

# A B C N E W S L E T T E R

## CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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#### 2015 #31

#### August 21, 2015

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#### **Donor Fear, Draw Time May Predict Donor Reactions**

Donor fear has long been recognized as a predictor of vasovagal donor reactions – which include dizziness, nausea, and fainting. New research suggests that donor fear in combination with the time it takes to draw the donor's blood strongly predict vasovagal reactions, particularly among new donors, according to researchers at Ohio University and America's Blood Centers member Community Blood Center of Greater Kansas City.

In addition to maintaining donor safety, preventing vasovagal reactions is vital to donor retention because donors who are fearful about donating, as well as those who experience reactions, are less likely to donate again. While several studies have shown that fear of donation, both prior to and during the donation, is a predictor of vasovagal reactions, asking about donor fear is not a part of standard operating procedures at blood centers. Previous research has also suggested that longer phlebotomies and fear of losing too much blood are possible contributors to higher donor reaction rates.

To investigate whether this combination of variables – fear of donation and length of blood draw – are associated with vasovagal reactions, Christopher France, PhD, of Ohio University, and colleagues reanalyzed existing data from a previous donor fear study conducted at the Community Blood Center of Greater Kansas City. Dr. France discussed his research in this area at ABC's Fund Development, Communications, and Donor Management Workshop in Chattanooga, Tenn., in June.

The study analyzed a sample of 2,730 whole blood donors who had successfully passed the donor health screening at high school drives. They collected donor demographics and asked donors to rate how afraid they were of having their blood drawn. The researchers also collected donor reaction codes, indicating whether or not they had a reaction, and where a reaction occurred. They combined the donor reports of fear vs. no fear with total blood draw time to determine if these factors were predictive of the phlebotomist-reported vasovagal reactions.

The analysis confirms previous findings that fear is a significant predictor of vasovagal reactions, and that vasovagal reaction rates increased with increasing blood draw time, approximately doubling in frequency when comparing draw times lasting more than 10 minutes against draw times lasting less than six minutes. "What is novel about the current findings is the demonstration that these



## OUR SPACE

#### Merlyn Sayers, MBBCh, PhD, President & CEO, Carter BloodCare

#### Patient Blood Management: Some Comments from Others and Some From Us

"The Ethics of Bloodless Medicine," published Aug. 14, was the last in a trilogy of articles in *The New Yorker* discussing lessons learned from transfusing, and not transfusing Jehovah's Witnesses. The reports are in keeping with the magazine's habit of regularly addressing medical topics (see also "<u>The Excrement Experiment</u>, <u>How a stranger's feces might save your life</u>," Nov. 24, 2014 and "<u>Can AIDS be Cured? Researchers get close</u> to outwitting a killer," Dec. 15, 2014).

These "Medical Dispatches" are a reminder that the lay press does not perform under the strictures of peer review that the academic press endures. If it did, it is unlikely that any journal editor would have endorsed the comment by a Pennsylvania hematologist oncologist that "a bag of blood that has been sitting in storage is like a dirty fish tank you haven't cleaned in months," as an appropriate description of the red cell storage lesion. This is erroneous on its face, based on multiple controlled trials. Nonetheless, more flamboyant discourse is an understandable prerogative in conventional journalism that is denied in academic literature. There are other examples. "Flesh eating bacteria" are more likely to draw attention than reference to vibrio vulnifcus and, similarly, "brain rotting disease" is more likely to pique curiosity than variant Creutzfeldt-Jakob disease.

This editorialist's carping about potential for disappointment with medical journalism's exaggerations aside, *The New Yorker* articles are a valuable reminder of some of the justifications for patient blood management. Experience with restricting transfusions for Jehovah's Witness patients, without apparent harm to them, certainly prompted suspicion that transfusion triggers were too generous. Suspicion has become all but conviction with publications showing that appropriately chosen patients tolerate what was previously regarded as unacceptable anemia.

*The New Yorker* articles did, however, also remind readers that some profoundly anemic patients die if not transfused. There are limits to how low the transfusion trigger can be set. Others recognize this. The category "Avoidable, delayed, or under-transfusion" is now included in the Serious Hazards of Transfusion reports of the UK's hemovigilance experience.

While the treatment of Jehovah's Witnesses has confirmed the value of selectively lowering transfusion triggers, tensions are emerging among those who regard this reduction as a general business opportunity and those who see it as a broad medical imperative. The business opportunity has emerged because administrators controlling hospital purse strings, confronted with dwindling reimbursements, recognize that costs can be contained if less blood is transfused. The medical imperative, on the other hand, recognizes that complications are avoided when unnecessary transfusions are eliminated.

Certainly, in light of current understanding, not all patients who were previously regarded as candidates deserved transfusion; however, every patient's candidacy now must be a medical decision, not a cost decision.

#### <u>MSayers@carterbloodcare.org</u>

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Ultrapm

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.

America's Blood Centers President: Susan Rossmann CEO: Christine S. Zambricki ABC Publications Editor: Betty Klinck Subscriptions Manager: Leslie Norwood Annual Subscription Rate: \$390

Send subscription queries to <u>mnorwood@americasblood.org</u>. America's Blood Centers 725 15th St. NW, Suite 700, Washington, DC 20005 Phone: (202) 393-5725 Send news tips to <u>newsletter@americasblood.org</u>. <u>Donor Fear and Draw Time</u> (continued from page 1)

draw time effects combine with the known effects of blood donor fear to further enhance the prediction of reaction risk," wrote the authors.

Fear of blood draws predicted an approximate threefold increase in the odds of experiencing a vasovagal reaction at each draw duration level examined, and these effects persisted after controlling for donor sex, weight, estimated blood volume, pulse rate, and first-time donor status – common predictors of vasovagal reactions. The lowest proportion of reactions (5 percent) was observed among donors who reported no fear and had the shortest draw times, whereas the highest proportion of reactions (31 percent) was observed among fearful donors with the longest draw times.

