3 p.m. ET. This presentation will briefly review the current status of the healthcare reform law and the regulations, but will focus on the practical steps that human resources professionals should be taking to meet the requirements with the least amount of financial impact.

The webinar titled "Compliant & Cost Effective – Managing Healthcare Reform," will feature a talk from Brad Johnson, a partner at Benefit Staff. Mr. Johnson has worked in the field of employee benefits for 20 years and is the founding partner of Benefit Staff LLC. His company provides benefit consulting services to employees that seek advice with pricing that is fully transparent. He is a former group insurance underwriter for some of the largest employers in the Midwest. Mr. Johnson has extensive knowledge working with single- and multi-location employers, with both insured and self-funded groups. ABC members can find more information and login details at <http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=4434>. ♦



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America's Blood Centers'
Medical Device Data Systems
(MDDS) Workshop
January 15-16, 2014 –
Washington, DC

DoubleTree Washington, DC - Silver Spring
Negotiated hotel room rate: \$139 + tax

2014 Workshop Fees

Member Registration: \$375 (early bird); \$425 (regular)

Non-Member Registration: \$745

There are four (4) \$800 scholarships available to ABC members to cover the cost of registration fees and help with travel expenses. The application form and details will be made available once registration opens.

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

Medical Device Data Systems, or MDDS, are devices intended to transfer, store, convert data from one format to another according to preset specifications, or display medical device data. They function solely as a conduit through which medical device data flows, is stored, or displayed. MDDS are regulated by FDA. In 2011, the FDA issued a final rule reclassifying MDDS to Class I, the lowest of the three regulatory classifications which are based on the level of control necessary to assure the safety and effectiveness of the device. Though issued in 2011, the impact is just beginning to be felt in blood centers, hospitals and other areas where medical devices are used.

This workshop will look at the MDDS requirements from all sides: the FDA, medical device manufacturers, blood centers, hospitals, and industry experts, and will cover the effects of this change on blood centers and other impacted health care institutions as well as provide direction on implementation of the FDA guidance requirements. Participants will learn what an MDDS is, the actual requirements, and how to navigate FDA device inspections and development in a quality systems environment.



There are three convenient airports that service the Washington area – Dulles International Airport, Reagan National Airport and Baltimore/Washington International Airport – which are served by all major US airlines. Please note that the closest airport is National. Hotel is metro accessible.

RESEARCH IN BRIEF

A study published in *Vox Sanguinis* suggests that noninvasive hemoglobin tests may offer a more pleasant donor experience than do fingerstick hemoglobin tests, but also may lead to deferral of donors who would be accepted to donate by fingerstick. Donor hemoglobin or hematocrit is routinely measured before giving blood to maximize donor safety. Currently, hemoglobin is usually measured in a fingerstick capillary blood sample, which donors consistently identify as one of the more negative aspects of donation. Noninvasive hemoglobin testing methods are now far along in development, and will provide a painless hemoglobin testing option and thus a more pleasant donation experience. None are cleared yet by the Food and Drug Administration. Pasqualepaolo Pagliaro, of the University of Bologna Hospital in Italy, and colleagues, evaluated rapid, noninvasive methods for hemoglobin screening in blood donors for accuracy, and to assess whether they had the potential to enhance recruitment and retention of blood donors. They conducted consecutive trials in which they tested the hemoglobin levels of 445 prospective blood donors using the noninvasive NBM 200 OrSense test and of 463 donors using Massimo's Pronto-7 noninvasive device. For both trials, the hemoglobin results were compared with routine pre-donation fingerstick hemoglobin values on the HemoCue device, and with venous hemoglobin values obtained from a Cell Counter Beckman Coulter AcT-5. In 350 donors, a questionnaire was administered about satisfaction with the new noninvasive premonition screening methods and their preferences as to the hemoglobin test. This study confirmed a lower correlation between noninvasive hemoglobin and laboratory venous hemoglobin measurement than that between HemoCue and the venous measurement. Compared with fingerstick, noninvasive hemoglobin tests eliminated pain and reduced stress, but had a lower level of specificity and sensitivity than did the fingerstick method, according to the researchers. "Regarding the appropriate classification of blood donors before donation, none of the portable devices is clearly superior to any other, because the sensitivity shown by noninvasive methods in detecting donors with unacceptable hemoglobin levels is accompanied by a higher rate of screening failure, despite acceptable hemoglobin levels," said the authors. They note that the Massimo device would result in the deferral of donors who would be accepted for donation based on either fingerstick or venous methods, and that more research is necessary to define the role of noninvasive hemoglobin testing in the donor setting, perhaps in combination with evaluation of the historical venous hemoglobin results.

