

2016 #18

May 27, 2016

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**The Association of Donor Recruitment Professionals Joins ABC**



The Association of Donor Recruitment Professionals (ADRP) is now an international division of ABC. ADRP's membership unanimously approved to disband their bylaws and merge with ABC during the ADRP annual business meeting on May 20 in Orlando, Fla. This partnership brings together two organizations committed to providing educational opportunities for professionals involved in all aspects of donor recruitment, experience, and management, both nationally and internationally.

ADRP has been exclusively dedicated to educating donor recruitment professionals in the blood, marrow and blood cell, organ, and tissue industries for over 45 years and has nearly 600 individual members. Over the past four years, ADRP has expanded its educational reach to include professionals in the fields of blood donor collections, marketing, and donor management. Each year, ADRP hosts an annual conference for recruitment, blood donor collections and donor management education, development, and networking.



*Christine Hayes, VP of Operations at LifeServe Blood Center and ADRP's Board President-*

Under the terms of the agreement, ADRP will become an international division of ABC and will operate under a Charter of Business. The ADRP Board will transition into an Advisory Board within ABC, rather than a governance board. ADRP Board Members will retain board positions and titles on the Advisory Board, and the ADRP Board President will have an ex-officio, non-voting position on the ABC Board of Directors. Additionally, ADRP members will become subscribers of ADRP offerings and are not required to be ABC members. As a subscriber, individuals will be able to access four ADRP webinars annually, receive discount rates for the annual ADRP Educational Conference and Exhibit Hall, and continue to have access to ADRP's Web resources and access to an ADRP. Both

organizations are looking forward to the work that lies ahead of them to execute this newly formed partnership. ♦


**OUR SPACE**

ABC Chief Medical Officer Louis Katz, MD

### Looking hard for something that is not Zika to opine about!

Generally tired of talking about Zika, so I thought I would recommend a recent read to those in our audience who shrink from reading anything about statistics. The tome is titled, *The Seven Pillars of Statistical Wisdom*, by Stephen Stigler, the Ernest DeWitt Burton Distinguished Service Professor in the Department of Statistics at the University of Chicago. He asks “What is statistics?” Then, in language accessible to a lay audience, sets out to distinguish statistics from math and provide an account of the discipline’s history and to “articulate the central intellectual core of statistical reasoning.” The historical context that pervades the book is a particular delight and adds a layer of pragmatism that was often missing in my course work.

His pillars are covered in seven chapters and 240 pages. I can paraphrase his language. The first is the value of reducing or compressing (i.e. discarding) data. Think about how much a number like the mean of a set of observations tells you. The value of adding to data beyond a certain point diminishes (geometrically in most cases). When we measure probability (e.g. make statistical inferences), we can create value when we are cautious, and chaos when we are not or when we are rigid (think of p values). The internal variation of data can be measured and will contribute enormously to inference. Asking questions from alternate perspectives yields different and often useful answers. Planning and designing before one observes are critical to controlling and measuring the important inputs that influence an outcome. Finally, there is the value of subtracting what you know from what you observe and studying what’s leftover (residuals in the jargon) to find more complete explanations of a data set.

There is a bit of algebra and a tiny amount of calculus in the text, but they can largely be ignored if you are mathematically disinclined. I tried the book on my best friend, a retired editor of computer publications—he told me to get a life—but who knew he was a philistine? At the end of the book, a non-scientist, blood center CEO (and some of the rest of us) will be in a better position to keep his/her medical director (or CFO), more honest than he or she was before reading it.

**Citation:** Stigler SM. *The Seven Pillars of Statistical Wisdom*. 2016. Harvard University Press.

[lkatz@americasblood.org](mailto:lkatz@americasblood.org) ♦

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

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## The “1 Percenters” We All Love

The following article is a contribution from [Dave Leitch](#), Principal at [Branch Consulting & Analytics](#). He is also a self-proclaimed numbers geek who loves a good graph.

I’m going to let you in on a little secret—hardly anyone really wants to donate blood. Despite the fact that this noble act takes place about 35,000 times every day across the country, almost all blood donations are given by people who would probably rather be doing something, almost anything, else. Notwithstanding this internal struggle to not donate, millions of generous people still do give blood year after year—over 13 million donations annually—and we are grateful that so many of them do.

### Who Gives?

About 6 percent of the entire United States population gives blood each year. Only 38 percent of the population is eligible to give blood, so that leaves about 32 percent of the population that currently *could* give blood, but who choose *not* to donate.

