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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2013 #20 **May 31, 2013**

INSIDE:

ABC Members Head to Milwaukee for Interim Meeting and MD Workshop

Set on the beautiful Lake Michigan shoreline, the America's Blood Centers Interim Meeting and Medical Directors (MD) Workshop will be held in Milwaukee, Wis. from Aug. 3 to 6. The meeting, co-hosted by BloodCenter of Wisconsin, will offer attendees the opportunity to learn about advances in blood banking and transfusion medicine and share best practices, while enjoying the sites of Milwaukee, such as the Milwaukee River Walk and the architecturally stunning Milwaukee Art Museum.

MD Workshop and SMT Forum. Gilles Delage, MD, vice president of Medical Affairs, Microbiology at Héma-Québec, and chair of ABC's Scientific, Medical, and Technical (SMT) Committee, will welcome attendees as the meeting gets underway with the MD Workshop on Saturday, Aug. 3. Experts will present on several transfusion medicine topics, such as the value of blood pressure and pulse in preventing adverse donor events, donor dissatisfaction following deferral, point of care testing for blood components, and molecular red blood cell (RBC) phenotyping.

A view of the Lake Michigan shoreline in Milwaukee.

The sessions on Sunday, Aug. 4 will begin with the ABC Members Meeting and presentations from Foundation for America's Blood Centers (FABC) grant award recipients. The SMT Forum will then kick off that afternoon with two presentations on a subject generating much interest recently within the transfusion medicine world – pathogen reduction technologies. An emerging transfusion transmissible infection portion of the SMT Forum will cover babesiosis, hepatitis E, and transmissible spongiform encephalopathies. The forum will then close with a discussion of hot topics.

(continued on page 3)

OUR SPACE

ABC Interim CEO William M. Coenen

What Happened to the "I" ?

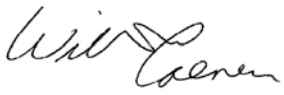
The acronym for America's Blood Centers' "core values," IDEA, represents Innovation, Data Integration and Benchmarking, Education and Networking, and Advocacy. Although these values are not unique in themselves, they become powerful tools for ABC to serve its members. These tools are where the knowledge and leverage of *all* outweigh that of *one*.

Over the last couple of months, ABC has been refocusing its resources on advocacy and education, supporting these values with a renewed energy in the ABC Data Warehouse (DW) efforts. ABC staff has been working diligently on a new initiative to improve the processes for entering and validating the data coming into the DW. With over 50 percent of member collections already being pushed to the DW, this repository of member blood center data will become a valuable tool in supporting our advocacy and education work.

As ABC refocuses and reshapes its core values, I have been asked, "What happened to the "I" in the core values? Has ABC abandoneded innovation?" The answer is an unequivocal no. An organization that does not embrace new ideas or opportunities is not serving its membership well. Innovation is, again, an area in which ABC's collective knowledge and leverage outweighs that of any one blood center.

One only has to look at some of the successes of the past to assess the value of innovation to ABC members – the recent reduction in blood center items covered by the proposed medical device tax; the quality engineering programs that led to IMPAQ (Improving Manufacturing Practices and Quality); Blood Centers Exchange (BCx); the ABC-D program that helped increase donations offsetting the decline experienced in the early 2000s; Appropriate Inventory Management (AIM); and the Foundation for America's Blood Centers (FABC), which funds initiatives that benefit and support ABC members.

Yes, there have been some bad "I"s along the way, but success and innovation can only come from a willingness to try new things. Although it is not currently ABC's main focus, Innovation has certainly not fallen off our radar, and should opportunity come knocking, we'll be ready to open the door and help members start a conversation.



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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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Interim Meeting Headed to Milwaukee (continued from page 1)

Blood Center Leadership Forum. On Monday, Aug. 5, Michelle Stefan, vice president of Corporate and Community Resources at Carter BloodCare, and chair of the ABC Meetings Committee, will introduce the Blood Center Leadership Forum, which focuses on current issues, innovations, and best practices in blood donor center operations. The Blood Center Leadership Forum will also explore changes occurring within hospital systems. Lynne Briggs, vice president and chief information officer at BloodCenter of Wisconsin, will talk about Radio Frequency Identification (RFID) within transfusion medicine, an especially relevant topic following the Food and Drug Administration's approval of iTrace for Blood Centers, the first application to use RFID technology in blood establishments to enhance blood safety (see page 4).

The forum will continue the Cooperate to Compete discussion that began at ABC's 50th Annual Meeting in Scottsdale, Ariz., last year, highlighting the importance of collaborating and sharing information to succeed in healthcare and any competitive industry (see *ABC Newsletter*, 4/6/12). After giving a rousing talk about the role of regulation in competitive markets at this year's Annual Meeting in March, Mark Fagan, adjunct lecturer in public policy at Harvard University, will return to contribute his insights to the Cooperate to Compete session.

A Night Overlooking the Lake. As always, the Interim Meeting offers not only valuable updates about the blood community and transfusion research, but also a chance to enjoy the host city and network with colleagues. Hosted by BloodCenter of Wisconsin, guests will be treated to an evening at Lake Park Bistro, a Parisian-style restaurant that features traditional and modern twists on French cuisine. Guests will have exclusive access to the historic venue, nestled on a bluff overlooking Lake Michigan, with scenic views, a newly renovated indoor pavilion, and outdoor terrace. Attendees will also enjoy cocktails and plentiful hors d'oeuvres throughout the evening, while listening to a mix of classic, soul, rock, and jazz music.