Citation: Belardinelli A, *et al.* Noninvasive methods for hemoglobin screening in prospective blood donors. *Vox Sang.* Aug;105(2):116-20.

An article published recently in *Transfusion Medicine Reviews* discusses how blood donation and transfusion are portrayed in comics. The representation of blood transfusion and donation in comic strips has not previously been studied. The authors of this review, Jean-Jacques Lefrère and Bruno Danic, presented some comics from around the world that are devoted wholly, or in part, to the themes of transfusion and blood donation. The theme of a superhero using transfusion to transmit his virtues or his powers was repeated throughout the 20th century in North American comic strips, including in Superman, whose powers include that his blood is compatible with all blood types. Almost all American superheroes become blood donors in comics: Dr. Nemesis, Peter Parker alias Spider-Man, Bruce Wayne alias Batman, and even androids, such as the Human Torch. In some comic strips, superheroes have used transfusion to maintain their powers or to clean their body weakened by infection or a dangerous drug. The authors note that superheroes likely become blood donors in many comic strips because "this donation symbolizes a social act with civic responsibility and altruism." More recently, some comic strips have been conceived from the outset with a promotional aim to perpetuate positive images of blood donation, directed toward young readers. While there are many positive illustrations of blood donation and transfusion in comics, there have been a few negative images, which have generally corresponded to historical episodes of negative transfusion-related events, such as the AIDS epidemic in the 1980s. "The

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RESEARCH IN BRIEF (continued from page 7)

image of transfusion and blood donation given by the comic strips may be more than simple entertainment,” write the authors. “The readership of comics is primarily children, some of whom will become blood donors. Furthermore, for those comic strip readers who are later transfused during their lives, the more or less conscious memory of these childhood readings may resurface as either hopes or fears.” The article is available to subscribers or for purchase at <http://bit.ly/16frQM4>.

Citation: Lefrère JJ, Danic B. Transfusion and blood donation in comic strips. *Transfus Med Rev.* 2013 Jul;27(3): 154-65.

A study published July 16 in the *Journal of the National Cancer Institute* showed that the addition of the erythropoiesis-stimulating agent epoetin alfa to chemotherapy reduced the risk for anemia in patients with high-risk breast cancer. Epoetin alfa given along with intensive dose-dense chemotherapy eliminated the drop in hemoglobin that otherwise occurs in this setting and more than halved red blood cell transfusion rates reported Volker Moebus, MD, of Germany’s Klinikum Frankfurt Höchst, and colleagues found. However, thrombotic events occurred in 7 percent of epoetin alfa-treated patients compared with 3 percent among controls. “With the exception of this risk, erythropoiesis-stimulating agents appear to be safe drugs for the treatment of chemotherapy-induced anemia or the primary prevention of anemia in patients with intensive dose-dependent chemotherapy regimens,” concluded the authors. The trial showed no harm in terms of poorer overall survival or relapse-free survival after a median follow-up of 62 months. However, the trial was underpowered for those endpoints, Larry Norton, MD, of Memorial Sloan-Kettering Cancer Center in New York City, and colleagues cautioned in an accompanying editorial. “Overall, this study provides important evidence that erythropoiesis-stimulating agents may be safe in the curative treatment of cancer. At the same time, we must acknowledge that the data are insufficient to support the routine use of erythropoiesis-stimulating agents in this setting. The authors should be congratulated for addressing this important issue (with implications beyond breast cancer) as well as for providing additional evidence (in the parental trial) supporting the effectiveness of dose-dense scheduling,” concluded the editorial authors. (Source: *MedPage Today*, 7/17/13)

Citations: Moebus V, *et al.* Adding epoetin alfa to intense dose-dense adjuvant chemotherapy for breast cancer: Randomized clinical trial.” *J Natl Cancer Inst.* 2013;105:1018-1026.