Further, the proportion of fearful vs. non-fearful reactions grows larger with longer draw times. For draw times under six minutes, fear was associated with 10.7 percent more vasovagal reactions, whereas for draw times over 10 minutes, fear was associated with 21 percent more reactions. The authors note that this may be because donors with longer draw times are exposed for longer to factors that frighten them and that longer draw times can be associated with needle injury.

"During the early phase of phlebotomy, all donors are exposed to a similar set of potentially threatening stimuli (e.g., needles, pain, blood). With longer phlebotomies there is simply more time to be exposed to these stimuli and hence possibly greater opportunity to react," wrote the authors.

Based on these results, the authors suggest that donors should be screened for fear as part of the health screening process, particularly for younger and less experienced donors who are more likely to have reactions. Further, they suggest that phlebotomists give special attention to fearful donors to reduce their distress during donation.

Flow rate pumps to increase the speed of collections or smaller bags to reduce donation volume have been implemented in other countries to address concerns over draw time, however, it is unlikely these would be implemented in the US very soon, if at all, wrote the authors. In the interim, blood centers should improve education for fearful donors by providing accurate information about normal variability in draw times and reassuring them that the total amount of blood drawn does not vary across donors.

They add that future research should include a more fine-grained analysis of the association between fear, draw time, and different types of adverse reactions. Further, it may be helpful to investigate further the role of fear at different phases of the donation process to better identify when fear is interacting with other known predictors of reactions and to highlight when fear-mitigating interventions should be implemented.

"Much of the work regarding the prevention of vasovagal reactions in the US has focused on deferring small donors and limiting the draw to 450 from 500 mL. I have often thought that more focused engagement of the donors in the chair by donor room staff ought to be very important," said America's Blood Centers Chief Medical Officer Louis Katz, MD, who was not involved in the study. "This study should be the impetus to investigate such interventions formally."

**Citation:** France CR, *et al.* Fear of blood draw and total draw time combine to predict vasovagal reactions among whole blood donors. Transfusion. 2015 Aug. 11. [Epub ahead of print]



#### A Call to Action from ABC CEO Christine Zambricki

#### Impending Deadline: Critical Need to Submit Comments Opposing Dramatic Cuts to Blood Reimbursement

In response to the drastic cuts proposed by the Centers for Medicare and Medicaid Services (CMS) for blood and blood product reimbursement (<u>CMS-1633-P</u>), America's Blood Centers has launched an association-wide effort to oppose the reductions and support appropriate Medicare pricing for the nation's blood supply. With an impending deadline for public comment of Aug. 31, 2015, <u>ABC members and blood community supporters are urged to double their efforts **this week** to inform policymakers of what we see as a threat to patient safety and an adequate blood supply.</u>

Here are ABC's efforts to date, as well as what needs to happen next:

Nearly 100 Members of Congress have been contacted by ABC members thus far as a result of ABC's call to action, (MCN 15-061) and ABC is following up here in Washington. The second phase of ABC's grassroots initiative was launched today, with an urgent appeal for ABC members to submit comment letters to CMS describing the impact of these cuts on their community blood centers (MCN 15-063). ABC members should also take the opportunity to inform and solicit support from friends of the blood community who share their commitment to a sustainable blood supply, such as their employees, boards, and donors.

ABC will be submitting formal comments to CMS in strong opposition to the proposed cuts. To support this critical grassroots effort, ABC is working with AABB, the American Red Cross, the American Hospital Association, the National Rural Health Association and others to submit comments in support of responsible pricing for the nation's blood supply. In your nation's capital, ABC is busy educating congressional offices and CMS staff to assure that ABC's voice is heard.

What are the issues and what are the implications of the proposed rule? On July 8, CMS proposed severe reductions in Medicare payment rates for all blood components provided in the outpatient setting. These cuts, ranging from roughly 25 to 66 percent were published in CMS' 2016 hospital outpatient prospective payment system rules with a deadline for public comment of Aug. 31. As seen in the chart below, the impact is substantial.

2015 and Proposed 2016 Medicare Payment Rates for Selected Blood Components					
HCPCS Code	Product	Current 2015 Rate	Proposed 2016 Rate	Change	
P9010	Whole blood	\$217.16	\$166.85	-23.17%	
P9016	Red blood cells (RBCs), leukoreduced (LR)	\$189.37	\$131.12	-30.76%	
P9017	Fresh frozen plasma, frozen within 8 hours	\$74.82	\$50.88	-32.00%	
P9035	Platelets, apheresis, LR	\$497.57	\$349.38	-29.78%	
P9037	Platelets, apheresis, LR, irradiated	\$674.16	\$486.47	-27.84%	
P9057	RBCs, frozen/deglyc, LR, CMV-negative, irradiated	\$448.67	\$150.97	-66.35%	
P9058	RBCs, LR, CMV-negative, irradiated	\$274.67	\$185.81	-32.35%	
Source: Health Research Associates, Altadena, Calif.					

(continued on page 5)

Oppose CMS Cuts (continued from page 4)

There is no rational analytical foundation to support the proposed reductions. In theory, the 2016 rate schedule is based on 2013-2014 data but according to the information provided by CMS for 2013-2014, costs actually increased during this period. CMS data is also known to underestimate the cost of blood due to inadequate capture of total expense and underreporting by hospitals. Moreover, blood collection organizations receive payment only for blood actually transfused, not available that is not used, and have already pared collections to avoid waste. Thus the "insurance value" of blood to the hospital is not captured in cost reports.

The proposed reimbursement rates appear to be far less than the acquisition costs and in many cases less than the actual cost of producing the blood product. Some experts have suggested that these figures are so low that they must be in error; however, the possibility of an error is no guarantee that the mistake will be corrected!