Pre- and Post-Meeting Events. Prior to the Interim Meeting, attendees will also have the opportunity to tour Blood Research Institute on the evening of Friday, Aug. 2. The ABC and GSABC boards will also meet on Friday, and BCA will hold a medical directors networking conference. Following the meeting, on Tuesday, Aug. 6, members of Plasma LLC will be able to attend the Plasma Summit, which will explore the latest opportunities in the plasma industry and plasma therapy markets. The BCx board will also meet on Tuesday.

If you or a colleague did not receive an e-mail invitation with a link to register for the Interim Meeting, please contact Lori Beaston at lbeaston@americasblood.org. Those interested in sponsorship opportunities may contact Abbey Nunes at anunes@americasblood.org. ♦

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.

FDA Clears First-Ever RFID-Enabled Blood Tracking System

The Food and Drug Administration announced this week that it has granted 510(k) market clearance for the first-ever radio frequency identification (RFID)-enabled blood product tracking system, developed by a coalition of America's Blood Centers' members and other organizations. Many national health agencies have been focused on reducing medical errors and enhancing the safety and quality of healthcare, and the iTrace product fits into this framework by improving the efficiency, effectiveness, and safety of the blood supply chain.

The Transfusion Medicine RFID Consortium, spearheaded by BloodCenter of Wisconsin, has been working to develop, test, and gain FDA clearance for this technology for the past six years, under the direction of Rodeina Davis, BloodCenter of Wisconsin's previous chief information officer. The consortium also includes the Brookfield, Wis.-based information systems consulting firm SysLogic, Inc., S3Edge, the University of Wisconsin-Madison RFID Lab, Carter BloodCare, Mississippi Blood Services, and the University of Iowa/DeGowin Blood Center, and Mississippi Baptist Hospitals. The consortium revived funding from two National Institutes of Health grants, along with an early grant from the Foundation for America's Blood Centers.

"Thanks to all of the outstanding work of the entire consortium team, we have been successful in defining a standard for the transfusion medicine industry with the 510(k) clearance of iTrace for blood centers," said Tina Chang, CEO of SysLogic, one of the founding members of the consortium.

RFID is a tool widely used for identification and tracking of various objects, explained FDA in a press release. In a typical RFID system, a small memory-storage chip is placed on the item being tracked. RFID readers send and receive radio waves to detect chips and read their data. iTrace leverages high-frequency RFID tags and technology to provide greater visibility to blood products and their location, movement, and status. "The RFID technology basically gives us another set of eyes and ears on where the blood

(continued on page 5)

RFID-Enabled Blood Tracking System (continued from page 4)

physically is at all times," said Lynne Briggs, vice president and chief information officer at BloodCenter of Wisconsin.

By using RFID technology in concert with barcodes and the blood establishment computer software (BECS), iTrace automates blood bag checking at donor sites, simplifies the checking of blood products to the manufacturing process, and streamlines the preparation of blood products for shipment to hospitals or transfusion centers. Unlike a barcode, RFID tags do not have to be in the person's "line-of-sight," meaning that the user does not have to visually match up the tag to the scanning device, as one does with a barcode. RFID also has a longer read range than do barcodes, and RFID tags are re-writable.

"These unique properties of RFID technology made it intriguing as an alternate means to track and trace blood products. As an industry, blood was also well positioned with an international data standard – ISBT – which could be translated into RFID," said Ms. Briggs, who took the lead on this project in January 2012 following the retirement of her predecessor, Ms. Davis, who began and led the movement toward an RFID solution for the blood supply (see *ABC Newsletter*, 1/6/12).

To test the iTrace product in a robust environment, it was in production to track blood products as they moved from fixed and mobile sites, through the blood center, and to distribution. "The blood center pilot showed excellent gains in process efficiencies related to reconciliation activities and value in the visibility of product location," said Ms. Briggs.

This RFID technology truly offers a solution for the entire blood banking community, as the ISBT RFID Working Party created a standard for the use of RFID within blood banking, which iTrace follows. "The entire team, and our long-term leader Rodeina, are all very proud to have lived the definition of perseverance and commitment," said Ms. Briggs. "We feel lucky to have been a part of something greater than ourselves, and grateful for the teamwork and friendships we have developed and the industry support we received."

Now that iTrace has gained FDA approval, S3Edge will be commercializing and selling the product. Those who would like to learn more about the product or contact S3Edge may visit www.s3edge.com. (Sources: BloodCenter of Wisconsin press release, 5/29/13; FDA press release, 5/29/13) ♦

Journal Article Suggests Economic Rewards for Donors is Beneficial

The World Health Organization and most national blood services support voluntary, non-remunerated blood donation, based on the view that offering economic incentives threatens the safety and sufficiency of the blood supply by attracting non-altruistic donors. However, an article recently published in *Science* suggests that economic rewards can increase blood donation without materially threatening the adequacy of the blood supply.

The US and most other developed nations rely completely on voluntary, unpaid whole blood donors, as paid donors are more likely to test positive for transmissible diseases, and in pursuit of compensation, may be more likely to conceal information that would cause deferral. The Food and Drug Administration requires that any blood product collected for transfusion obtained with a monetary incentive be labeled as from a "paid donor," although the agency does allow for small gifts such as T-shirts, coffee mugs, or raffle tickets that are not readily convertible to cash.