Chang Dang, *et al.* Epoetin alfa: to give or not to give. *J Natl Cancer Inst.* 2013;105:1001-1003. ♦

BRIEFLY NOTED

AABB issued last week Association Bulletin #13-03 updating its recommendations for hepatitis A virus (HAV) common source outbreaks. The AABB Board of Directors has approved recommendations of the AABB Transfusion Transmitted Diseases Committee that address criteria for donor deferral and blood component retrieval in known or suspected common source outbreaks of HAV infection, according to the *AABB Weekly Report*. The revisions update previous recommendations for post-exposure prophylaxis and management of potentially HAV-infected donors and blood components. This bulletin supersedes Association Bulletin #04-08, which was released following an HAV outbreak in Ohio during 2004. AABB members can view Association Bulletin #13-03 at www.aabb.org/resources/publications/bulletins/Pages/ab13-03.aspx. (Source: AABB Weekly Report, 7/26/13)

BRIEFLY NOTED (continued on page 9)

BRIEFLY NOTED (continued from page 8)

The Healthcare Cost and Utilization Project (HCUP) and the Agency for Healthcare Research and Quality (AHRQ) released a report detailing the most frequent procedures performed in US Hospitals during 2010, with blood transfusion topping the list. The authors of the report used codes entered by healthcare providers during short-term stays in non-Federal, general, and other hospitals to assess the most frequently performed hospital procedures. Blood transfusion was found to be the most common all-listed procedure performed during hospitalizations in 2010, occurring in 11 percent of stays with a procedure; the rate of hospitalization with blood transfusion had more than doubled since 1997, according to the report. Transfusion was reported during 91 stays per 10,000 population during 2010. It is important to remember that these data provide an analysis of the population frequency at which inpatients are transfused, but are not useful in judging the volume of transfusion in the US (for more analysis, see Our Space on page 2). The results of the 2011 National Blood Collection and Utilization Survey show an 8.2 decrease in red blood cell transfusions since 2008. The HCUP report can be viewed at <http://1.usa.gov/14QoU6H>. (Source: HCUP, AHRQ Statistical Brief #149, 2/1/13)

As this year marks the 25th anniversary of the first umbilical cord blood transplantation (UCBT), Blood published an article reviewing growth of the field over the last 25 years and plans for future exploration. Umbilical cord blood offers an alternative hematopoietic stem cell source for patients with hematologic diseases in need of a stem cell transplant. While UCBTs were initially limited to children due to the low cell dose infused, the results for adult umbilical cord blood transplantation have improved. Adult UCBTs have become more successful with greater emphasis on cord blood units of sufficient cell dose and human leukocyte antigen match and with the use of double umbilical cord blood units and improved supportive care techniques, write Karen K. Ballen, of Massachusetts General Hospital Cancer Center, and colleagues. More than 30,000 UCBTs have been performed worldwide, and randomized studies to compare graft sources are underway. Research regarding UCB hematopoietic stem cells and their applications have shown that mismatched UCBT is feasible and might in the future achieve similar results to human leukocyte antigen-matched hematopoietic stem cell transplants, write the authors. However, they note that UCBT faces several new challenges, including that delays in immune reconstitution have led to an increased incidence of late viral infections, which can be fatal, after UCBT. Research to meet these challenges is underway. “When we look back after the next 25 years, we anticipate an abundant UCB supply, digitalized UCB selection, multiple new indications, and significantly improved clinical outcomes,” conclude the authors.