Decreasing blood use and increasing cost pressures on blood collectors from hospital system contracts have led to significant decline in blood center margins, with at least 28 percent of non-profit blood centers operating in the red. The blood community has streamlined internal operations while maintaining, at minimum, Food and Drug Administration-regulated collections, product testing, and processing. The current blood economy puts our nation's blood system at risk, even without accounting for the affordability of innovations and safety measures such as babesia testing and pathogen reduction technologies.

The basic infrastructure necessary to sustain the nation's blood supply is jeopardized by these drastic cuts. Sustaining blood availability requires volunteers throughout the country who willingly donate their blood for the good of their communities. The importance of the donor cannot be overestimated, making the blood community unique when compared to pharma or device manufacturers. The cost to recruit the donors of the future, in particular donors with rare blood types and minority donors, is daunting. Maintaining the staff, systems, and processes to do so successfully requires an adequate reimbursement model.

As the deadline of Aug. 31 for public comment approaches, ABC members and blood community supporters are urged to prevent these dramatic cuts. ABC members should respond immediately to <u>MCN 15-063</u> by sending a comment letter today to CMS and copy the letter to congressional representatives. A call to the local or Washington congressional office to educate your representatives about our concerns is essential. The voice of ABC can be multiplied by involving employees, board members, community leaders and dedicated donors in this effort.

The *ABC Newsletter* readership goes far beyond ABC membership, extending to individuals in the blood industry and beyond who have an interest in supporting a safe and adequate blood supply. ABC urges these individuals to write a comment letter to CMS on behalf of patients everywhere, opposing these cuts and educating CMS on the impact the cuts will have in their communities. Mack Benton at ABC is available at <u>mbenton@americasblood.org</u> to assist with additional information and guidance.

The message is clear. It's all hands on deck with ten days to go until the deadline of Aug. 31. The time is now to prioritize this critical action. It only takes about 15 minutes out of the day, the same time it takes to stop at Starbucks and get a cup of coffee, to write a letter that may save millions.

Christine & Zambricki

<u>czambricki@americasblood.org</u>

## America's Blood Centers<sup>®</sup> INSIDE ABC It's About Life.

*The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.* •

#### **ABC Welcomes Rachelle Fondaw as Director of Education Programs & Grants**

America's Blood Centers this week welcomed Rachelle Fondaw as the association's new director of Education Programs and Grants. She brings with her a plethora of knowledge in adult education and learning management systems (LMS), having developed and managed learning experiences for adults for more than 10 years.

Ms. Fondaw's main focus will be creating educational content, such as online learning modules, for the newly developed America's Blood Centers Professional Institute (API), which is the one-stop-shop for all of ABC's educational offerings including face-to-face learning, online learning, publications, and learning communities. Ms. Fondaw will lead ABC in the selection of an LMS and the creation of blood banking certification programs that ABC plans to offer as part of the API.

"America's Blood Centers is thrilled to have Rachelle join the team. Her knowledge and experience, coupled with her excitement for the API initiative make her a great fit," said Abbey Nunes, ABC's chief member experience officer. "We are looking forward to the great accomplishments that lie ahead!"

Ms. Fondaw began her career in the automotive industry, where she spent more than 15 years, serving in a number of positions at Volkswagen Group of America. She cut her teeth as a training manager at Volkswagen, where she was primarily responsible for working with subject matter experts across the organization to provide training to the retail network in the US and Canada.

Ms. Fondaw is no stranger to the trade association world, having worked for the last year as the education manager at Transportation Intermediaries Association, a non-profit association in the third-party logistics industry. During that time, she managed education programs, implemented and integrated a new learning management system, and updated and rebranded web-based courses. She also learned about the positive impact that associations can have upon their members and the industry it serves.

"I enjoy collaborating across organizations to move people and their organizations forward, and have a passion for continuous improvement and continuous learning. I am excited to be joining ABC and look forward to working with everyone," said Ms. Fondaw.

#### **ABC Helping to Collect Information on Incident Viral Hepatitis Infection**

America's Blood Centers is facilitating a cooperative effort with the American Red Cross, the Centers for Disease Control and Prevention, and the Council of State and Territorial Epidemiologists. The organizations are asking blood centers to report incident hepatitis B virus (HBV) and hepatitis C virus (HCV) infections in repeat blood donors who lack traditional behavioral risk factors to state or local public health personnel for prioritized investigation.

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**INSIDE ABC** (continued from page 6)

While viral hepatitis is reportable in all US jurisdictions, it has not been routine for blood centers to report the results of recent prior testing on repeat donors, which can identify incident infections (i.e., a donor with negative testing on a prior donation, who is confirmed positive on nucleic acid testing on a second donation within 12 months).

This collaborative effort to report such cases will provide local public health personnel with important epidemiological information. Specifically, the absence of common behavioral risk factors in successful blood donors suggests the possibility of healthcare-associated infection (HAI). Recently acquired viral infection among repeat blood donors can be a sentinel event signaling a possible HAI in the donor. Recognizing and investigating these acute infections may yield important information for state and/or local public health departments in order to facilitate public health interventions. At least six HAI outbreaks or transmissions have been detected since 2008 by public health investigation of such reports according to the CDC, in each instance from a single donor.

ABC notes that this reporting of incident infections in repeat blood donors requires a small amount of extra information compared to routine HBV and HCV reporting. ABC will provide its member blood centers with a short form to assist them. Be on the lookout for an e-mail from ABC with further instructions. Please contact ABC Chief Medical Officer Louis Katz, MD, with any questions at <a href="https://www.lkatz.com">lkatz@americasblood.org</a>.

#### Don't Miss Your Chance to Register for ABC's Financial Management Workshop!

Calling all chief financial officers, chief operating officers, and other blood bank finance professionals! America's Blood Centers is offering a premiere educational and networking opportunity through its 2015 ABC Financial Management Workshop in Chicago, Ill. from Sept. 16 to 17. Sessions will cover a plethora of hot topics in blood banking finance including fraud, the current state of the blood banking industry, unrelated business income, and cyber liability.