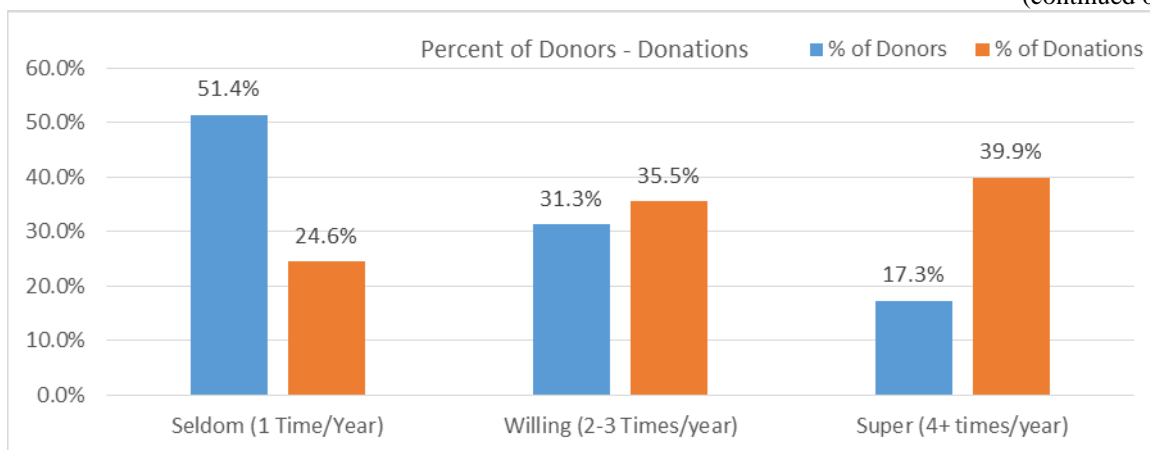
An eligible donor can give up to six times per year and based upon blood donor base analysis research, conducted by [Branch](#), an average whole blood donor gives blood anywhere from 1.5 times to up to 2.1 times per year. But there is something interesting about the “top tier” of regular donors.

Essentially there is a special group of people who are “Super Donors.” They love to donate blood, and they donate far more than twice a year—averaging four or more times per year and accounting for **40 percent or more** of all donations in any specific region.

Now if we measure this group as a percentage of people who give blood (6 percent) we come up with a small, remarkable number: **1 percent of the population supplies the country with 40 percent of its blood supply.**

We, at Branch Consulting, took a deeper look at these Super Donors, using demographic consumer data from a third-party, and we found the average super donor is 48 years old, versus 43 for all donors, with 36 percent of them making an income of \$100,000 or more, versus 33 percent of all donors, and are generally home-owners, 79 percent versus 75 percent of all donors. None of this Super Donor data showed a true distinction from the other donors’ data. So why are some donors more willing to donate more than others? [Branch](#) found one simple, common factor: Time. No one has enough time to do everything they *want* to do, let alone everything they *need* to do, so blood donation? It always falls last on the list of priorities.

(continued on page 5)





**America's Blood Centers®**  
It's About *Life.*

## 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.*

### Missing Type Campaign Goes Global

Missing Type Campaign goes international on August 15 to 21. It started as a United Kingdom-based NHS Blood and Transplant (NHSBT) initiative to obtain new blood donors. Businesses, brands, and influencers were asked to remove the letters, “A,” “B,” and “O” from their websites, Twitter handles and signage without an explanation. The campaign was a success and inspired 30,000 new donors to register and give blood. ABC is now participating in the campaign internationally ([MCN 16-050](#)), along with 22 other countries, and asking its member centers to get involved. Visit the [ABC Member Site](#) for more information on this campaign and attend the webinar on June 6, at 4 p.m. EST, with the campaign’s creator, NHSBT Assistant Director for Donor Services and Marketing Jon Latham. Contact [Mack Benton](#) with questions and updates on your outreach efforts ♦

### Links for Life Golf Tournament



Kick off the ABC Summer Meeting in style by participating in the 6th Annual Links for Life Golf Tournament, which will take place on Monday, August 1. The Kaneohe Klipper Military Golf Course, a Marine Corps golf course located on the Kaneohe Bay in Oahu, Hawaii will host the event. Consistently ranked as one of the world’s best military courses, Links for Life golfers will be treated to a first-class golf experience.

“This championship military course is bordered by the dramatic green velvet Ko’olau mountain range on one side and Pacific Ocean laced with white sand beaches on the other. The layout is challenging, yet enjoyable. And the bonus—you have a great reason for any bogey saying the gorgeous Hawaii setting distracted you,” said Albert Yoza, chief financial officer at Blood Bank of Hawaii and golf enthusiast.

Transportation will be provided to and from the ABC Summer Meeting hotel, the Hilton Waikiki, to the golf course. Registration includes lunch, cart, green fees, snacks and drinks on the course, and a tournament goodie bag. Shotgun start will begin at 12:30 p.m. After the tournament, golfers will be transported back to the Hilton for a reception and dinner, including awards such as, longest drive, closest to the pin, and winning team.

Registration is \$200 per golfer for any ABC member, including spouses and family members. You can register through your Summer Meeting registration or contact [Lori Beaston](#). Industry partners are also welcome and encouraged to attend. Please contact [Jodi Zand](#) for sponsorship opportunities.

Limited club rentals are available for \$50 per set. Please contact [Jodi Zand](#) for more info on rentals. Don’t miss this chance to help fund educational initiatives. Golf skill is not required, just the ability to come out to a beautiful location, and support a great cause. As Kevin Belanger, CEO of Shepard Community Blood Center and former Links for Life Chair, said about Kaneohe Klipper, “The Marines do it right, a great ocean front course with view of the mountains and a great time for fellowship.” ♦





## The “1 Percenters” We All Love (continued from page 3)

The 32 percent of people who are eligible and have not yet (and may never) donate fall into three main categories:

- Never Donated – These people could have anxiety about the process, squeamishness about needles, stories from others, or have personal or religious beliefs against donating;
- Unlikely to Donate – People who may choose to donate at some point, but it will take a major event to motivate them, e.g. a family emergency or catastrophic event; and
- Have Not Been Asked to Donate – These people will donate if asked, and if the opportunity presents itself at the right time. Might explain why more than 85 percent of all first-time blood donations occur at blood drives.