(continued on page 6)

Economic Rewards for Blood Donors (continued from page 5)

Some blood donation organizations have found that people are more willing to give blood when the act is motivated by an altruistic desire to help others and the community, not in return for compensation. The World Health Organization supports this stance and has set a goal for all countries to obtain their blood supplies from only volunteer donors by 2020. However, the authors of this study write that there has been a lack of evidence supporting the view that economic incentives affect blood donation adversely. Early studies upon which voluntary, non-remunerated blood donation policies have been based often used small sample sizes and the controls for confounding factors were not distributed equally between donors who received incentives and those who did not.

The authors present more recent studies on how incentives affect blood donation, focusing on studies that used large, representative samples of existing or potential donors to identify and isolate casual effects. Although in surveys most respondents report having an aversion to receiving an economic reward for blood donation, recent observational studies that control better for confounding factors have found that a range of items, from coupons to a paid day off from work, increase blood donation.

Similarly, observational data from the US and Switzerland observing the effect of rewards for blood donation among non-donors and existing donors, among subjects who have never been offered rewards before, and those who have been offered irregularly, showed that the rewards increased donation. As might be expected, the effect was greater if the reward was worth more money. Overall, 18 of 19 distinct incentive items in observational experiments increased donations, with only free cholesterol testing, a common incentive in the US, having no effect.

Temporary blood donation incentives may have long-term effects, but these studies found no post-intervention effects. Also, these results highlight that temporary rewards had spatial and short-term temporary effects on donations, suggesting that incentives may be most valuable during temporary shortages. It is unknown whether incentives sacrifice the adequacy of a blood supply built upon altruism and whether incentivized donors turn into life-long blood donors.

While blood safety is the major reason for maintaining a voluntary, non-remunerated blood supply, these studies do not really assess this aspect – that is whether paid blood donors are more likely to test positive for transmissible diseases or lie about conditions that may cause blood donor deferral. However, it is important to note that the rewards in these studies were presented for presenting to donate, not for successfully making the donation. Rewarding donors simply for trying to donate should mitigate any incentive for people to provide false information so that they qualify to give blood, write the authors.

The authors note that the studies presented have several limitations, including that they only observed the effect of offering rewards once or occasionally, rather than continued use of incentives, which should be further explored. Also, regulatory regulations in most countries prohibited observing the effects of offering cash as opposed to a small gift. The authors suggest that future studies explore the use of symbolic or social rewards, as opposed to those carrying monetary value. Lastly, current research on incentives and blood donation has come from wealthy countries, and it is not likely appropriate to apply the findings to other economic settings.

“In light of the recent evidence, it is time to re-examine policy guidelines for increasing and smoothing blood supply including whether incentives can play a role,” conclude the authors. They acknowledge that there is disagreement as to whether it is ethical to offer compensation or incentives for blood donation, but it is clear that economic rewards have a positive short-term effect on blood donation.

(continued on page 7)

Economic Rewards for Blood Donors (continued from page 6)

In December 2011, the issue of paid donation gained some attention when the Court of Appeals of the Ninth Circuit ruled that a federal law banning payment for organs, including bone marrow, does not apply to the donation of peripheral blood stem cells (PBSCs). The National Marrow Donor Program (NMDP) has maintained its policy against compensation for either type of donation, and America's Blood Centers is part of a coalition led by NMDP that opposes payment for stem cells. ABC continues to support blood donation motivated by altruism in order to guarantee the safety of the blood supply (see *ABC Newsletter*, 12/9/11, 4/6/12).

Citation: Lacetera N, Macis M, Slonim R. Public health: Economic rewards to motivate blood donations. Science. 2013 May 24;340(6135):927-8.

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SAVE THE DATE

America's Blood Centers' Financial Management Workshop

September 19–20, 2013
Dallas, Texas

Hotel Information
Rate: Single/Double $134 per night plus tax.

Sheraton DFW Airport Hotel
www.sheraton.com/dfwairport

2013 Workshop Fees (early bird/regular)
Registration: $375/$425

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 in July.

"This is a workshop you really can't afford to miss! In addition to the workshop's peer-networking value, you will be empowered by attending sessions on fraud, the current state of the industry from different perspectives, and you will leave with ways to improve the bottom-line."

– William M. Coenen
Interim Chief Executive Officer
America's Blood Centers

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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, AABB, and ARC Submit Joint Comments to FDA on Syphilis Draft Guidance

America's Blood Centers, AABB, and the American Red Cross (ARC) recently submitted joint comments to the Food and Drug Administration on the draft guidance titled "Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis."

The draft guidance, published in March, replaces the June 2003 draft guidance titled "Revised Recommendations for Donor and Product Management Based on Screening Testing." It 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 (see *ABC Newsletter*, 3/1/13).

The comments can be viewed on AABB's website at http://bit.ly/11tavZF. (Source: ABC, AABB, and ARC joint comments, 5/22/13)

ABC Announces IT Webinar on Logical Observation Identifier Names and Codes

America's Blood Centers will hold an IT webinar on June 19 titled "LOINC: What Blood Centers Need to Know." LOINC stands for Logical Observation Identifier Names and Codes. Kevin Land, MD, senior director of Field Operations at Blood Systems, will provide a better understanding of LOINC. Participants will also hear from a blood center that has implemented LOINC to meet their customer's needs.

The webinar will be held from 2-3:30 p.m. EDT. Details and login information can be found in MCN 13-077 at http://members.americasblood.org/go.cfm?do=FileCenter.View&fid=4334. ♦

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer's name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Publications Editor Betty Klinck at newsletter@americasblood.org. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

Q&A with ABC's *Executive Services 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: My blood center has had to reduce its expenses. How has ABC worked to reduce its expenses?