In addition to the valuable sessions and networking opportunities, participants can now earn 10.0 CPE Credits. Register now and book your hotel by **Aug. 28**! More information can be found <u>here</u>. Registration can be accessed via the direct e-mail invitations from ABC. Please direct questions regarding registration to Lori Beaston at <u>lbeaston@americasblood.org</u>.

#### **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 <u>newsletter@americasblood.org</u>. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

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#### **RESEARCH IN BRIEF**

The UK's National Health Service Blood and Transplant (NHSBT) reports that platelets stored for six-to-seven days were not inferior to those stored for two-to-five days in hematology patients. In the US, platelets may only be stored for five days, unless collected in systems approved for seven-day storage after being screened for bacteria with a point-of-issue test cleared by the Food and Drug Administration as a "safety measure." With the recent FDA approval of pathogen reduction technology, blood services have grown more interested in extending platelets to seven-day storage. While studies have shown that extended platelet storage causes structural and functional changes in vitro, few studies have examined the hemostatic utility of extended-storage platelets in patients. Sheila MacLennan, and colleagues of NHSBT, the blood and tissue provider of England and North Wales, conducted a trial to investigate the efficacy of bacterially screened platelets stored for six or seven days compared to those stored for two to five days in stable adult thrombocytopenic hematology-oncology patients, using a validated measure of bleeding and platelet increment data. Patients were allocated to "blocks" of two-to-five or six-or-seven-day platelets in random order. The primary outcome was the proportion of successful transfusions during the first block, defined as a corrected count increment (CCI) of more than 4.5 at eight to 24 hours post-transfusion. CCI is often used as a surrogate for platelet transfusion efficacy. Of the 122 patients evaluated, 87 (71 percent) and 84 (69 percent) had successful transfusions after two- to-five and six- or seven-day platelets of mean ages 3.8 and 6.4 days, respectively. Based upon their analysis, the researchers determined that six- or seven-day platelets were statistically non-inferior to two- to five-day

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#### **RESEARCH IN BRIEF** (continued from page 8)

platelets. The trial showed no difference in bleeding events within the first block or in all blocks and no difference in the median interval to the next platelet transfusion, suggesting that extended-shelf-life platelets provide comparable clinical function to two-to-five-day stored platelets. They also found no evidence of an increase in transfusion reactions with the extended-storage platelets. Extending platelet dating does not appear to have negative clinical outcomes for hematology patients and significantly improved the management of platelet stocks within blood centers and hospitals, conclude the authors. The availability of seven-day platelets has contributed to a 2 percent decrease in platelet wastage at NHSBT. The authors note that this study is limited by the low accrual rate.

**Citation:** MacLennan S, *et al.* A randomized noninferiority crossover trial of corrected count increments and bleeding in thrombocytopenic hematology patients receiving 2- to 5- versus 6- or 7-day-stored plate-lets. Transfusion. 2015 Aug;55(8):1856-65.

Results from qualitative interviews of male blood donors who reported having had sex with another man (MSM) even once since 1977 suggest that MSM donors are concerned with blood safety and support a scientifically-sound MSM deferral policy. In May, the Food and Drug Administration proposed changing the current lifetime blood donation deferral for MSM to a deferral of one year since the last exposure. The main concern about relaxing the MSM policy is maintaining the currently very low risk of transfusion-transmitted HIV. Brian Custer, PhD, MPH, of Blood Systems Research Institute and the University of California, San Francisco, and colleagues conducted a survey among male donors at four Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) blood centers around the US to assess noncompliance with the MSM policy. The Blood Donation Rules Opinion Study (Blood DROPS) results suggest that while donor compliance with the lifetime MSM deferral policy is imperfect, donors say they will be more likely to comply with a one-year deferral (see ABC Newsletter, 7/31/15). The new qualitative interview portion of Blood DROPS provides insight into the perceptions and practices of current or previous donors with MSM history. Forty HIV-negative MSM completed an online survey, indicating that they had donated blood and were willing to be interviewed. During individual interviews, the donors were asked about donation experiences and motivations, perceptions of the current MSM policy, policy change preferences, and the possible impact of a change to a time-limited referral. Ninetyfive percent of participants endorsed modifying the current MSM policy, with many suggesting that a science-based deferral period should be less than one year. Some participants suggested incorporating questions about specific HIV risk behaviors into the donor questionnaire for all donors. While interviewees recognized that HIV infection rates are higher in MSM than in the general population, they considered themselves to be low-risk for HIV and donated blood "to save lives." Importantly, interviewees were concerned about blood safety and promote a science-based deferral, suggesting that communications about the new policy should focus on epidemiological arguments and avoid those based on social equality for homosexual men. Interviewees emphasized that a fixed-time deferral for MSM does not accurately identify those who pose "true" HIV-transmission risk, but that rather all donors should answer questions about high-risk behaviors. The authors suggest that these perceptions should be incorporated into any communications regarding the MSM deferral policy.

