

N E W S L E T T E R

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Last week, we were attending the ABC Summer Meeting and did not publish a weekly newsletter.

# 54th ABC Summer Meeting Informed, Relaxed, and Swayed Members

Issue #28 August 12, 2016



In a three-day flurry of leis, coconut-infused dishes, and insightful presentations, the ABC Summer Meeting provided the perfect opportunity for member center leadership to relax, network, and be educated on the industry's most pressing issues. Naturally, some of the most pressing topics on everyone's mind was Zika, as well as the latest research into donor hemoglobin and iron levels. A number of presentations spoke to these topics, with

hearty discussions from both presenters and attendees.

The meeting kicked off on August 2 in the Hilton Waikiki Beach on Kuhio Avenue with the incisive medical directors' workshop, including, but not limited to, presentations on the proposed changes to the federal common rule that guides human subject research, the role of blood centers in chimeric antigen receptor T-cell (CAR-T) development and use, and emergency approval for Jehovah's Witnesses for hemoglobin (HB) substitutes. The audience also had lively discussions in the "Morbidity and Mortality Workshop" and was ablaze with Zika talk in the "Hot Topics" presentation.

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Louis Katz, MD, ABC's chief medical officer, discussed the proposed changes to the decades old "common rule" announced in a Notice of Proposed Rulemaking in September 2015. The document has specific relevance to the blood community, especially in relation to a need or not, for "informed consent" for use of anonymized biospecimens, including blood and tissue donations, that are to be classified as "human subjects" in the new approach. "Where we get into trouble," Dr. Katz said, is when the need for informed consent encompasses samples that are entirely anonymous and how consent for such use in any way protects the source of the specimen. Adding a layer of unnecessary consent would just compound

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#### OUR SPACE

Jim AuBuchon, MD, CEO and President of Bloodworks Northwest

#### A Hand Up or Handout?

Zika virus causes grave concern among public health officials where mosquito-borne transmission is possible. Beyond the risk the virus represents to fetal central nervous system (CNS) development, it might wreak havoc on the developing CNS throughout its developmental period—many years.

Congress will (eventually) pass appropriations to help control this virus and its vectors. The Centers for Disease Control sees blood safety as one of five areas of focus, and we could attempt to lay claim to a portion of these funds directly from federal agencies or through state health departments that provide the boots on the ground in this war. New revenue sources are welcomed by cash-strapped blood collectors beset by falling blood use and hypercompetitive pricing, donor losses, costs of new procedures and SOPs, loss of units in inventory as Zika spreads, and the cost of testing. Increased cost for new safety measures ought to be passed to hospitals for reimbursement through the usual chain. However, hospitals seek lower, not higher, prices (despite their higher margins than ours), so an opportunity for direct federal assistance is tempting, particularly if the funds were targeted toward pathogen reduction to protect from the unremitting appearance of new safety threats.

Should our community push for a share of the \$1 billion or more likely to be allocated to Zika? Despite inherent attractiveness, there are good reasons to say "no." Health department budgets were decimated during the Great Recession as states slashed "non-essential" services. Funding for mosquito surveillance and control vanished. Control of Zika vectors represents the greatest opportunity to prevent its morbidity (and other such threats that are likely not far behind). We depend on information from these departments to make proactive decisions in mosquito-borne epidemics, and that information is just not there at present. It is arguable that funding us will reduce funding for these more important tasks. Critically, hospitals have been increasingly shielded from the true cost of providing a safe and adequate blood supply for several years, as we have competed with each other on price. The result is a blood system with reduced margins and capability to respond to catastrophic events. "Letting hospitals off the hook" for Zika mitigation demeans the value of the crucial services that we offer, including rapid responses to new threats to the blood supply. The more we protect our customers from the cost of safe blood, the less they will value what we do.

HHS has commissioned RAND to study the sustainability of our blood system's structure and ability to respond to crises. Direct federal payment for blood safety measures is a new (and likely unsustainable) approach to funding our efforts that might confound that analysis. It has always been a community's responsibility to support the transfusion needs of its members, traditionally through a free-enterprise approach with payments rendered for services provided. Does Zika ask us to change this course? And at what ultimate cost?

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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.