### Donor Motivation

What keywords and phrases motivate donors most to give blood? What are their attitudes about incentives and giveaways? [Branch](#) asked these questions and then cross-compared these responses with annual donor activity, and with donation-by-generation (Boomer, GenX and Millennial.) What we found was no difference in motivation across any of these factors. Essentially, *a donor is a donor is a donor*. The super donors are internally driven. Keywords, phrases and incentives/giveaways, except for a small percentage of donors, do not have a meaningful impact on the average super donor’s, or any regular donor’s, motivation to participate. Yet, donors at each level of giving have the potential to increase their participation and ‘step up’ to the next level.

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**AMERICA'S BLOOD CENTERS**  
**54TH SUMMER MEETING**

  **America's Blood Centers™**  
It's About *Life*.

**“In the late 1700s, Polynesian navigators voyaged thousands of miles of open ocean and discovered Hawaii.**

Using modern day wayfinding techniques, together we will explore ways to navigate the challenging times ahead facing the blood banking industry. Let the island host culture inspire us with its Aloha Spirit, high energy of world-famous Waikiki, natural beauty, entrancing hula and the thrill of fire knife dancing. Discover our paradise this summer.”

– Kim Anh Nguyen, MD, PhD, president and CEO, Blood Bank of Hawaii



Honolulu International Airport (HNL) is served by most major airlines. Visit <http://www.honoluluairport.org>.

August 1-4, 2016 – Honolulu, HI  
Hilton Waikiki Beach on Kuhio  
special room rate: \$240 + tax

#### **Future Leader Scholarship Program**

Supported by the FABC, these scholarships offer non-C-suite blood center executives the opportunity to advance professionally by attending the ABC Summer Meeting. Details available upon registration.

#### **Registration Fees**

ABC Summer Meeting: \$760  
Non-members (non-vendor), contact Lori Beaston at [lbeaston@americasblood.org](mailto:lbeaston@americasblood.org) for invitation and registration fees and information.

#### **Meeting Schedule**

##### **Monday August 1:**

Links for Life Golf Tournament  
Links for Life Golf Reception

##### **Tuesday, August 2:**

Medical Directors Workshop  
Hospitality/Networking

##### **Wednesday, August 3:**

SMT Forum  
Blood Center Leadership Forum

Host Event by Blood Bank of Hawaii

Hospitality/Networking

##### **Thursday, August 4:**

ABC Members Meeting

For sponsorship opportunities contact Jodi Zand at [jzand@americasblood.org](mailto:jzand@americasblood.org).

The “1 Percenters” We All Love (continued from page 5)

### Changing Behavior

While blood supplies are fairly stable on a day-to-day basis, shortages do occur. Most blood centers send out a broad plea to donors and the media that “action is needed *now*,” resulting in a large outpouring of donations, followed by another lull—rinse and repeat. Changing this cycle requires a stronger, more analytically-driven management, and understanding, of the donor base. There is a subset within each donor group that can be engaged, persuaded, and motivated to move into a higher level of giving. Data and analytics play a key role in identifying, then targeting, this subset of donors who have the highest probability of increasing their frequency of donation. ‘Stepping up’ even a small percentage—10 to 15 percent—of the right donors in the Seldom and Willing groups will allow blood centers to stay ahead of shortages.

To successfully navigate our current and changing environment, it is incumbent upon blood centers, non-profits, and companies struggling to reach their goals to ask the questions: “Are we looking at this data closely enough, and understanding it?” “Are we listening to our customers?” “Are we reaching that subset of donors/clients who are ready to go to the next level?” and, “Are we ready to change?” ♦

## LETTER TO THE EDITOR

**Re: *Administering transfusions of plasma and platelet (PLT) concentrates treated with pathogen reduction (PR) technology might result in a net loss of life in patients resuscitated after a massive hemorrhage(s), according to a commentary in Transfusion.*** [ABC Newsletter, May 20, 2016.](#)

Hess *et al.* hypothesize that reduced platelet count increments (CI) and in vitro coagulation factor levels imputed to pathogen reduction treatment (PRT) of platelet (PC) and plasma components may adversely impact mortality of hemorrhagic trauma patients (Hess *et al.* 2016). Their analysis used CI data, but not hemostasis outcomes, selectively extracted from studies with PRT components in patients without traumatic bleeding conflated with a secondary outcome measure (mortality due to exsanguination) from the Pragmatic Randomized Optimal Platelet and Plasma Ratios data for 1:1:2 dosing of PC, plasma, and red blood cells (RBC) (Holcomb, Tilley *et al.* 2015). Dosing of PCs in patients with hypoplastic thrombocytopenia is markedly different from that of trauma.