**Citation:** Saving lives, maintaining safety, and science-based policy: qualitative interview findings from the Blood Donation Rules Opinion Study (Blood DROPS). Transfusion. 2015 Aug. 14. [Epub ahead of print]

#### **RESEARCH IN BRIEF** (continued from page 9)

Results from a phase 1 safety and efficacy trial suggest that idarucizumab, an antibody fragment, can safely reverse the effects of the direct oral anticoagulating, dabigatran. New direct oral anticoagulants offer numerous benefits over vitamin K antagonist anticoagulants used to prevent stroke and to treat and prevent venous thromboembolism. These include improved and more predictable pharmacokinetics, a rapid onset of action, and shorter half-lives. However, the lack of effective antidotes to reverse these anticoagulants has slowed their widespread acceptance. Stephen Glund, PhD, of Boehringer Ingelheim, the developer of dabigatran (Pradaxa) and idarucizumab, reports in The Lancet the results of a placebocontrolled, double-blind, phase 1 study of the safety, tolerability, and efficacy of increasing doses of idarucizumab for the reversal of anticoagulant effects of dabigatran. Healthy volunteers received dabigatran and then idarucizumab two hours after the last dose of dabigatran. After a five-minute infusion of idarucizumab, anticoagulation was immediately reversed to baseline levels. The reversal effect was sustained for more than 24 hours for all doses of 2g and above. There were no clinically relevant safety concerns. These results support those of a previous study published in The New England Journal of Medicine (see ABC Newsletter 7/26/15, page 9). The Food and Drug Administration has granted idarucizumab breakthrough therapy designation, and Boehringer pursues accelerated approval, according to a statement.

**Citation:** Glund S, *et al.* Safety, tolerability, and efficacy of idarucizumab for the reversal of the anticoagulant effect of dabigatran in healthy male volunteers: a randomized, placebo-controlled, double-blind phase 1 trial. Lancet. 2015 June 15.

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#### **BRIEFLY NOTED**

Knowledge Based Systems Inc. has updated its Donor Hemovigilance Analysis and Reporting Tool (DonorHART) to support denominator data at the collection center-level, announced AABB in the Aug. 14 weekly report. The system allows blood centers to capture and analyze information on donor reactions and reaction rates at sub-sites within the organization. The updated version allows users to generate reports and conduct analysis based on what has been entered for each of their collection centers. The previous version only allowed organization-level reports. More information about the AABB US Donor Hemovigilance Program can be found online. Related to this effort, America's Blood Centers recently launched an online survey to gauge the interest of ABC members in automating their donor hemovigilance efforts using the ISBT/AABB consensus hemovigilance definitions and integrating reporting into the ABC Data Warehouse. ABC encourages its member blood centers to complete the survey, which can be accessed in MCN 15-064. Contact Louis Katz, MD, ABC's chief medical officer, at lkatz@americasblood.org with any questions. (Source: AABB Weekly Report, 8/14/15)

The proceedings of the 2015 National Heart, Lung, and Blood Institute's State of the Science in Transfusion Medicine symposium were recently published in *Transfusion*. The symposium, held March 25 to 26, brought together blood bankers, transfusion medicine researchers, federal regulators, and other industry stakeholders to explore the key research priorities in blood banking and transfusion medicine that need to be addressed in the next five to 10 years to optimize patient and donor outcomes (see *ABC Newsletter*, 4/3/15). The article, now available online to AABB members and *Transfusion* subscribers, explores in detail the research topics presented by four NIH-convened working groups in the areas of blood donors, plasma transfusion, platelet transfusion, and red blood cell transfusions.

**Citation:** Spitalnik SL, *et al.* 2015 proceedings of the National Heart, Lung, and Blood Institute's State of the Science in Transfusion Medicine symposium. Transfusion. 2015 Aug. 10. [Epub ahead of print]

#### **REGULATORY NEWS**

The Food and Drug Administration on Aug. 18 granted Ortho Clinical Diagnostics 510(k) clearance for the Ortho Vision Analyzer, a highly interactive, fully automated analyzer for transfusion medicine laboratories. The Ortho Vision Analyzer is an instrument designed to automate *in vitro* immunohematology testing of human blood utilizing ID-MTS gel card technology. Ortho Vision Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cards and digital image processing. The device can be used as a standalone instrument or interfaced to the customer's laboratory information system. The FDA approval information can be found <u>here</u>. More information can be found in the Ortho Clinical Diagnostics <u>press release</u>. (Source: Ortho Clinical Diagnostics press release, 8/18/15) ◆

#### 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.



#### STOPLIGHT®: Status of the ABC Blood Supply, 2014 vs. 2015

■ No Response ■ Green: 3 or More Days ■ Yellow: 2 Days ■ Red: 1 Day or Less

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



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**2015 Workshop Fees (early bird/regular)** 2-day registration: \$390/\$445

There are four (4) \$800 scholarships available for this workshop. Application and additional details are included in registration.

<sup>6</sup> The Institute for Transfusion Medicine (ITxM) is thrilled to host the upcoming ABC Financial Management Workshop in Chicago. We anticipate lively discussion and exchange of ideas on how best to manage financially through these uncertain times in blood banking, mainly due to the cost cutting pressures within healthcare and the decrease in blood use. This will be an excellent opportunity to network with your peers and share your expertise on good financial practices and understanding of not only knowing how your business is doing financially, but why. We look forward to seeing you at our LifeSource facility in Rosemont in September.

> – Jim Covert President and CEO, ITxM

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









Chicago O'Hare airport (ORD - 3 miles), a hub for United and American, is served by all major US airlines; Midway airport (MDW – 29 miles) is served by discount carrier Southwest Airlines.

#### MEMBER NEWS

Blood Bank of Delmarva (BBD), Newark, Del., announced on Aug. 20 that it has begun producing pathogen reduced platelets. BBD was among the first to sign an agreement with Cerus Corp. following

the Food and Drug Administration's approval of its Intercept Blood System for platelets and plasma in December 2014. The Intercept Blood System is designed to reduce the risk of transfusion-transmitted infections by inactivating a broad range of pathogens such as viruses, bacteria and parasites that

may be present in donated blood. The nucleic acid targeting mechanism of action of the Intercept treatment is designed to inactivate established transfusion threats, such as hepatitis B and C, HIV, West Nile virus, and bacteria, as well as emerging pathogens such as chikungunya and dengue viruses. "I am pleased that BBD is able to offer pathogen reduced platelets to our hospitals and their patients. This product provides a greater level of safety by lowering the risk for transfusion-transmitted infections," said Chris Nare, lead executive of Laboratory Services and Distribution at BBD. The implementation of the Intercept Blood System aligns with BBD's mission of providing safe and effective blood products that best serve the local hospital and patient community, according to a blood center statement. "The Intercept product closely aligns with our vision of being a best in class blood bank and community partner. Offering pathogen reduced platelets to the hospitals we serve is a major milestone of our ongoing focus on innovation that supports patient wellbeing," said Roy Roper, president and CEO of BBD. (Source: BBD press release, 8/20/15)