#### **America's Blood Centers**

President: Susan Rossmann CEO: Christine S. Zambricki Editor: Lisa Spinelli Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$390

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#### <u>ABC SUMMER MEETING</u> (continued from page 1)

the level of complexity the new proposed rules are designed to reduce and would limit research. The National Academy of Sciences has called for the executive branch to rescind the proposed rule and pursue a more comprehensive analysis and reformulation of the common rule that will accomplish the stated goals of human subject protection and simplification.



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Jennifer Andrews, MD, clinical assistant professor of pathology and pediatrics at Stanford University, relayed her address at the recent National Institutes of Health State of the Science workshop on pediatric transfusion medicine and noted the dearth of high quality research into central clinical issues in the discipline. With no centralized database and lack of large-scale, well-designed, studies it is very difficult to ensure optimal pediatric transfusion practices. The lack of uniformity and consensus on transfusion methods differs not just at the level of individual hospitals, but is also dependent on who is the attending doctor on duty that day, said Dr. Andrews. A true set of standard guidelines for optimal care in e.g. massive transfusion and cardiac surgery is still lacking.

CAR-T cell have garnered many publications and attention in the media and Yasuko Erickson, MD, chief medical officer from Mississippi Valley Regional Blood Center, (filling in for Laurie Sutor, MD, vice president of medical and technical services at Carter BloodCare), presented an informative review on immunotherapy of cancer generally and CAR-T practices specifically. The graphical representations of how these antigen-infused T-cells bind to tumor cells were helpful in displaying the concepts and innovations in CAR-T therapy, such as using antigen receptor CTLA-4 which creates more of a "zipper" effect when binding to tumor cells; or doubling/tripling antigen receptors for CD28, CD27 and CD3 to help cause cell death in the tumor without killing normal cells, or the T-cells themselves. Attendees agreed, including Dr. Andrews, that CAR-T is likely to become a standard of care for pediatric oncology patients who are too sick for other, more established, treatments.

Ralph Vassallo, MD, chief medical and scientific officer for Blood Systems, Inc., reviewed data on hypertension and heart rate with their relation to blood donation. Data showed that first-time donors experienced significant drops in blood pressure after donating. But Dr. Vassallo cautioned that the spike one sees at the onset of the data might be from a "white coat" effect and shouldn't be turned into a marketing slogan of "donating blood helps lower your blood pressure."

Marc Germain, PhD, vice president of medical affairs at Héma-Québec, presented a retrospective cohort study on regular female blood donors of childbearing age and the effects on fetal outcomes. Specifically, the investigators looked at preterm birth rate, birth weight, intrauterine growth retardation, and rate of fetal death for babies entered into the national birth registry database cross-referenced with information on their mothers', aged 18 to 45, blood donation frequency. There was no increased risk of



low birth-weight nor preterm delivery of babies associated with donation, no association of hemoglobin deferrals with adverse outcomes. The study will be published soon in *Transfusion*, he noted.

Richard Gammon, MD, medical director of OneBlood, spoke next on the emergency approval for Jehovah's Witnesses (JW) for use of hemoglobin substitutes. He discussed the long history of bloodless medicine programs in Florida—dating back at least 15 years in at least one hospital and their informed consent policy for JW patients, and how different hospital electronic medical records (EMR) systems have a number of alert options to ensure JW patients do not receive blood or blood products without their expressed consent.

#### <u>ABC SUMMER MEETING</u> (continued from page 3)

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Jed Gorlin, MD, vice president of medical and quality affairs for Innovative Blood Resources, followed Dr. Gammon's presentation with his own on JW bloodless transfusion options. JW patients have helped blood community professionals and hospitals reconsider their viewpoints on blood use, contributing to more conservative use of blood. Dr. Gorlin cautioned that not all JW are alike. Most will not accept red blood cell transfusions, but many will accept derivatives and alternatives. A detailed informed consent sheet can reduce obstacles to providing care for these patients. Dr. Gorlin also advised attendee of the value of preenrolling their center or hospital in the investigational new drug (IND) studies with SANGUINATE, a hemoglobin substitute, ahead of need. He also suggested the hemoglobin alternative Hemopure as an option for some patients refusing transfusion, though neither alternative have proven to have efficacy yet.