Similarly, the dosing of plasma in patients with acquired coagulopathy without trauma is markedly different from dosing in the PROPPR study. There may be equipoise as to the optimal PC suspension media, 100 percent plasma or 40 percent plasma with platelet additive solution (PAS), for transfusion in trauma with massive bleeding. However, contrary to the hypothesis of Hess *et al.*, multiple years of clinical experience in countries using conventional PCs suspended in PAS and PRT PCs suspended in PAS has not shown evidence of increased mortality in routine use, including massive bleeding (Corash and Benjamin 2016). Active hemovigilance surveillance of 115 patients with a diagnosis of trauma supported with PRT plasma and PCs in PAS, and 675 patients transfused with more than 10 plasma components in 24 hours and PRT PCs showed no increased morbidity, or mortality over seven days compared to patients without massive bleeding (Corash, Lin *et al.* 2016). Septic complications are a major source of morbidity in trauma patients; and PRT has demonstrated reduction of the risk for transfusion related sepsis (TRS). INTERCEPT PCs are licensed for suspension in either 40 percent plasma, 60 percent PAS, or 100 percent plasma. The types of PCs transfused for support of massive bleeding merits consideration in view of the trend in PROPPR for improved outcomes with 1:1:1 dosing.

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LETTER TO THE EDITOR (continued from page 6)

Thus far, the cumulative clinical data with PRT PC and plasma do not support the speculative hypothesis posed by Hess *et al.* PRT PC and plasma components have reduced the risk of transfusion-related sepsis and have been therapeutically effective in patients with massive bleeding.

[Laurence Corash, MD](#)

Chief Scientific Officer  
Cerus Corporation

[Richard J. Benjamin, MD, PhD](#)

Chief Medical Officer  
Cerus Corporation

Corash, L. and R. J. Benjamin. The role of hemovigilance and postmarketing studies when introducing innovation into transfusion medicine practice: the amotosalen-ultraviolet A pathogen reduction treatment model. *Transfusion*. March 2016. 56 Suppl 1: S29-38.

Corash, L., J. S. Lin, et al. Haemovigilance surveillance of plasma prepared with amotosalen-UVA pathogen inactivation transfused to patients with trauma or massive bleeding. *Blood Transfusion*. 2016. 14(Supplement 1): s74.

Holcomb, J. B., B. C. Tilley, *et al.* "Transfusion of plasma, platelets, and red blood cells in a 1:1:1 vs a 1:1:2 ratio and mortality in patients with severe trauma: the PROPPR randomized clinical trial." *JAMA*. February 3, 2015. 313(5): 471-482. ♦

## CORRECTIONS

In a brief last week, we stated that Hess *et al* “assert(ed) that trauma patients given pathogen-reduced (PR) platelets with a 30 percent lower potency due to PR and plasma potency loss of 20 percent might be associated with 400 deaths each annually.” This is correct, but the authors also estimated that trauma accounts for only about 15 percent of massive transfusions in the U.S., so the excess mortality estimate may be several fold higher. We regret the omission.

## RESEARCH IN BRIEF

**In a randomized, open-label clinical trial, researchers found severe hemophilia A patients treated with plasma-derived factor VIII containing von Willebrand factor (vWF) developed inhibitors less frequently than patients receiving a variety of recombinant factor VIII preparations.** This 42-site international trial screened 303 patients and randomized 264 previously untreated or minimally treated male toddlers (under 6 years old) with severe hemophilia A to receive infusions of either plasma-derived factor VIII or recombinant factor VIII (lacking vWF). Of 251 toddlers analyzed, 125 patients received plasma-derived factor VIII and 126 patients received recombinant factor VIII. The primary outcome was the development of an inhibitor with a titer of at least 0.4 Bethesda units by the Bethesda assay with the Nijmegen modification. Inhibitors developed in 29 patients from the plasma-derived group (20 at high-titer) and 47 patients in the recombinant factor group (30 patients at high-titer). The cumulative incidence of all inhibitors was 26.8 percent (95 percent confidence interval [CI], 18.4 to 35.2) with plasma-derived factor VIII and 44.5 percent (95 percent CI, 34.7 to 54.3) with recombinant factor VIII; the cumulative incidences of high-titer inhibitors were 18.6 percent (95 percent CI, 11.2 to 26.0) and 28.4 percent (95 percent CI, 19.6 to 37.2), respectively. An analysis of recombinant products excluding second generation full-length factor VIII gave similar results.

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RESEARCH IN BRIEF (continued from page 7)

In an editorial, Donna DiMichele from the Division of Blood Diseases at National Heart, Lung and Blood Institute speculated the clinical impact of these findings may not be consistent given the high rate of inhibitor development in recipients of plasma-derived factor, and speculated about mechanisms that may contribute to the immunogenicity of these products.


**Citation:** Peyvandi F., Mannucci P.M., et al. A Randomized Trial of Factor VIII and Neutralizing Antibodies in Hemophilia A. *NEJM*. 2016. 374:2054-64

DiMichele, DM. Hemophilia therapy — navigating speed bumps on the innovation highway. *NEJM*. 2016. 374:2087-9.