A: In the SEQuaLS assessment, we received many questions surrounding this subject – reducing expenses. The easy answer is: that we have reduced expenses significantly. Let us try to explain without getting too stuck in the details.

Eighty percent of ABC's revenues for the core budget come from member dues, with the remaining twenty percent coming from meetings and workshops, as well as fees for accounting and infrastructure services that ABC performs for other entities. A one percent increase in member dues currently equals about $27,700 of ABC's revenue. During the last five years, ABC has lost $188,000 in revenues due to membership changes (mergers, acquisitions, etc.) and loss of a subsidy from our former group purchasing organization. At the same time there have been only two dues increases, combined totaling an average of $2,817 per member.

Sixty percent of ABC expenses come from personnel costs. ABC has a small, highly trained staff that is required to manage and coordinate a number of projects that cross traditional department lines. Including the recent staff changes, a reduction of eighteen percent, ABC's personnel costs are lower than they were five years ago. In addition, we have made changes to our service suppliers to find alternative, less expensive solutions. On the other hand, during any given year there are additional unbudgeted expenses that are approved by the ABC Board of Directors, such as the additional expenses incurred during fiscal year 2013 to fund the advocacy work to reduce the burden of the medical device tax on our members. The campaign was successful and should save members over $11 million.

Bottom-line, ABC understands the tremendous pressures members are experiencing to reduce their operating budgets and we can assure members that we will do our part by using our resources judiciously.

RESEARCH IN BRIEF

A recently conducted study and an accompanying editorial published this month in *Transfusion* focus on unexpected antibodies of undetermined significance, reminding readers that these antibodies could be clinically significant in certain cases. Alloimmunization to non-ABO blood group antigens remains a clinically significant problem for blood banks and transfusion services. In fact, hemolytic transfusion reaction due to non-ABO antigens were the second-leading cause of transfusion-associated mortality reported to the Food and Drug Administration in 2011. Despite advances in laboratory methods, challenges still exist in detecting blood group antibodies, including the disappearance, or evanescence, of blood group alloantibodies over time, write Christopher A. Tormey, MD, and Jeanne E. Hendrickson, MD, in an editorial in *Transfusion*. Transfused patients may develop alloantibodies that quickly decrease in titer, making the window of detection narrow. To increase detection of low-titer,

(continued on page 10)

RESEARCH IN BRIEF (continued from page 9)

non-ABO alloantibodies, new methods like gel-based or solid-phase screening, have been developed. "However, increased sensitivity often comes with some cost, namely, positive screen results that may yield no specific blood group antibody (or antibodies) upon further testing," they write. Occasionally, these reactions represent clinically significant antibodies, but they are often viewed as insignificant nuisances, explain the editorialists. There have been few comprehensive studies examining these types of reactions, but a paper published this month in *Transfusion* by Chang Liu and Brenda J. Grossman, MD, of Washington University, address the issue of non-specific alloantibody reactions in a gel-based platform via a retrospective review of unexplained positive results at their facility. Antibodies of undetermined significance (or AUS) were the single most common result reported during the duration of the study – approximately 18 percent of total positive antibody screening tests were determined to be AUS. Also, they found that about 15 percent of patients with AUS had a subsequent alloantibody (or antibodies) identified with additional testing. The editorial authors note that this study raises important questions, such as whether alternative antibody screening methods should be explored and what actions should be taken to help evaluate the possibility that an AUS represents a low titer alloantibody. "Since AUS can represent an actual alloantibody in some cases, a systematic approach to evaluating their significance is warranted," write the authors. The editorial suggests taking the following steps: conducting a laboratory evaluation for warm and cold autoantibodies; performing enhanced tube-based testing; evaluating for alloantibodies against low-incidence antigens; obtaining another sample several days later; and conducting patient interviews to determine pregnancy or transfusion history. They also highlight the importance of seeking results of historical alloantibody testing from other facilities. "AUS is a common finding in our pre-transfusion testing, and even though most represent clinically insignificant antibodies, a fraction may be early developing clinically significant antibodies or clinically significant antibodies to low incident antigens. Further investigation may be necessary," Dr. Grossman told the *ABC Newsletter*.

Citations: Liu C, Grossman BJ. Antibody of undetermined specificity: frequency, laboratory features, and natural history. Transfusion. 2013 May;53(5):931-8.

Tormey CA, Hendrickson JE. Antibodies of undetermined significance: nuisance or near miss? Transfusion. 2013 May;53(5): 926-8.

***The Lancet* published on May 24 a series of articles about blood transfusion, which was compiled by Lawrence T. Goodnough, of Stanford University, who also wrote an editorial and co-authored two pieces in the series.** While blood transfusion is necessary for many patients and is often lifesaving, there are also risks to transfusion, and some research suggests that increased transfusions can lead to longer hospital stays and poorer outcomes. This three-part series focuses on the effect of patient blood management on the use of blood products, transfusion-free alternatives, and better ways of managing blood supply to meet increasing demand. In the first piece in the series, "Concepts of blood transfusion in adults," the authors discuss their assessment of best transfusion practices on the basis of evidence-based clinical trials, published clinical practice guidelines, and emerging pathways for improving blood use in clinical patient outcomes. The second piece explores the use of alternatives to allogeneic blood and ways to manage blood loss and anemia, both in the case of surgery and trauma. The third piece discusses challenges in the management of the blood supply, as blood suppliers are seeing short-term reductions in blood demand, while modeling suggests that during the next 5-10 years, blood availability in developed countries will need to increase again to meet the demands of the aging population. The series can be found at www.thelancet.com/themed/transfusion-medicine.