As part of its annual convention on Aug. 8 in Charlotte, N.C., the Alpha Phi Alpha Fraternity, Inc. hosted a community blood drive with the Community Blood Center of the Carolinas (CBCC). Members of Alpha Phi Alpha donated blood during this event and at CBCC's Charlotte donor center, exceeding its goal of 30 units of blood. The blood drive was also part of the Carolinas Sickle Cell Collaborative (#StepUp4Sickle) – a partnership with CBCC, regional healthcare and sickle cell advocacy partners, and local African American groups – to support local sickle cell patients who often require multiple blood transfusions for their treatment.



Members of Alpha Phi Alpha donate blood during the Alpha Phi Alpha Fraternity convention in Charlotte, N.C.

#### Elba Garcia, DDS, the Dallas County commissioner, District 4 – revealed today, the winner of her

first "Summer Blood Drive Challenge" with Carter **BloodCare** between the cities of Grand Prairie and Irving, Texas. Dr. Garcia announced that Grand Prairie was the winner of the friendly competition during which city leaders were asked to encourage their citizens to give blood with Carter BloodCare from June 9 to Aug. 9 and designate that their donation was to be counted toward the challenge in their respective city's name, according to a Carter BloodCare press release. The challenge was open to any and all



Dallas County Commissioner Elba Garcia, DDS, District 4, (left) watches on as City Councilwoman Lila Thorn of Grand Prairie, Texas accepts a certificate on behalf of the city winning the Summer Blood Drive Challenge.



#### **MEMBER NEWS** (continued from page 13)

potential blood donors and donations at any location could be counted toward the competition. Grand Prairie leaders were able to encourage 284 people to give blood with Carter BloodCare and mention the Summer Blood Drive Challenge on behalf of their city. Irving proved a tough competitor with 241 donors giving blood during that time and indicating they did so because of the Challenge and on Irving's behalf. A total of 153 people from both cities were first-time blood donors with Carter BloodCare, coming in to donate for the challenge. Accepting the award on behalf of Grand Prairie was City Councilwoman Lila Thorn. "We are delighted to be the winners," said Ms. Thorn. "I don't think a single meeting went by without a mention of blood donation, during the last 60 days in our community. Most importantly, the challenge brought increased awareness of the need for blood in the summer months." Dr. Garcia presented Mayor Pro Tem Gerald Farris of Irving with a certificate to thank his city leaders and communication team for a valiant effort in raising awareness about blood donation and the importance of a safe and sufficient community blood supply. "We enjoyed the challenge and there are definitely no losers in this competition because hospital patients benefit from each donation," said Mayor Farris. "It reminded me to get back on the track of regular blood donation as I was accustomed to doing in the past." Dr. Garcia added, "Summer is one of the greatest times of need for local blood centers, like Carter BloodCare. Increased travel and outdoor adventures can contribute to accidents and the potential need for blood transfusions; yet, those interests compete with the time that a donor might normally spend giving blood." Each city campaigned through social media, video announcements, city council meetings, and other municipal communication channels. Grand Prairie even distributed rubber wrist bands to promote the cause. Each city also hosted blood drives and recruited their citizens to give blood at the local Carter BloodCare donor centers – of which there is one in each city. Five-hundred twenty-five people presented to give blood on behalf of the challenge, and most likely thousands more heard about the need for blood donors in the summer, because of the cities' communication efforts. All blood donors who participated in the Summer Blood Drive Challenge have been invited to celebrate at the Grand Prairie Farmer's Market with food, entertainment, and shopping at the market. (Source: Carter BloodCare press release, 8/11/15)

#### **CLASSIFIED ADVERTISING**

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: <u>mnorwood@americasblood.org</u>.

#### **POSITIONS AVAILABLE**

Vice President of Blood Donor Services. Unyts, Western New York's only Organ, Tissue, Eye and Community Blood Bank has an immediate opening for an executive level position in our Blood Donor Services Division. This exciting position will provide leadership and direction to the division, while meeting the blood, plasma and platelet needs of our regional hospitals, as well as direct and oversee donor recruitment and collection operations. Responsibilities will also include strategic planning and development, creation of annual expense and collections budget, and monitoring of annual operating and collection goals against budget. Bachelor degree with seven-10 years of blood banking or blood donor experience required. Master's degree preferred. Demonstrated expertise in leading organizations utilizing combined technical and interpersonal skills required. Ideal candidate will possess superior leadership, supervisory and communication skills with the ability to facilitate change and growth through collaboration and team while successfully promoting Unyts Mission, Vision and Values. Please apply online at http://www.unyts.org/about-us/careers.

Vice President of Quality and Compliance AD009 (San Antonio, TX). Responsible for leading, managing and coordinating the quality, regulatory, and compliance activities related to all donor, patient and component

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#### **POSITIONS** (continued from page 14)

testing services provided by QualTex Laboratories' headquarters and satellite locations. Will coordinate all external audits for the organization. Must exhibit leadership and must maintain current knowledge of regulatory requirements for all areas of testing services provided by QualTex Laboratories. Must be knowledgeable of all Standard Operating Procedures (SOPs) pertinent to quality and regulatory management. Bachelor's degree in Medical Technology, Applied Science, or related discipline required. Six years blood banking/transfusion medicine/clinical laboratory experience required. Six years of Quality and Management experience required. Computer experience required. Three years driving experience with good driving record required. MT (ASCP), SBB/BB, ASQ-CQA or CMQ/OE certifications preferred. Texas or Georgia operator driver's license required. US Passport preferred. Visit our website at www.biobridgeglobal.org. E-mail résumé to hr\_dept2@biobridgeglobal.org. Call Human Resources (210) 757-9557. BioBridge Global and its subsidiaries are proud to be an EEO/AA-M/F/D/V/Genetic Data employer that maintains a Tobacco & Drug-Free Workplace. All qualified applicants will receive consideration for employment without regard to race, color, ethnicity, religion, sex, national origin, disability, veteran status, genetic data or other legally protected status.