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A lively morbidity and mortality workshop featured such cases as a "shocking" severe vasovagal reaction from William Crews, MD, medical director of laboratory services at Carter BloodCare; and Kip Kuttner, DO, medical director from Miller-Keystone Blood Center, presented a case in which a baby received an intrauterine transfusion and subsequently experienced severe anemia two months after birth.

Dr. Katz discussed the blood industry's hot topic of Zika, and informed member centers that the FDA has opened a public docket on the deferral of men who have sex with other men (MSM) policy, with the FDA requesting evidence for alternatives to time-based deferrals. He also requested suggestions for topics for future webinars and meeting presentations.

> Day two opened with a chant from a traditional Hawaiian chanter about working together as a team to move forward.

The Hawaii Department of Health's Chief of Disease Outbreak Control Sarah Park did an overview of the Hawaiian dengue outbreak from earlier this year and talked about how the island had responded more reactively than proactively. "We never considered about dengue for blood transfusions," said Dr. Park. "In the thick of things we weren't thinking about that." She said one valuable lesson was that her department has learned a lot about how to share information with

the Blood Bank of Hawaii going forward, of particular importance in light of the risk from Zika virus.

"Zika in Blood Centers" was addressed by Dr. Germain, Dr. Katz, and Susan Rossmann, MD, PhD, chief medical officer at Gulf Coast Regional Blood Center (GCRBC).

Dr. Germain and Dr. Rossmann gave talks similar to those at the AABB Zika symposium in June, which was covered in <u>Newsletter #21</u>. Dr. Rossmann updated the audience that there have now been 15 active travel-related Zika cases in Miami-Dade County. GCRBC has been using the Roche Cobas 6800/8800 for Investigational New Drug Zika testing and out of 35,500 specimens, no positives have been found.

Dr. Katz complimented OneBlood leadership in Florida for having a solid Zika plan in place and implementing Zika testing so quickly after the first vector-borne Zika case was found in Miami-Dade County. He discussed blood community issues with parts of the FDA guidance and response to local transmission in Fla., as well as the efforts of the blood community to engage the agency in adjustments.

John Armitage, MD, president and CEO of the Oklahoma Blood Institute, presented "Patient Centric Trans





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#### <u>ABC SUMMER MEETING</u> (continued from page 4)

Fusion," discussing a perceived need to change the messaging presented to donors, medical personnel, and recipients about the hazards of transfusion and include awareness of the "quality of life" advantages that might accrue in some populations with more liberal transfusion. "We need to promote this miracle drug, not raise fears of risk of transfusion-transmitted diseases like HIV," he said. He also discussed the idea of individualized transfusion care, e.g., giving a cancer patient a transfusion before a major holiday, to enhance their quality of life proactively and not waiting for symptomatic anemia to supervene.

For several years, and especially after the hemoglobin cutoff limit for men was raised to 13.0 g/dL earlier this year, iron stores and iron replacement have been on everyone's mind. Drs. Gorlin and Gammon both addressed the issue of hemoglobin and iron stores for frequent female donors and discussed how iron supplements can be used to replenish iron stores. Dr. Gammon described an AABB committee meeting on these issues and is looking at providing educational material for donors on iron replacement.

The second half of the day centered on succession planning, both for member centers' executive teams as well as donor recruitment. An outside consultant on human capitol issues, Mike Zwell, discussed the benefits, challenges, and key elements in developing an effective executive team succession plan. He discussed how to overcome employee anxiety, how to develop an encouraging workplace culture with self-transforming minds. A panel of Mr. Zwell; Jacquelyn Fredrick, CEO and president of BloodCenter of Wisconsin; Vanessa Merina, communications director at Stanford Blood Center; and David Wellis, PhD, CEO of San Diego Blood Bank, discussed the tools and elements that encompass an effective succession plan along with their own personal experiences with such programs.

Ms. Merina then went into her presentation on attracting the millennial and post-millennial donors with effective and creative marketing plans. She highlighted the wildly successful Blood Bank of Hawaii campaign called Save Lives, Free Rides, with Uber. She noted convenience is key, competitive spirit, connectivity, and making blood donations feel "cool" in recruiting and engaging potential young donors.