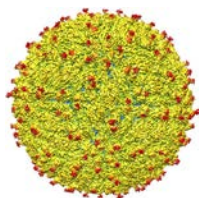
**Sickle cell disease (SCD) patients in the U.S. become alloimmunized at a higher rate than patients with SCD in other countries, according to a study in *Transfusion Medicine*.** SCD patients who are treated using chronic transfusion are at a high risk of red blood cell (RBC) alloimmunization that complicates provision of optimal transfusion support. Investigators at Case Western Reserve University in Cleveland, Ohio screened 173 studies and reviewed 24 that reported rates of RBC alloimmunization in SCD patients. Fifteen reports with 3,708 patients were from the U.S. and 10 studies with 2,203 patients were from South America, the Caribbean, the Middle East, Africa, and Europe. Patients in the U.S. had a higher weighted alloimmunization rate ( $22.33 \pm 0.13$  percent versus  $16.25 \pm 0.35$  percent,  $p < 0.0001$ ) and a greater number of alloantibodies per transfused patient ( $0.45 \pm 0.003$  versus  $0.20 \pm 0.005$ ,  $p < 0.0001$ ) than other countries. Rates between countries varied widely (from 2.6 percent to 79.19 percent outside the U.S. and from 7.07 percent to 38.24 percent in the U.S.).

As would be expected, the ethnic diversity of the donor pool—limited and predominantly Caucasian in the U.S. compared to the SCD population— influenced the results. Patients in the U.S. were 98 percent black compared to a donor base that is 89 percent Caucasian. By contrast, in Brazil the patients were 44 percent multiethnic, 36 percent black and 20 percent Caucasian, while the donors were 60.8 percent multiethnic, 9.4 percent black, 29.3 percent Caucasian and 0.5 percent “other.”

The authors conclude that improved minority donor recruitment strategies and genotyping to provide highly matched RBCs “may need to be pursued to minimise alloimmunization.” The applicability of more conservative transfusion strategies to the mitigation of high alloimmunization rates is also considered.

**Citation:** Zheng Y and Maitta RW. Alloimmunisation rates of sickle cell disease patients in the United States differ from those in other geographical regions. *Transfusion Medicine*. 2016. Online Early. DOI: 10.1111/tme.12314. 

**BRIEFLY NOTED**



**The U.S. Department of Defense will provide an extra \$1.76 million to military laboratories for Zika virus (ZIKV) surveillance and to study the effect on deployed service personnel around the world.** The money comes as an addition to the \$51 million already provided by “network partners” to support emerging infectious disease surveillance and will be issued to enhance ZIKV surveillance in Army, Navy, and Air Force labs across 18 countries and territories. (DoD [website](#), May 16, 2016)

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BRIEFLY NOTED (continued from page 8)

**A Swiss double-blind, randomized multi-center study in *JAMA* finds no significant improvement in neurodevelopmental outcome at 2 years' corrected age for preterm infants who received prophylactic early high-dose recombinant human erythropoietin (rhEPO) over those infants who received placebo.** Erythropoietin has been considered a promising candidate to reduce morbidity associated with the encephalopathy of prematurity due to its putative neuroprotective activity. Researchers randomized 448 infants, born between 26 weeks and 31 weeks, 6 days, gestation between 2005 and 2012, to 25µg/kg erythropoietin or placebo. The infants were assessed with the Mental Development Index (MDI) second edition at two years of age—finishing in 2014. The mean MDI was not statistically significantly different between the rhEPO group and the placebo group and there were no differences found between the groups for secondary outcomes, including motor development.

**Citation:** Natalucci G., Latal B., *et al.* Effect of early prophylactic high-dose recombinant human erythropoietin in very preterm infants on neurodevelopmental outcome at 2 years. *JAMA*. May 17, 2016. DOI: 10.1001/jama.2016.5504.

**Red blood cell transfusion is not independently associated with excess morbidity or mortality among patients with renal cell cancer (RCC).** This study reviewed 3,832 patients' information from the Korean Renal Cell Carcinoma database used in seven hospitals across the country and found 11.7 percent of patients had received red blood cells either during or within seven days of surgery. Transfused patients had worse overall survival rates as well as cancer-specific survival and relapse-free survival. However, once adjusted for age, co-morbidity, Eastern Cooperative Oncology Group performance status, and the stage of the cancer, researchers found red blood cell transfusion “does not influence the prognosis of patients who received curative surgery for RCC.”

**Citation:** Hyun Park Y, Kim Y.J., *et al.* Association between Perioperative Blood Transfusion and Oncologic Outcomes after Curative Surgery for Renal Cell Carcinoma. *Journal of Cancer*. May 5. 2016. DOI: 10.7150/jca.15073. ♦

## RECENT REVIEWS

**Available evidence shows Kogenate Bayer and Helixate NexGen are not associated with an increased risk of developing counterproductive antibodies in previously untreated patients (PUPs), announced the European Medicines Agency (EMA) on May 13.** These two recombinant factor VIII products, both made by Bayer Pharma AG to treat hemophilia A, were the subjects of three large multi-center cohort studies from 2013 to 2014. The results from those studies found both products increase the risk for inhibitor development. A review of the data by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) in 2013 found the data did not support the claim and stands by those claims yet again after this second review. The PRAC noted several limitations of the original studies, including the possibility of residual confounding; a number of parameters may have an impact on the incidence in PUPs for the original studies; and that there has been no signal for a similar trend of increases in inhibitor incidences with Kogenate Bayer in previously treated patients in other studies.