Citation: Ballen KK, *et al.* Blood. 2013 July 25;122(4):491-8. Epub 2013 May 14. ♦

We Welcome Your Letters

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



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REGULATORY NEWS

The Food and Drug Administration held a webinar on July 25 about the Center for Biologics Evaluation and Research's (CBER) Direct Recall Classification program, which gets recall information to consumers in a more timely manner. FDA advises firms on their recall strategies and monitors their recall to determine whether it is effective. The agency also publicizes recalls so consumers and health professionals can find out what types of products are being recalled. During the webinar, Laura Hieronymus, senior recall coordinator with CBER's Office of Compliance and Biologics Quality, discussed the importance of timely recall information for consumers and the impact that the Direct Recall Classification program has had on speeding up the information flow between the industry and FDA. During the webinar, Ms. Hieronymus reviewed CBER's Direct Recall Classification Program, and walked attendees through how to access their establishments' Additional Information report through CBER Online. She also walked attendees through the process of submitting Additional Information reports to CBER for recall classification purposes. A description of the webinar and link to the presentation can be found at www.fda.gov/AboutFDA/Transparency/Basics/ucm361441.htm. (Source: FDA website, 7/26/13)

The Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) recently released two patient safety primers available online. AHRQ's Patient Safety Network (PSNet) published on July 23 a patient safety primer about understanding a systems approach to

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REGULATORY NEWS (continued from page 10)

medical errors, which provides background on systems approach theory and relevant, research-based information to help healthcare providers apply this thinking to healthcare so they can identify situations or factors likely to give rise to human error. It introduces methods that can be used to change the underlying systems of care to reduce the occurrence of errors and minimize their impacts on patients. This resource can be accessed at <http://psnet.ahrq.gov/primer.aspx?primerID=21>. The other patient primer published by PSNet on July 26 discusses root cause analysis in healthcare. This primer is intended to guide healthcare providers and leaders through root cause analysis as a key concept in patient safety, with background and contextual information, highlighting the relevant materials to support root cause analysis in the healthcare environment. It can be accessed at <http://psnet.ahrq.gov/primer.aspx?primerID=10>. (Source: PSNet e-mail update, 7/26/13) ◆

LEGISLATIVE NEWS

A new bipartisan bill introduced in the US House of Representatives last week would exempt Food and Drug Administration user fees from sequestration, the automatic federal budget cuts that took effect in March, reported *The Hill*. FDA's budget is substantially supported by user fees from the industries it regulates. The budget cuts are expected to shave about \$85 million from the agency's budget in 2013 by hitting those fees. The cuts would likely have a direct impact on FDA's Center for Biologics Evaluation and Research (CBER), as user fees are estimated in the FDA fiscal year 2014 Congressional Budget Justification to support approximately 42 percent of financial resources in CBER. User fee legislation allows FDA to collect user fees from medical device and drug manufacturers to supplement funding for the review and approval processes for these products. Lawmakers supporting this bill said the reduction in user fees caused by sequestration could harm consumers by forcing regulators to do more with less. "Whether one agrees or disagrees with sequestration, I don't believe private dollars should be held hostage by the policy," said Rep. Anna Eshoo (D-Calif.), a lead sponsor of the new bill. "It discourages investment in medical innovation and denies patients access to timely therapies. The measure, the FDA Safety Over Sequestration (SOS) Act, would allow FDA to receive its regular stream of user fees despite sequestration. On Thursday, Stephen J. Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed) issued a statement applauding the Senate for passing bipartisan legislation similar to that introduced in the house, which would exempt FDA user fees from cuts under sequestration. "Since the sequester took effect earlier this year, medical device and diagnostics companies have been paying the full amount of user fees to FDA as negotiated under last year's new Medical Device User Fee Amendments, enacted by the FDA Safety and Innovation Act (FDASIA); however, the sequestration prevents the agency from accessing the full amount of those funds. In fiscal year 2013 alone, \$2.9 million in medical device user fees will not be available to the agency, and going forward, additional user fees are at risk because of sequestration," said Mr. Ubl. "User fees paid by industry to FDA should not be treated the same way as taxpayer dollars. The fees paid by medical technology companies under FDASIA represent an agreement between industry, FDA, and Congress. Under that agreement, the industry agrees to supplement FDA's appropriated budget with user fees, and the agency agrees to performance commitments designed to increase the efficiency and predictability of the review process." He notes that AdvaMed looks forward to working with Congress and other stakeholders on this important issue. (Sources: *The Hill*, 7/18/13; AdvaMed press release, 8/1/13) ◆