Associate Director of Transfusion Medicine and Cellular Therapy. The Department of Pathology (http://pathology.ucsd.edu) seeks an academic transfusion medicine physician to join the Division of Laboratory and Genomic Medicine. The individual will serve as associate director of Transfusion Medicine and Cellular Therapy at the UC San Diego Medical Centers in Hillcrest and La Jolla and the new Center for Advanced Laboratory Medicine. These services support the hemotherapy and human biologics manufacturing needs of the Health System's strategic clinical programs (advanced surgery and transplantation, cancer. cardiovascular diseases, women and infants care), Level I trauma and regional burn centers, and the affiliated Rady Children's Hospital-San Diego. The position involves a broad range of clinical and administrative responsibilities, as well as teaching medical students, residents, and fellows. This academically rich environment offers exceptional opportunities for translational and clinical research collaboration with leading investigators at UC San Diego, the California Institute for Regenerative Medicine, and several nearby institutions. Applicants must possess MD/PhD degrees and be qualified for unrestricted medical licensure in the state of California; and, be certified/eligible by the American Board of Pathology, with subspecialty certification in blood banking/transfusion medicine. For a full description and to apply, visit: http://apptrkr.com/623151. AA-EOE

Clinical Laboratory Scientist. Have a Passion for Reference Laboratory Work? Want a Sign-On Bonus? Join Us! Blood Centers of the Pacific (BCP) in San Francisco is seeking a Clinical Laboratory Scientist (CLS) to join our dynamic team of specialists in blood banking (SBBs) to perform complex serological testing: including red cell antibody ID, compatibility and platelet testing. BCP's Reference Lab is a highly respected lab within the blood banking and hospital communities locally and throughout the United States. BCP has a large repository of rare blood enabling us to assist with help in providing units for the most difficult patients throughout the country. Position requires a current California CLS license and three years relevant experience. SBB is preferred. If you are qualified, but not SBB certified, BCP has educational benefits that will help cover the cost of obtaining certification. All you need is the desire and the skills! Our work environment is exciting and the team is a highly functioning close-knit group. To apply, visit our employment page at: http://www.bloodcenters.org/about-us/employment/ (Requisition #15000444). Blood Centers of the Pacific

(Requisition #15000444). Blood Centers of the Pacific is an equal opportunity employer. EEO/Minorities/Females/Disabled/Veterans/Other Protected Groups

Manager Laboratory Technical Services. Blood Centers of the Pacific is a nonprofit, community-based organization that provides blood and blood components to hospitals, physicians and patients throughout Northern California. It also houses the Blood Systems Research Institute which conducts medical research to improve blood safety and patient care. Blood Centers of the Pacific helps 50,000 patients every year with blood donated by community volunteers. We seek a Manager for its manufacturing & technical services department in San Francisco. Will oversee services such as blood component QC, validation testing and documentation, quarantine/quarantine resolution, equipment repair, preventive maintenance, compliance and process improvement. In addition to standard managerial duties will perform bench work assignments as needed. Requires a four year degree in related field; three years related experience in blood banking, hematology and/or serology - one of which must be in a supervisory capacity. Requires a valid California Clinical Laboratory Scientist (CLS) license. Component production experience strongly preferred. To apply, visit our employment page at: http://bit.ly/1EIXgZT. (Requisition #15000885). Blood Centers of the Pacific is an equal opportunity employer. EEO/Minorities/Females/Disabled/Veterans/Other Protected Groups

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**POSITIONS** (continued from page 15)

Manager, Immunohematology Reference Laboratory. Blood Centers of the Pacific in San Francisco, CA seeks an Immunohematology Reference Laboratory Manager. We are a nonprofit, community-based organization that provides blood components and clinical/technical services to hospitals, physicians, and patients throughout Northern California. We were the first established community blood center in the U.S. We are also co-located with the Blood Systems Research Institute which conducts medical research to improve blood safety and patient care. Blood Centers of the Pacific distributes over 150,000 components to patients annually. Successful candidate will be responsible for all aspects of testing, technical operation, and workload of reference laboratory including staff supervision, employee counseling and evaluation, reference testing at satellite centers, and other standard supervisory functions. Other duties include budget management, relevant projects, training and education. Requires BA/BS in relevant field; eligibility for State of California Clinical Laboratory Scientist License and four years relevant experience. Current California Clinical Laboratory Scientist license preferred. Certification as a Specialist in Blood Banking (SBB) or equivalent OR Doctorate in an imunohematology-related field. To apply, visit our employment page at:

#### http://www.bloodcenters.org/about-us/employment

(Requisition #15000707). Blood Centers of the Pacific is an equal opportunity employer. EEO/Minorities/Females/Disabled/Veterans/Other Protected Groups

Supervisor, Reference Laboratory. Blood Bank of Hawaii is seeking a qualified individual to supervise its basic-level immunohematology and product quality control testing services. We are a nonprofit, communitybased organization that provides blood components and clinical/technical services to hospitals, physicians, and patients throughout Hawaii. Successful candidate will provide supervision for patient and product quality control testing, donor lookback and batch release. Responsibilities include supervision of four to five FTEs, employee counseling and evaluation, and other standard supervisory functions. Requires BA/BS in relevant field; eligible for State of Hawaii Clinical Laboratory Scientist License and four years relevant experience. Previous blood bank/hematology experience desired. Certification as a Specialist in Blood Banking (SBB) is preferred, but not required. Please visit our website at www.BBH.org.