**Citation:** EMA. [Inhibitor development in previously untreated patients with severe haemophilia A treated with recombinant factor VIII products](#). May 13, 2016. ♦



## REGULATORY NEWS

The American Hospital Association (AHA) announced the **Helping Hospitals Improve Patient Care Act of 2016** was introduced into the U.S. House of Representatives Ways and Means Committee on **May 18**. The legislation would adjust readmission penalties for socio-economic status of patients and allow off-campus hospital outpatient departments currently under construction or mid-build to continue receiving higher rates than similar facilities not owned by hospitals. The bill, which was introduced after many rural and low-income area hospitals complained they were unfairly singled out under the Affordable Care Act's [Hospital Readmissions Reduction Program](#), would also delay Centers for Medicare and Medicaid Services authority to end Medicare Advantage programs for those that do not achieve minimum quality ratings. The Federation of American Hospitals and the Association of American Medical Colleges have both come out in support of the bill, however, AHA has said it was still reviewing the bill. (Source: AHA, May 18, 2016.)

The Food and Drug Administration (FDA) issued a **final guidance on how manufacturers report and conduct postmarket surveillance of class II and class III medical devices**. The guidance, released May 13, provides manufacturers with recommendations on making surveillance study submissions. Device manufacturers subject to 522 orders, an order requiring companies to submit a surveillance study within 15 months of receiving the order, will now have more guidance on what information to include and how to format the studies. (Source: RAPS.org, [FDA Finalizes Guidance on Postmarket Device Surveillance](#).) ♦

## THE WORD IN WASHINGTON

ABC encourages all members of the ABC community to vote and be active in primary elections this spring in support of the candidates of their choice. If you are involved in one of the following primary or caucus campaigns or plan on contacting your U.S. Congress members, ABC would be delighted to hear from you. Tell your story or send your pictures to [Mack Benton](#).

Here is what remains of this “never-a-dull-moment” election cycle:

- **May 28:** Democratic presidential convention in Wyo.
- **June 4:** Democratic presidential primary in the U.S. Virgin Islands
- **June 5:** Presidential and congressional primary in Puerto Rico
- **June 7:** Presidential and congressional primaries in Calif., Mont., N.J., N.M., and S.D.; Democratic presidential caucus in N.D.; Congressional primary in Iowa; U.S. House of Representatives primary in N.C.
- **June 14:** Democratic presidential and congressional primary in Washington, D.C.; Congressional primaries in Maine, Nev., N.D., S.C., and Va.

Click [here for an up-to-date list of 2016 election dates by state and by date](#). ♦

## GLOBAL NEWS

The Netherlands-based blood supply organization Sanquin has partnered with the World Health Organization (WHO) to present a donor recruitment marketing campaign for the **13th Annual World Blood Donor Day on June 14**. Sanquin and the WHO will be dramatizing a meeting of blood

(continued on page 11)



GLOBAL NEWS (continued from page 10)

**World Blood Donor Day on June 14.** Sanquin and the WHO will be dramatizing a meeting of blood donors coming face-to-face with their recipients and capturing the moments on film. The moments will be set up in everyday life settings where the donor will reveal himself to the recipient. The marketing campaign is to help motivate more people, especially youths, to donate blood and to thank blood donors for their donations. This online campaign is free for other organizations and blood centers to use and can be customized for a fee. For more information, email [Imke Sikkema](mailto:Imke.Sikkema). ♦

## INFECTIOUS DISEASE UPDATES

**A large-scale, early-stage HIV vaccine clinical trial is slated to start November 2016 in South Africa, pending regulatory approval, the National Institute of Allergy and Infectious Disease (NIAID) announced on May 18.** The study, HVTN 702, will follow 5,400 adult men and women given two experimental vaccines: a canarypox-based vaccine called ALVAC-HIV; and a bivalent gp120 protein subunit vaccine with an adjuvant as well as yearly booster shots. Participants will receive a total of five injections in a year. Both ALVAC-HIV, supplied by Sanofi Pasteur, and the protein vaccine, supplied by GlaxoSmithKline, have been modified to be specific to HIV subtype C, the predominant HIV subtype in southern Africa. HVTN follows a smaller trial, HVTN 100, and is based on the Military HIV Research Program-led [RV144 clinical trial](#). (Source: NIAID, May 18, 2016.)

**The [Centers for Disease Control and Prevention \(CDC\) reported 279 pregnant women in the U.S., including Puerto Rico and other territories, have been infected with the Zika virus \(ZIKV\) on May 12.](#)** The number was found combining data from the U.S. Zika Pregnancy Registry and the Zika Active Pregnancy Surveillance System in Puerto Rico and is more than double the May 11 total of 113 pregnant women meeting clinical criteria for ZIKV reported to CDC through ArboNET. In February 2016, the CDC launched the Zika surveillance systems to report and actively monitor pregnancies and congenital outcomes among pregnant women with laboratory evidence of possible ZIKV infection. No locally transmitted vector-borne Zika cases have been recognized in the continental U.S. Seven cases transmitted by sex within U.S. territories have been reported. (Source: CDC, May 12, 2016.) ♦