A Night in Paradise. With a breathtaking ride winding around the Oahu coastline, the Blood Bank of Hawaii hosted a perfectly picturesque networking event and cultural experience with a traditional Hawaiian luau. Members traveled back in time as we drove past Diamond Head, along dramatic cliffs and coastlines to Oahu's underdeveloped south shore area. Guests were greeted with

traditional leis of nut and sea shells while learning traditional hula dance moves. A buffet feast of tra-

ditional Hawaiian food, like kalua pork and poi was also provided along with libations. Members laughed and huddled through wind and sheets of rain to watch the traditional Polynesian dances and history lesson on the different cultures that traveled and settled in Hawaii. The finale included an impressive fire dancing display not long after sunset.



ABC would like to thank all of the speakers, attendees, and sponsors who made the Summer Meeting in Hawaii a success. A special thank you to Blood Bank of Hawaii for planning many of the events and for contributing illuminating and heartfelt touches, like traditional Hawaiian sayings every morning. ABC members can find presentations from the Summer Meeting on the <u>ABC Member Site</u>. If you attended the meeting, don't forget to fill out your evaluations via the ABC Meeting App! Contact <u>Leslie Maundy</u> with any questions regarding the app. •



#### 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.

#### Links For Life Golf Tournament Success

It would be hard to imagine a more picturesque and relaxing kickoff to the 2016 ABC Summer Meeting than the one 24 golfers experienced on Monday, August 1, at the Kaneohe Klipper Golf Course. With the deep turquoise blue water rippling to one side and lush mountains peering over the golfers on the other, the golfers' support for the Foundation for America's Blood Centers (FABC) Links for Life Golf Tournament was a wild success.



Once clearing security, golfers signed in and received their golf

gift bags with the option of signing up through a contribution to the FABC for "longest drive" and "closest to the pin" contests, three mulligans, and a guessing game if they were going to lose a ball to the ocean. Next, golfers enjoyed a lunch where they were welcomed by FABC Board Chair Pascal George, then presented the rules of the game by the official ABC golf guru, Kevin Belanger, CEO of Shepeard Community Blood Center. After a traditional Hawaiian dessert of Guava Chiffon Cake, the first team of six was ready to tee off, despite a morning of torrential rain at the course which closed the front nine holes for most of the morning, the clouds parted and the sun appeared shortly after the first team's tee-time.



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After the completion of the 12<sup>th</sup> hole, golfers drove their carts up a hill and were greeted by a breathtaking ocean view as they teed off for Hole 13. As teams wrapped up their games, they headed back to the course restaurant for some after golf refreshments while they waited for the remaining teams to finish. Once everyone completed their game, and turned in their score-cards, golfers loaded their clubs onto the shuttle to go back to the ABC Meeting hotel for a reception and award ceremony.

Golfers and other meeting attendees were greeted by ABC CEO Christine Zambricki, DNAP, CRNA, FAAN, who thanked the golfers, as well as the meeting and golf sponsors, for their attendance and support. Mr. George and Jodi Zand, ABC manager of fundraising and events, joined Dr. Zambricki on stage to present gifts to the winning team—Tom DeLacy and Bennett Theriot of Roche, and Rob Van Tuyle of Blood Systems with a score of 64. The longest drive winner was Ruth Sylvester, ABC director of regulatory services, and the Closest to the Pin winner was FABC Board Member Greg Ballish. Kevin Belanger won the drawing of all the golfers who guessed correctly if they would hit their ball in the ocean (he didn't!). After the awards, guests enjoyed a lovely evening in the outside courtyard.



Special "thank you" to all the sponsors and ABC members who participated in the golf tournament and supported FABC. Also thank you to ABC staff who volunteered to make the event a success, particularly our former U.S. military members Ms. Sylvester and Toni Mattoch, ABC director of quality services, not only for their service to our country, but for their assistance in facilitating a group of civilians onto a military base.

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#### INSIDE ABC (CONTINUED FROM PAGE 6)

The funds raised from the FABC golf tournament will continue to support educational initiatives of ABC such as the America's Blood Centers Professional Institute (API). Please stay tuned for future FABC events!