(continued on page 11)

RESEARCH IN BRIEF (continued from page 10)

Citation: Goodnough LT. Blood management: transfusion medicine comes of age. Lancet. 2013 May 25;381(9880):1791-2.

Goodnough LT, Levy JH, Murphy MF. Concepts of blood transfusion in adults. Lancet 2013 May 25;381(9880):1845-54.

Spanh DR, Goodnough LT. Alternatives to blood transfusion. Lancet. 2013 May 25;381(9880):1855-65.

Williamson LM, Devine DV. Challenges in the management of the blood supply. Lancet. 2013 May 25;381(9880):1866-75.

An AABB survey conducted in 2011 by Annette J. Schlueter and colleagues for the AABB Biovigilance Tissue Working Group measured the long-term impact of standards for tissue storage and issuance that were implemented by The Joint Commission in 2005. The results of the study, published online in *Transfusion* on May 14, followed up on a baseline AABB survey performed in 2005 to determine the level of involvement that hospital departments have in tissue handling and oversight. The AABB Biovigilance Tissue Working Group implemented a web-based survey that asked 1,069 hospital institutional members about human tissue types used, departmental responsibilities, and their view of AABB involvement. Of the 336 respondents, 84 percent use allogeneic and/or autologous tissue. Sixty-one percent have stored tissue on consignment. Respondents reported that blood bank and transfusion services and combined blood and tissue services have increased responsibility for storing and monitoring eye tissue and heart valves and reporting suspected post-implantation infections. Additionally, blood bank and transfusion services and combined blood and tissue services assume more stem cell and cord blood management duties as compared to other departments. The study found that blood bank and transfusion services are more involved with regulatory oversight than it was in 2005. Also, the survey revealed that member hospitals seek more guidance from AABB on implementing procedures and/or standards, clarifying the responsibilities of blood bank and transfusion services in tissue management and oversight and advocating with tissue vendors for standardized labeling.

Citation: Schlueter AJ, *et al*. Changes in hospital human tissue oversight in the United States between 2005 and 2011: results of a follow-up AABB survey. Transfusion. 2013 May 15. [Epub ahead of print]

BRIEFLY NOTED

A commentary published this month in *Transfusion* discusses the effect on blood availability if the interdonation interval of 56 days is prolonged. The authors, Merlyn Sayers, MB, BCh, PhD, and Jeff Centilli, of Carter BloodCare, describe regulatory and blood organization meetings over the past several years where experts have discussed the need to better manage donor iron stores. Throughout these meetings, it has become clear that the Food and Drug Administration and its Blood Products Advisory Committee (BPAC) feels that iron depletion in blood donors is of concern. However, there has been disagreement over the best course of action. Some have proposed changing the male hemoglobin cutoff from 12.5 g/dL to 13.0 or 13.5 and lowering the female threshold to 12.0 g/dL. At a 2010 BPAC meeting, the committee voted in favor of changing the male threshold but voted against changing the female threshold. During this meeting, the committee did not vote on lengthening the interdonation interval past 56 days, but their discussion implied committee members were apprehensive due to concern about threatening the adequacy of the blood supply. During this meeting, the American Red Cross presented data that

(continued on page 12)

BRIEFLY NOTED (continued from page 11)

showed changing the hemoglobin criteria would have little effect on collection numbers, while prolonging the interdonation interval would have a "significant detrimental effect." Carter BloodCare wondered if these same effects would be observed for a single, large, community, independent blood program, especially when also analyzing donors and their donations separately by ABO and Rh-D type. The authors conducted an analysis that covered all blood donations during 2011 at Carter BloodCare, dividing the donors into ABO and D groups and calculating what percentage donated from one through six times per year. With those results in hand, they then estimated what percentage of different ABO and D inventories might have been lost with a lengthening of the interdonation interval to 70, 84, and 112 days. At 70 days, the maximum number of donations an individual would be able to make per year would be five. Consequently, the program would lose one donation a year from individuals donating six times. An increase of only two weeks in the interdonation interval, from 56 to 70 days, eliminating only one donation from the six-times-a-year donors would reduce the group O D+ inventory by 1.04 percent. At an interval of 84 days, the loss is 3.1 percent, and at 112 days it is 8.2 percent. The percentage annual losses for the group O D- inventory at the same intervals would be 1.7, 4.5, and 11.1 percent, respectively. "If donation patterns at our blood center are a reflection of how recruitment is managed elsewhere, then a consequence [of changing the interdonation interval] will be putting the precarious supply of some blood types at greater risk." Going forward, the authors suggest that as the donor population ages, blood centers must gain a better understanding of altruism, across all age groups, and how new knowledge could be used in recruitment. Blood donor recruitment would be key to offset any change in the interdonation interval. They also note that regulators could promote a variety of approaches to the management of donor iron stores. Also, the National Heart, Lung, and, Blood Institute could continue its invaluable contributions to research by encouraging studies exploring if iron deficiency, in the absence of anemia, does have health consequences, write the authors. They conclude that this information is vital to maintain donor health and to keep the donors well-informed.

Citation: Sayers M, Centilli J. Contemplating the effect on blood availability if the interdonation interval of 56 days is prolonged. Transfusion. 2013 May;53(5): 1132-6.