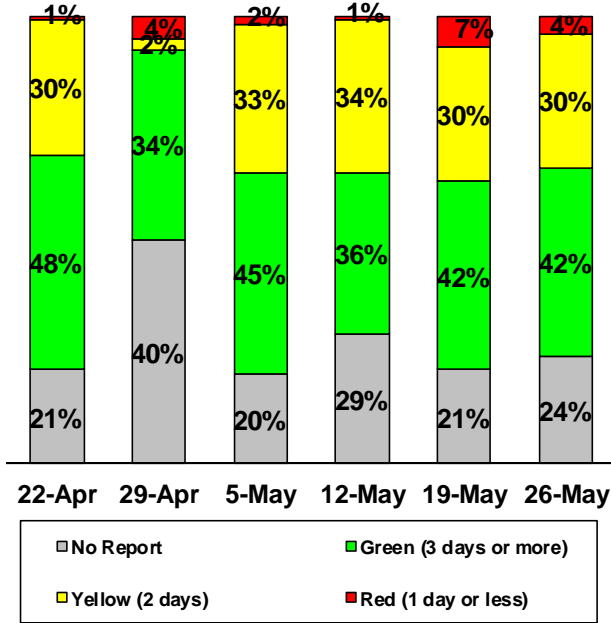
### We Welcome Your Articles

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 Lisa Spinelli at [newsletter@americasblood.org](mailto:newsletter@americasblood.org). You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.

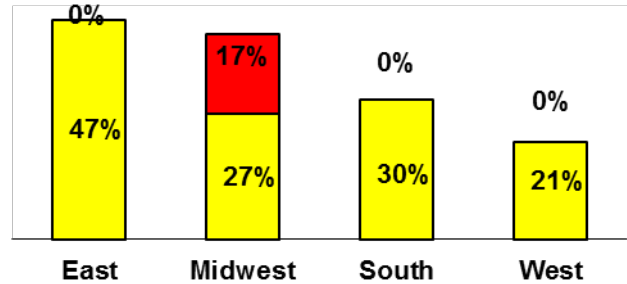


## STOPLIGHT®: Status of America's Blood Centers' Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, May 26, 2016



Percent of Total ABC Blood Supply Contributed by Each Region  
 East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:  
[www.AmericasBlood.org](http://www.AmericasBlood.org)

### MEMBER NEWS

**Blood Bank of Alaska unveiled a \$41.5 million new building in Anchorage on May 20.** The new center will service upward of 21 hospitals in the area, including the military hospitals. According to the blood bank, one in three Alaskans will need blood in their lifetime. (Source: YourAlaska-Link.com, [Alaska Blood Bank Grand Opening of New Facility](#), May 20, 2016.)



The New York Blood Center's (NYBC) Laboratory of Complement Biology received a \$2.3 million grant from the National Institutes of Health to study how sickle cell disease (SCD) patients respond to blood transfusions. The funding, announced on May 25 in a [press release](#), will go toward studying mechanisms to control successful transfusions in patients with SCD. Karina Yazdanbakhsh, PhD, head of the laboratory, will investigate the process by which maladaptive antibodies reject transfused cells, helping to mitigate patient side effects. The research will focus on follicular helper T cells and how they control alloimmunization in SCD patients. A central goal in this initiative will be to discover potential biomarkers that can be identified in advance, delineating those patients who may be at higher risk of encountering complications. "By

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## MEMBER NEWS (continued from page 12)

intricately profiling these follicular helper T cells, we expect to discover ways in which the activity of these cells can essentially be 'switched off' just before a transfusion, as a means to prevent alloimmunization," Dr. Yazdanbakhsh said in the release. "Another component we are investigating is how sickle cell disease reacts to the effects of vaccination. By characterizing these cells we hope to discover how to manipulate them to optimize vaccination in these patients who are at high risk of infections." 📌

## PEOPLE



### **BloodCenter of Wisconsin (BCW) and Versiti President and CEO Jacquelyn Fredrick announced her retirement, effective in early 2017.**

"After 35 years of dedicated service to the transfusion medicine and transplantation industry, it is time for me to pass on the privilege of leadership," said Ms. Fredrick, who is also a member of the ABC board, in a statement on May 24. "It has been an honor and a privilege. Seeing the medical and scientific advancements made possible by the continued outstanding generosity from our donors, donor families, and community partners has been a joy I will never forget." Under Fredrick's leadership, BCW created a national organization known as Versiti, a non-profit holding company consisting of four affiliate blood centers: BCW, Heartland Blood Centers, Michigan Blood, and Indiana Blood Center. The Versiti affiliates

provide more than 200 hospitals with blood and blood-related services. Ms. Fredrick has also served as president of AABB, Chairman of the Board for the Blood Centers of America, Inc., as well as on numerous research and foundation boards in Milwaukee. In May 2012, she received an honorary Doctorate of Business and Public Health from UW-Milwaukee. Former Versiti Board Chair and current board member, Peter Ziegler, will oversee the committee charged with conducting a national search for Fredrick's successor.