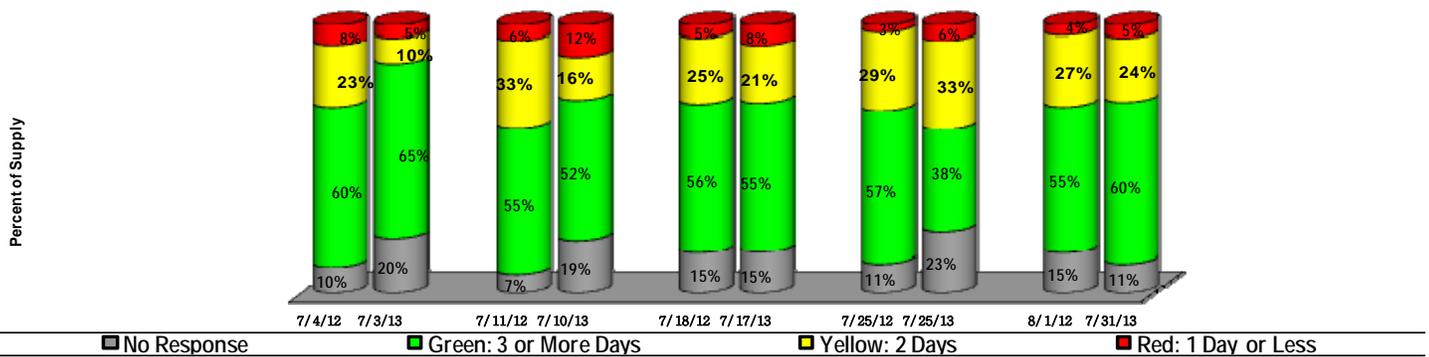
GLOBAL NEWS

NHS Blood and Transplant (NHSBT), the blood and organ provider of England and North Wales, has launched a major new strategy with the four UK health departments called “Taking Organ Transplantation to 2020.” This initiative seeks to help NHSBT match world class performance in organ donation and transplantation, said Lynda Hamlyn, NHSBT chief executive, in *NHSBT News*. The strategy sets out actions required by “NHSBT, the wider NHS, governments, and society as a whole to make NHSBT a world leader in saving lives through organ transplantation,” said Ms. Hamlyn. While the UK’s National Health Service (NHS) has made great strides in organ availability and transplant over the last five years, there are still more than 7,000 people on the UK national transplant waiting list, and during the last financial year, more than 1,300 people either died while on the waiting list or became too sick to receive a transplant, according to the NHSBT website. The new strategy focuses on:

- Increasing the number of potential donors;
- Improving donor conversion rates;
- Making the most of donor organs;
- Increasing retrieval and transplantation of organs;
- Resuscitation of retrieved organs;
- Improving survival of transplant patients; and
- Improving systems to support organ donation and transplantation.

More information about the strategy can be found at www.nhsbt.nhs.uk/to2020/. (Source: *NHSBT News*, 7/14/13; NHSBT website, 7/14/13) ♦

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

MEMBER NEWS

Rady Children’s Hospital-San Diego will be the site of a blood drive on Aug. 4 that culminates a week-long National Kids Day celebration presented by Cox Communications and Money Tree at all six San Diego Blood Bank donor centers. National Kids Day is a day set aside each year to celebrate and honor the country’s children. “As a primary provider of blood to Rady Children’s, the San Diego Blood Bank is especially concerned with the health and welfare of our community’s young