AABB has updated its full-length and abbreviated donor history questionnaire materials – version 1.3 Medication Deferral Lists and flowcharts corresponding to the use of medications on the lists – to include Absorica as an additional isotretinoin-containing medication. The modified documents are not consistent with AABB content currently posted on the Food and Drug Administration website. However, the AABB Donor History Task Force and the FDA liaisons to the task force discussed the updates, including the mechanism for reporting implementation of the questionnaire documents to the FDA. Version control of the materials has been maintained by expanding footer information on specific pages of the amended documents. Blood establishments may add the information about Absorica to the materials they currently use or replace their current documents with the updated AABB materials. Licensed blood establishments may report this modification, along with the date of implementation, in their next annual report under 21 CFR 601.12(d), including a brief description of the change or by submitting copies of the relevant updated version 1.3 Medication Deferral List and flowchart with the report. Questions may be directed to Regulatory@aabb.org. (Source: AABB Weekly Report, 5/24/13) ♦

REGULATORY NEWS

The Food and Drug Administration's General and Plastic Surgery Devices of the Medical Devices Advisory Committee will meet on June 26 to discuss whether the regulation of blood lancets should be moved from class I to class II or class III. The committee will meet from 8 a.m. to 5 p.m. in Gaithersburg, MD, and will discuss whether new scientific data are sufficient to support this change. More information about the meeting can be found at http://1.usa.gov/16Qn3CP. (Source: FDA advisory committee meeting notice, 5/29/13)

GLOBAL NEWS

The European Blood Alliance (EBA) announced last week that all EBA members may now join the Eurobloodpack Purchasing Group (EPG). The EPG is a collaborative that allows the participating blood services to benefit from the scale generated by group purchasing and significantly reduces costs. It also provides opportunities to share resources in supplier and product audit, and will increase operational flexibility across blood services through the use of common blood pack specifications and the merging of defect and quality monitoring data. The initiative began in 2009, when an EBA working group developed a standard whole blood pack specification, as well as a common validation protocol. In 2011, NHS Blood and Transplant (NHSBT), the blood supplier of the UK and North Wales, took charge of the initiative and became responsible for the procurement of the Eurobloodpack. The group of six member blood services, led by NHSBT, has now completed the tender process and awarded a four-year contract for blood packs to Macopharma, Fresenius Kabi, and Haemonetics. These companies were awarded business for 11 different pack designs, which covered whole blood donation packs and ancillary packs. Although the current agreement is with the six countries involved in the initial collaboration, the resulting agreement with suppliers is now open to all EBA members and other countries where NHSBT has a close affiliation, such as Canada, Australia, and New Zealand. This initiative to collectively tender and purchase the EBA Eurobloodpack was also awarded two prizes in the Ireland National Procurement Awards 2012 ceremony. It won the Overall Excellence in Procurement Award and the International Procurement Award. More information is available in the NHSBT press release http://bit.ly/10hCJGj. Those interested in learning more about the Eurobloodpack may contact Neil Beckman at neilbeckman@nhsbt.nhs.uk. (Source: EBA announcement, 5/20/13; NHSBT press release, 4/26/13)

The World Health Organization's website for World Blood Donor Day 2013, to be held on June 14, is now live. World Blood Donor Day is celebrated each year on June 14 to raise awareness of the need for safe blood and blood products and to thank voluntary unpaid blood donors for their life-saving gift of blood. With the slogan "Give the gift of life: donate blood," this year's campaign, the 10th anniversary of World Blood Donor Day, will focus on the value of donated blood to the patient, not only in saving life, but also in helping people live longer and more productive lives. Blood centers can visit the website for details surrounding this year's celebration http://bit.ly/143Ec89. (Source: WHO World Blood Donor Day website, 5/29/13)

INFECTIOUS DISEASE UPDATES

HEPATITIS C VIRUS

Research published in the May issue of *Transfusion* shows that two pathogen reduction technologies effectively inactivated hepatitis C virus (HCV) in blood products. While advances in blood donor

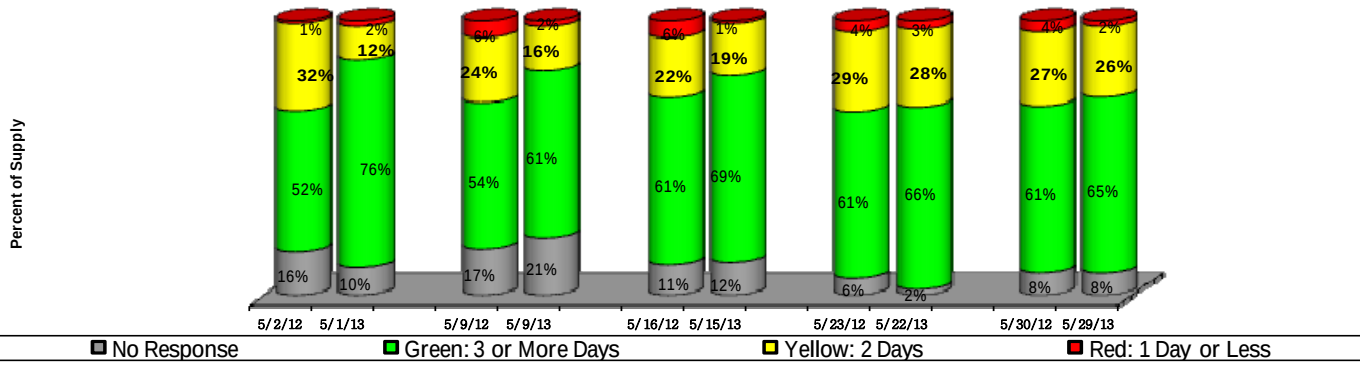
(continued on page 14)