### **John Hagins, president and chief executive officer of Community Blood Center (CBC) in Appleton, Wis., has won the won the 2015 to 2016 Ronald Gilcher Award from the Association of Donors Recruitment Professionals (ADRP).**

Mr. Hagins was presented the award at the ADRP annual conference last week in Orlando, Fla. The award recognizes senior executive members of blood centers or similar organizations who have "made significant contributions to the recruitment profession both within his or her organization and in wider capacities." Mr. Hagins began his career with the American Red Cross in 1987, serving in various roles, including five years as the CEO of the Greater Alleghenies Region of American Red Cross. He joined ABC member center CBC in November 2013. "I would like to thank the ADRP Awards Committee and those that nominated and endorsed my nomination for this award. I am not only humbled to be in the company of such distinguished past recipients, but the fact that this recognition would come from peers that I admire makes this so special," Mr. Hagins said in a statement.



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### ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!



PEOPLE NEWS (continued from page 13)

**John K. Iglehart, founding editor of healthy policy thought and research journal *Health Affairs*, has been named as the [2016 recipient of the William B. Graham Prize for Health Services Research](#) from The Baxter International Foundation and the Association of University Programs in Health Administration (AUPHA).** The award is presented annually to a researcher who has made a significant impact on the health of the public in one of three primary focus areas: health services management, health policy development, and healthcare delivery. Mr. Iglehart has served as a national correspondent for *The New England Journal of Medicine* (NEJM)—in which he has written 150 Health Policy Reports and Perspectives, for NEJM, and was previously the vice president of the Kaiser Foundation Health Plan and the director of its Washington, D.C., office. He will be presented the award on Thursday, June 23, 2016, during the AUPHA Annual Meeting in Kansas City, Missouri. ♦

## MEETINGS

June 9 - 11

### **14<sup>th</sup> International Cord Blood Symposium, San Francisco, Calif.**

AABB, with support from the Cord Blood Association, will host the 14<sup>th</sup> International Cord Blood Symposium from June 9 to 11 in San Francisco, Calif. The scientific program brings all of the umbilical cord blood related fields of hematopoietic stem cell transplantation, banking, and potential in regenerative medicine together in one interactive three-day conference. The [program](#), registration details, and other information can be found [here](#).

August 1 - 4

### **ABC 55<sup>th</sup> Summer Meeting Honolulu, Hawaii**

Registration has begun for the ABC 55<sup>th</sup> Summer Meeting in Honolulu, Hawaii, hosted by Blood Bank of Hawaii. It will take place August 1 to 4, 2016 at the Hilton Waikiki Beach and will feature the ABC Medical Directors Workshop and the Foundation for America's Blood Centers Golf Tournament. [Click to register](#).

September 8

### **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.**

This free, first-come-first serve, public workshop titled the [Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval](#) was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products (HCT/Ps) subject to premarket approval, including stem cell-based products. The workshop will take place at White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room in Silver Spring, Md.

September 12 - 13

### **FDA Public Hearing on HCT/Ps, Bethesda, Md.**

Early registration for this public hearing to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products will last until June 1. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found [here](#). ♦

## 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 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 Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: [lmaundy@americasblood.org](mailto:lmaundy@americasblood.org).

## POSITIONS AVAILABLE:

**Fairbanks Center Manager.** The Blood Bank of Alaska (BBA) is looking for a Fairbanks Center Manager. The Fairbanks Center Manager is responsible for oversight and coordination of the daily operational collection functions and related product processing work flow for the BBAF Center. Directs the activities of such team to facilitate reaching and exceeding goal. Oversight and partnership with BBA management team in planning, program formulation, and technical decision making with particular reference to the role, functions, and operation of the blood bank's technical areas. This position is full-time exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, a health and wellness program, and a 401 (k) program are also available. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply online at [www.bloodbankofalaska.org](http://www.bloodbankofalaska.org).

**Assistant Professor / Professor of Transfusion and Cell Therapies.** The Faculty of Medicine at Helsinki University, Finland, invites applications for the position of assistant professor / professor of transfusion and cell therapies. The Faculty and Helsinki University Central Hospital are among the 10 best medical centers at European level and the 50 best centers in the world. The applicant will carry out and supervise scientific research, provide research-based teaching and follow scientific progress and take part in societal interaction in his/her field and in international collaboration. International and cross-disciplinary experience, success in obtaining research funding and playing an active role in research community will be appreciated. The appointee and the Finnish Red Cross Blood Service (FRC BS) may negotiate over a suitable secondary position. FRC BS is a non-profit organization responsible for collecting blood and supplying blood products all over Finland. FRC BS also hosts the Finnish Stem Cell Registry. FRC BS has an annual research budget of over 2 million euros and publishes about 35-40 scientific publications each year. Further information can be found at:

<https://www.helsinki.fi/en/open-positions/assistant-professor-professor-of-transfusion-and-cell-therapies>.

**Apheresis Registered Nurse.** The Apheresis Registered Nurse is responsible for supporting and monitoring standard operating and special blood banking procedures to ensure safety of blood products and alignment with organization goals and compliance with regulatory guidelines. This position will be responsible for assisting with donor counseling function for reactive testing markers and to serve as a resource RN for blood bank personnel, donors and the public. Must be able to create and maintain accurate, detailed reports and records. Must be able to work independently and have critical thinking skills. This position is full-time non-exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, a health and wellness program, and a 401 (k) program are also available. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply online at [www.bloodbankofalaska.org](http://www.bloodbankofalaska.org). 