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MEMBER NEWS (continued from page 12)

people,” said San Diego Blood Bank in a press release. “Many of these kids are battling life-threatening diseases such as leukemia, bone cancer, aplastic anemia, sickle cell anemia, and heart disorders. Without routine blood transfusions, they would not survive.” Also this week, San Diego Blood Bank teamed up with NBC 7 to hold the NBC 7 Summer Blood Drive today, Aug. 2. All donors who give blood at the drive will be entered to win one of 50 passes from Universal Studios and will be awarded a True Blood T-shirt from San Diego’s Comic Con. Donors will enjoy refreshments from Jersey Mike’s. (Sources: San Diego Blood Bank press releases, 7/25/13, 7/31/13)

Blood Bank of Hawaii’s Young Street Donor Center drew blood and excitement on July 24 when Miss Hawaii 2013, Crystal Lee, visited the center as a blood donation advocate. Upon learning about the summer trend of low donor turnout, Ms. Lee had an idea. “I wanted to do something exciting and different that would get people in the door to help save lives,” said Ms. Lee, whose focus as Miss Hawaii is to educate the public on the importance of donated blood. “I decided to sponsor a whole day.” Ms. Lee recruited friends and family, using Facebook to help get the word out, to fill the donor center’s appointments for the day. “She was walking her talk, putting her platform of the importance of ‘donating the gift of life’ into action,” said a press release from Blood Bank of Hawaii. A record was set at the donor center that day – nearly half of the collections came from first-time donors. The center was a lively, social environment that day, as cheerful Miss Hawaii contestants, donning their crowns and sashes, thanked and handed out homemade cupcakes to donors, who posted photos to social media. Local news outlets were on-site to capture the event, publicizing the need for volunteer blood donation. Ms. Lee will continue to speak about the importance of blood donation in the upcoming Miss America competition. News coverage of the event can be viewed at <http://bit.ly/133f4w9>. (Source: Blood Bank of Hawaii press release, 7/30/13) ♦



Miss Hawaii 2013, Crystal Lee (far left), hosted a spirited blood drive, joined by BBH President and CEO Kim-Anh Nguyen, MD, PhD (far right) and other Miss Hawaii contestants.

PEOPLE

Celso Bianco, MD, former executive vice president of America’s Blood Centers and current president-elect of ISBT, has been elected to Group Services for America’s Blood Centers’ (GSABC) board of directors, announced a GSABC press release last week. Dr. Bianco served as ABC’s executive vice president from 2000 until his retirement in August 2012. In that position he lead ABC in various medical, scientific, and technical advocacy initiatives before regulatory and governmental agencies. Since beginning his career in this field in the 1970s, Dr. Bianco has become a well-respected and influential leader in transfusion research and blood safety policy. Through his research, important information involving cells and the immune system were discovered. Dr. Bianco is recognized throughout the blood and transfusion medicine field for his outstanding achievements. He has co-authored more than 200 scientific publications and abstracts on numerous topics including:



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plasma membrane receptors, immunology, infectious disease, plasma proteins, and transfusion medicine. Dr. Bianco also has received ABC's Thomas F. Zuck Lifetime Achievement Award and the Canadian Blood Services' Lifetime Achievement Award. "We at GSABC feel that Dr. Bianco's knowledge, dedication, and expertise to the blood services industry will be a great asset to the future of our organization as we continue to move ahead to better serve our members and providers," said GSABC in the press release. (Source: GSABC press release, 7/24/13) ♣

MEETINGS**Aug. 13 Webinar: Focused Continuity of Operations Planning (FCOOP): A Management Approach**

The Centers for Disease Control and Prevention's Office of Public Health Preparedness and Response will hold a webinar on Aug. 13 at 2 p.m. ET titled "Focused Continuity of Operations Planning (FCOOP): A Management Approach." During this webinar, presenters from the South Central Preparedness & Emergency Response Learning Center will discuss a process, known as FCOOP, and how it can be simple, structured, participative, efficient, and effective process for developing and maintaining COOPs. Those interested should register as soon as possible to ensure a place in the webinar. More information can be found at www.cdc.gov/phpr/perlc/webinar_alabama.htm. ♣

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: lnorwood@americasblood.org.