INFECTIOUS DISEASE UPDATES (continued from page 13)

screening tests have significantly reduced the risk of acquiring HCV through a blood transfusion in the US and other developed nations, the virus continues to spread in developing countries, where HCV is still transmitted through unscreened blood transfusions. Pathogen reduction technologies, such as photodynamic treatment with methylene blue (MB) and visible light, as well as irradiation with short wave ultraviolet (UVC) light were developed to inactivate viruses and other pathogens in plasma and platelet concentrates, respectively. So far, their inactivation capabilities for HCV have only been tested in inactivation studies using model viruses for HCV, but recently, a system for the propagation of infectious HCV in cell culture was developed. Axel Seltsam of the German Red Cross Blood Service and colleagues investigated the inactivation of HCV by MB plus light and UVC irradiation. They found that HCV was sensitive to inactivation by both procedures. The researchers also note that this study shows that functional assays with human HCV offer an efficient tool to directly assess the inactivation capacity of pathogen reduction procedures. "Pathogen reduction technologies such as MB plus light treatment and UVC irradiation have the potential to significantly reduce transfusion-transmitted HCV infections," conclude the authors.

Citation: Seltsam A, *et al*. Two pathogen reduction technologies – methylene blue plus light and shortwave ultraviolet light – effectively inactivate hepatitis C virus in blood products. Transfusion. 2013 May;53;(5):1010-8. ♦

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

Héma-Québec announced in a press release this week that it will establish a mothers' milk bank in Spring 2014. "An important step has been taken with respect to allowing Héma-Québec to supply hospitals with mothers' milk that is pasteurized, safe, and of recognized nutritional value," said Jean De Serres, MD, CEO of Héma-Québec. The new mandate, approved by the National Assembly, will complement the current activities of Héma-Québec, which already has the essential components of the infrastructure and expertise needed

HÉMA-QUÉBEC

Blood Products
Stem Cells
Human Tissues

(continued on page 15)

MEMBER NEWS (continued from page 14)

to operate such a bank. "This reality is not well-known, but there is currently no regulatory framework for mothers' milk bank activities in Canada. Héma-Québec's competence in managing biological products, such as blood and human tissue, will ensure the safety of this product," said Dr. De Serres. Héma-Québec will recruit donors for the mothers' milk bank primarily from umbilical cord blood donors registered in the Stem Cell Donor Registry. The donors must be in good health and satisfy qualification criteria. Microbiological tests will be performed when the donors are selected. Bacterial tests will also be performed when the milk is processed, and the distribution system used for blood products will also be used for the milk. The mothers' milk bank will be used for premature babies who cannot be breastfed by their mothers. According to the scientific literature, premature babies born at 32 weeks or earlier receive the most benefit from breast milk, said the Héma-Québec press release. More information is available at http://bit.ly/11Eiuch. (Source: Héma-Québec press release, 5/29/13)

PEOPLE

Lauren Bailey, Lori Haas, and Roseanne Michalowski have recently joined Community Blood Center of the Carolinas' (CBCC) sponsorship development team. Each is responsible for educating the public on the importance of blood donation and recruiting new sponsors and donors. **Kanika Ellis** also recently joined CBCC as a business analyst/project manager. Previously, Ms. Bailey wrote for *The Charlotte Observer* and was a dance teacher. In her role at CBCC, Ms. Bailey also works on marketing and social media. She graduated from the University of North Carolina-Chapel Hill with a degree in advertising, English and creative writing. Before joining CBCC, Ms. Haas was a pharmaceutical representative with Women's Choice Pharmaceuticals. She graduated from UNC-Charlotte and earned a master's degree from Pepperdine University. Ms. Michalowski has been a blood donor recruitment representative and worked in sales. She is a graduate of Long Island University. Prior to her role at CBCC, Ms. Ellis was a project manager at CCCi and Duke Energy, and a business analyst at Blue Ridge Analytics. She graduated with a Bachelor of Arts in business management from Clark Atlanta University. (Source: CBCC press release, 5/20/13)

Miriam A. Markowitz has officially assumed her new position as CEO of AABB, replacing outgoing CEO Karen L. Shoos, who has held the position since 1994, AABB announced in a press release this week. AABB announced in April that Ms. Markowitz would succeed Ms. Shoos, taking the helm of this $25 million organization and its staff of about 100 (see *ABC Newsletter*, 4/5/13). Prior to joining AABB, Ms. Markowitz was chief operating officer at Georgetown University Medical Center. In this role, she served as a strategy advisor and supported relationship development with outside organizations regarding program development, public-private partnerships, and regulatory and policy-making issues. She currently serves on the board of directors for the National Marrow Donor Program as vice chair. She is an adjunct at Georgetown University, and also recently completed two terms as mayoral appointee to the District of Columbia Board of Medicine, serving as consumer member. More information can be found in the AABB press release at www.aabb.org/pressroom/pressreleases/Pages/pr130529.aspx. (Source: AABB press release, 5/29/13)

MEETINGS

June 5-6 **HHS Advisory Committee on Blood and Tissue Safety and Availability Meeting**