Clinical Laboratory Scientist/Medical Technologist (Processing Laboratory; Full-time Position; \$35.58/hour). Blood Centers of the Pacific is a nonprofit, community-based organization that provides blood and blood components to hospitals, physicians and patients throughout Northern California. It also houses the Blood Systems Research Institute which conducts

medical research to improve blood safety and patient care. Blood Centers of the Pacific helps 50,000 patients every year with blood donated by community volunteers. We are looking for a Clinical Lab Scientist to perform required testing on whole blood and blood components including antigen screening, ABO grouping, Rh and serology determinations, and other routine donor and laboratory tests in a cGMP/TOM environment. Will consult with customer hospitals and perform other relevant duties as assigned. Must possess a current California CLS license. To apply, visit our employment page http://www.bloodcenters.org/aboutat: us/employment. Requisition #15000834 or #15000785. Blood Centers of the Pacific is an equal opportunity employer. EEO/Minorities/Females/Disabled/Vets/Other Protected Groups

Chief Operations Officer (Fresno, CA). Central California Blood Center (CCBC) is looking for an experienced chief operations officer (COO) to work directly with the President/CEO to execute our mission in the Central Valley of California. This executive leadership position as COO is accountable for operational objectives and will ensure strategic plan is met. In addition to oversight of daily operational functions, this position has oversight of the production related departments as well as to track and trend key performance indicators, quality metrics, and takes appropriate action to ensure business viability. History of successful execution of strategic objectives while demonstrating success in building teams to drive operational effectiveness in challenging, dynamic, and highly regulated environments required. Bachelor's degree required, MBA preferred with a minimum of five years of progressive managerial experience required. Experience managing donor services, lab testing and component manufacturing, product management, in addition to oversight of supply-chain and assets management preferred in a blood bank setting. All qualified applicants will receive consideration for employment without regard to race, color, ethnicity, religion, sex, national origin, disability, veteran status, genetic data or other legally protected status. Apply with resume and salary history at www.donateblood.org or to Adrienne Vanderberg at fax (559) 224-1310.

**Operations Supervisor-Donor Centers.** (Department: Metro Collections - Coon Rapids & Plymouth Donor Centers; Innovative Blood Resources, Location: St. Paul, MN; Job Type: Full time, 1.0 FTE, Exempt). To ensure collections operations at donor centers are run in a manner that results in safe and compliant blood products and service that consistently delights donor and sponsors. To ensure a working environment for staff on the applicable team that is supportive and productive through recognition, feedback, coaching and development. Knowledgeable about, and performs all type of blood collections including

#### **POSITIONS** (continued from page 16)

automated blood collection procedures (double Red Cell, Plasma, Platelets, Platelets plus Red Cell, Platelets plus Plasma). To apply please go directly to our website with an updated resume: <u>http://bit.ly/1PDYpbC</u>.

Assistant Manager Donor Testing. (Innovative Blood Resources, Department: Donor Testing Lab; Reports To: Manager Donor Testing Lab; Status: Full time, 1.0 FTE, Exempt; Schedule: Monday – Friday, 2nd Shift) Manages testing laboratory 2nd shift staff and coordinates operations associated with testing blood donors for infectious disease and immunehematology during these shifts. Provides adequate training and performance appraisals. To apply please go directly to our website with an updated resume: http://bit.ly/1LaQkK3.

Director of Donor Recruitment and Production Planning. (Innovative Blood Resources, Reports to: C.O.O. / C.F.O; Department: Donor Recruitment; Status: Full-Time, 1.0 FTE (40 hours per week), Exempt). Directs all Northland, Metro and Lincoln divisions of donor recruitment and donor contact management activities. Utilizes exceptional sales and account management skills to ensure goal attainment and efficient recruitment of blood donors to Innovative Blood Resources mobile and donor center facilities. Develops and implements strategies and tactics to manage customer relationships with existing and new blood drive sponsors to ensure customer satisfaction, improved processes, and increased production. Works closely with leadership to ensure effective production planning. Directs the management of the demand and supply optimization, and works collaboratively with the Donor Services leadership team to meet goals. To apply please go directly to our website with an updated resume: http://bit.ly/1fc6qHB.

District Director Donor Care. United Blood Services in Scottsdale, Ariz. is looking for an individual to lead the Donor Care Department. The ideal candidate will have a proven track record of excellent leadership skills; ability to create and develop an excellent customer service experience for a diverse workforce and donor base. Come and be a part of a caring organization whose mission is to save lives! Bachelor's degree in related field required. Knowledge of general business and management practices required. Five (5) years previous healthcare-related experience along with three (3) years supervisory experience required. Blood banking or healthcare-related experience preferred; must possess strong communication, analytical and statistical, leadership, organizational, problem-solving and human relation skills. Salary: DOE. Candidates must apply via http://www.unitedbloodservices.org/careers.aspx

(req#15000806). Blood Systems Inc. is an equal opportunity employer.

EEO/Minorities/Females/Disabled/Veterans

Hospital Services Manager. Blood Bank of Hawaii, a medium-size blood center (50,000 RBC distributions annually), has an exciting opportunity for a Hospital Services Manager. This leadership position is responsible for supervising and coordinating the operations, staffing and management of the Hospital Services department to include hospital satisfaction in meeting blood product needs, assuring quality customer service to all customers, and management and coordination of blood and blood component inventories. The ideal candidate will have knowledge of federal and state regulations as they relate to blood center operations, and at least five years of blood center experience. Three or more years of supervisory experience required. We offer a competitive salary and excellent benefits. Please apply via our website: www.bbh.org.