POSITIONS AVAILABLE:

Chief Medical Officer/Medical Director. Supervises the medical activities of the San Diego Blood Bank. Oversees the operation of Laboratory Services, Non-transfusable and In-vivo Research Product Services. Essential Duties: The Chief Medical Officer is responsible to the Chief Executive Officer and the following as essential job accountabilities: 1. The Chief Medical Officer provides general supervision for all medical activities and ancillary administrative duties relating to long term strategy and policies. 2. The Chief Medical Officer provides liaison between the San Diego Blood Bank and the medical community. 3. The Chief Medical Officer is responsible for the following: medical aspects of new product development, the preparation of grants, federal application, etc. and preparation of articles and abstracts for presentation and publication. 4. In conjunction with the Director of QA/Compliance, the Chief Medical Officer is responsible for the San Diego Blood Bank's Process Improvement Programs. 5. The Chief

Medical Officer is responsible for donor counseling program. 6. The Chief Medical Officer must maintain active medical licensure and board certification. Education: MD or DO degree; subspecialty board certification in Hematology (IM) or Transfusion Medicine (Pathology). Certifications/Licenses: Active California Medical License. See education. Apply online at: <http://sandiegobloodbank.iapplicants.com/ViewJob-475321.html>. EOE

Corporate Trainer. Carter BloodCare, a large community blood center in Texas, seeks a qualified Trainer to join their staff. This position reports to the Director of Training. Responsibilities include research, design,

POSITIONS (continued on page 15)

POSITIONS (continued from page 14)

development, and delivery of a variety of organizational, supervisory, and leadership training programs utilizing multiple delivery options such as instructor led facilitations, multimedia, and other appropriate training methodologies. Bachelor's degree preferred (preferably in Education or related field). Experience may take precedence. Presenter/Facilitator professional third party certification desirable (Myers Briggs, Achieve Global, DDI, ASTD, Kirkpatrick, etc). Three to five years' training delivery experience required. Previous experience in a regulated industry preferred. To apply, please visit www.Carterbloodcare.org.

Manager – Donor Recruitment. Come join our team of professionals at the Community Blood Center, Kansas City, Mo. Supervises administrative staff, administers outcomes for fixed site collection goals ensuring monthly/annual goals are achieved, trains/manages/motivates department staff and serves in key recruitment/communication/ organizational roles, educates customers/general public about need for blood/blood products, manages computer-based recruitment and data management programs, develops/implements annual recruitment plan for meeting assigned collection goals. Prepares/assesses/responds to monthly forecast, develops program to support conversion of donors to automated/other new technologies, and establishes strategic goals for all assigned areas/staff, promotes positive image of the blood center. Education: bachelor's degree or equivalent education/experience in related field required. Three years sales/marketing experience. Management experience preferred. Skills and Knowledge: Good supervisory skills with ability to effectively motivate/develop staff, effective verbal/written communication skills, sales/territory management skills. Self-motivated/self-starter with good organization skills. Demonstrated successful sales skills. Ability to deal with change/unpredictability. Ability to work flexible hours including weekends/evenings. Proficient personal computer skills/Microsoft Office Suite. Valid driver's license and maintain a good driving record required. Application must be completed online www.savealifenow.org. EEO/AA/M/F/D/V