The Department of Health and Human Services has announced a meeting of its Advisory Committee on Blood and Tissue Safety and Availability, to take place on June 5 from 8 a.m. to 5 p. m. and June 6 from 8 a.m. to 4 p.m. The meeting will be held at the Fishers Lane Conference Center in Rockville, Md. The committee will hear updates on recent activities of HHS and its agencies in support of previous committee recommendations. The focus of this meeting will be to address whether the current blood center system in the US is designed for optimal service delivery in the era of healthcare reform. In particular, the committee hopes to address the services currently performed by blood centers that are essential to the US healthcare system, how anticipated changes in healthcare may affect blood centers and the provision of services, as well as how the field of transfusion medicine will be defined in the next decade. More information is available in the Federal Register notice http://1.usa.gov/17aLtXC. ♦

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:

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

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

POSITIONS (continued on page 17)

POSITIONS (continued from page 16)

INBC, 210 W Cataldo, Spokane, WA 99201; Fax: (509) 232-4530; E-mail: Claudia.Campbell@inbcsaves.org. EEO/AA

Chief Operations Officer. Community Blood Center of the Carolinas, located in Charlotte, NC seeks a COO to take overall leadership, operational responsibility for a growing blood center. Responsibilities include regulatory compliance in operations, prepare and monitoring multi-departmental budgets and objectives to insure fulfillment of goals; perform strategic and business planning for the overall expansion of services, products and regions. Our ideal candidate has at least five years experience in a technical lab or laboratory manufacturing setting, including at least five years of management experience, with a background in blood banking or other related pharmaceutical/biologics manufacturing facility. Lean manufacturing and inventory management a significant benefit. BA required, MT(ASCP)SBB or MBA is preferred. Drug Free Workplace/Equal Employment Opportunity Employer. Interested candidates should send their resume and salary requirements to cbccteam@cbcc.us.

Staff Physician. Carter BloodCare, a large community blood center in Texas, seeks a qualified physician to join their staff of four transfusion medicine physicians. This position reports to the vice president of Medical and Technical Services (chief medical officer). Responsibilities include rotating call with the other physicians and shared daily oversight of medical and technical issues of the blood center. Depending on experience and interest, the physician could have practice opportunities in therapeutic apheresis, HPC collections and processing, transfusion services, HLA laboratory, and a large IRL reference laboratory. Travel to other sites is required. Many opportunities for teaching residents and fellows exist. Clinical research opportunities abound. M.D. or D.O, Texas licensure eligible, must be board eligible or certified within two years. Fellowship or two years' experience in Transfusion Medicine required. Contact Laurie Sutor, MD at (817) 412-5601 or Lsutor@carterbloodcare.org for more information.

CALENDAR

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

2013

June 2-5. **23rd Regional Congress of the ISBT, Amsterdam, The Netherlands**. For more information please visit www.isbtweb.org/amsterdam.

June 5-6. **Advisory Committee on Blood and Tissue Safety and Availability Meeting, Rockville, Md.** More information is available at http://1.usa.gov/17aLtXC. .

June 11-12. **2013 Plasma Protein Forum, Reston, Va.** More information and registration can be accessed at www.pptaglobal.org/pptaregistration/home.aspx.

June 11-13. **FDA Workshop: "Redefining the 'C' in cGMP: Creating, Implementing, and Sustaining a Culture of Quality", Baltimore, Md.** More information and registration details can be found at http://www.ispe.org/CGMP.

June 18-21. **Fund Development, Communications and Donor Management Workshop, America's Blood Centers, San Antonio, Texas.** Attendance restricted to ABC members and invited guests. Contact: Abbey Nunes. Phone: (202) 654-2980; fax: (202) 393-1282; e-mail: anunes@americasblood.org.

June 27-29. **Immune Deficiency Foundation 2013 National Conference, Baltimore, Md.** More information and online registration can be accessed at http://idfnationalconference.org/.

July 8. **AABB Public Workshop: Current Perspectives on TRALI Risk Reduction, Bethesda, Md.** Registration and more information about the agenda can be found at www.aabb.org/EVENTS/CONFERENCE/Pages/conf.aspx.

July 9-11. **HL7 & Meaningful Use Hands-On Workshop, Washington, DC.** More information can be found at www.HL7.org.

July 25-26. **FDA Public Meeting "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies," Silver Spring, Md.** More information can be found at www.gpo.gov/fdsys/pkg/FR-2013-05-22/html/2013-12124.htm.

July 29-31. **18th Annual GMP By The Sea, Chesapeake Bay, Md.** More information is available at www.pharmaconference.com/index_pharm.htm.

(continued on page 18)

CALENDAR (continued from page 17)

Aug. 3. **Medical Directors Workshop, America's Blood Centers, Milwaukee, Wis.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Aug. 4-6. **Interim Meeting, America's Blood Centers, Milwaukee, Wis.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Sept. 17-19. **BOOTS Session 11: "Demand-Based Recruitment and Collections," Orlando, Fla.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Oct. 12-15. **AABB Annual Meeting and CTTXPO, Denver, Colo.** For more information: www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx.

2014

May 11-15. **WFH 2014 World Congress, Melbourne, Australia.** For more information and to register, visit http://bit.ly/1227maC.

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

Aug. 5 Tuesday (note: new date and day) **Medical Directors Workshop, America's Blood Centers, Seattle, Wash.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Aug. 6-7 Wednesday-Thursday (note: new dates and days) **Interim Meeting, America's Blood Centers, Seattle, Wash.** Attendance restricted to ABC members and invited guests. Contact: ABC Meetings Dept. Phone: (202) 654-2901; fax: (202) 393-1282; e-mail: meetings@americasblood.org.

Oct. 25-28. **AABB Annual Meeting and CTTXPO, Philadelphia, Pa.** For more information: www.aabb.org/events/annualmeeting/attendees/Pages/future.aspx