Region Recruitment Manager. Puget Sound Blood Center is seeking a strategic leader to manage the departments responsible for donor group and volunteer recruitment goals. Responsibilities include: providing leadership and motivation to staff teams; developing systems and program analysis tools; improving communications enhancing community relationships to encourage donor and volunteer participation; positioning the Blood Program as a volunteer supported organization. Ideal candidates will have over eight years' experience direct recruiting, marketing, relationship-building or volunteer management experience and five years in a supervisory capacity. Requirements also include demonstrated familiarity with marketing and

planning systems; strong data analysis skills, demonstrated written, verbal and interpersonal communication skills; proficiency with PC software. Bachelor's degree in a related field or equivalent work experience. Blood recruitment industry experience a plus. This exempt, full-time position is based in Bellevue, Wash. Submit resume to Puget Sound Blood Center via e-mail at humanresources@psbc.org; fax: (866) 286-8495; USPS: Human Resources, Puget Sound Blood Center, 921 Terry Avenue, Seattle, WA 98104-1256. Reference Job #7032. **Closes August 23.** For disability/accommodation assistance with the application process contact HR at humanresources@psbc.org, or at (206) 292-6500, or at 921 Terry Avenue, Seattle, WA 98104. AAEOE.

Information Services Manager. The Stanford Blood Center is seeking an Information Services Manager. Reporting to the Senior Operations Director, the Information Services Manager maintains and enhances a robust and unified information system infrastructure, serves as the primary contact for information systems management and ensures the streamlined operation of the IS department through the use of technology to improve operational efficiencies and reduce costs in alignment with the business objectives of the organization. The Information Services Manager will provide technical expertise and leadership, casts short, intermediate and long term strategic direction and champion change through the effective implementation of new products and new ideas for existing products and systems. Candidates should have demonstrated managerial experience, including supervision, strategic planning, accountability and strong interpersonal skills. For a complete description, please visit <http://stanfordcareers.stanford.edu/> and reference Req. ID 10077813.

Collections Supervisor – Donor Centers. Are you a self-starter? Do you excel leading teams? Are interpersonal and problem-solving skills a core competency? Community Blood Center, Inc., a provider of high quality blood products and services, is seeking a Donor Center Supervisor to oversee blood collections at our centers. The Collections Supervisor of our Donor Centers fosters an environment where staff growth and development are promoted. Candidates to possess a bachelor's degree and/or relevant work experience. Minimum of three years of supervisory experience, excellent written and communication skills, and strong computer aptitude needed. Position travels to our centers on a regular rotation. Submit your resume to join our team: <https://home.eease.adp.com/recruit/?id=5981531>. Community Blood Center, Inc., 4406 W. Spencer St.,

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POSITIONS (continued from page 15)

Appleton, WI 54914. www.communityblood.org.
www.facebook.com/cbloodcenter.

Night Manager, Laboratory Services. LifeStream, a \$53M healthcare organization providing blood service to more than 80 hospitals in Southern California, is searching for a Night Manager, Laboratory Services. This position performs, reports and reviews test results for Reference and Quality Control procedures in an accurate and timely manner in compliance with Federal and State Regulations, AABB Standards, Manufacturer's recommendations, and internal operating procedures. Demonstrates proficiency, competency and understanding of fundamental principles of the immunohematology, hematology and microbiology laboratory procedures. Requirements: Four-year Bachelor of Science degree in Clinical Laboratory Science or related field (e.g., Medical Technology). Minimum two years as a Generalist required. Five years' experience preferable focused in areas of hematology and transfusion medicine. Current California Clinical Laboratory Scientist License. **(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.

Macopharma USA West Coast Account Manager. Develop and maintains relationships that lead to sales of blood bank filters, equipment, and related products. 75 percent travel. Must live near a major airport in the Western US. Responsibilities: develops and implements strategies to maintain and expand sales within assigned

territory, with an account by account plan. Forecasts demand for products within assigned territory, provides budget and sales activity reports, interfaces with the customer to understand the customer's overall objectives and requirements, contacts customers and potential customers on a regular basis to maintain account relationship, advise of new product and service offerings, and obtain feedback on products, provides post implementation support to customers, serves as point of escalation for issues that the customer encounters during product utilization, expedites resolution of problems/complaints, prepares/conducts technical/product presentations and demonstrations, participates in tradeshow, provides feedback for future product enhancements. Required experience: bachelor's degree from four-year college or university. Minimum five years' experience in blood banking or related industry; or equivalent combination of education and experience. Please send resume and salary requirements to careers@macopharmausa.com; no calls. ♦