#### ABC Members Meeting at the 2016 Summer Meeting

On Day three of the 2016 ABC Summer Meeting, the ABC Members Meeting met to discuss a number of important internal affairs, including the absorption of ADRP, an audit that ABC passed with absolutely no issues, the year-to-date financials of the association, and a vote was held on emeritus membership for four members. There was also a CEO report from ABC CEO Christine Zambricki, DNAP, CRNA, FAAN, which highlighted ABC's advocacy work, the datawarehouse project, and a status of the independent RAND study focusing on the sustainability of the nation's blood supply system. Dr. Zambricki also updated the members on the Missing Type Campaign, which turned into a lively roundtable discussion on what blood centers have happening in their area: iHeartRadio, Morgan Stanley, Hard Rock Café in Times Square, were just a few of the more recognizable business names given to the crowd.

Sameer Ughade, ABC's new director of information technology (IT) and business intelligence (BI), then spoke with an update on his IT & BI strategy and goals. He highlighted a roadmap to streamline technology and get the datawarehouse project, which has had a long history of starts and stops, up and running within a feasible timeline. He also touched on his plan for member centers' onboarding and keeping ABC's technology solutions simplified, enhanced and integrated.

stayed tuned for the MCN coming out soon!

starts and stops, up and running wrunn a reasible timenne. He also touched on his plan for member centers' onboarding and keeping ABC's technology solutions simplified, enhanced and integrated. Rachelle Fondaw, ABC director of education and grants, reported on the ABC Professional Institute strategy. On the eve of the Introduction to the Blood Banking Industry course release, through the ABC Professional Institute (API), Ms. Fondaw went over her vision for launching the pilot API programs and curriculums. She explained the processes and gave a quick glimpse into the learning portal. She expressed hope the members would complete the eLearning survey as well as participate in the pilot program. Please

The ABC Foundation President Pascal George gave a positive foundation report and noted that the industry continues to change and "change is unstoppable, and we will be ready for that." Along with change, Mr. George is looking to change FABC by adding at least two more high-level representatives on the FABC board by next fiscal year's end, March 31, 2017. As a good foundation president does, he made sure to call on the members to reach into their pockets to help fund more great meetings and workshops. "For fundraising to work, we must have both the moral support of the members and also the financial support of the members and sponsors, and of course we're always looking for feedback," he said.

The day wrapped up with a unanimous vote tallied in favor of the four emeritus members—Nora Hirschler, MD, Gary Levy, MD, Joe Yelo, and Margaret Wallace to be a part of ABC.

Special "Thank You" to Gabbie Sylvester for taking photos (many of which are used in this newsletter) and for volunteering to work at the Summer Meeting.









#### Take Part In The ABC Newsletter Survey

ABC Newsletter needs your help! We are looking for feedback on what you want to see more of, what you want to read less about and how you want your newsletter delivered to you. Please take a few moments to express your deepest desires for this decades-old mainstay of ABC and tell us what sections you find the most helpful, what content you feel may be lacking, and how you would like to see the newsletter delivered to you in the future. The survey is a mere seven questions long and will take you only two minutes to complete. Thank you for assisting us in delivering you the best newsletter possible!



#### **Missing Type Campaign Underway**

You may have noticed the missing letters on the header of the newsletter this week, that is because the <u>Missing Type Campaign</u> kicks off August 15 to 21. America's Blood Centers is encouraging all member blood centers to participate in this global donor-awareness initiative taking place in 21 countries by:

- Asking organizations, sports teams, community partners, schools, blood donors, restaurants, local celebrities, media partners, and **your own blood center** to remove the letters "A," "B," and "O" from their websites, logos, signage, and social media posts using **#MissingType**, without explanation on August 15;
- Revealing August 16 why the letters went missing; and
- Continuing to share, like, and retweet posts and images using **#MissingType** through August 21.



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Please keep in mind that no organization or individual is too small. Share with ABC your participating organizations as the campaign creators are tracking results on a master list.

ABC developed a dedicated <u>webpage featuring tools</u> and <u>resources</u> regarding the campaign for your use. This will be your hub for templates and information to assist you with your outreach.

Please contact <u>Mack Benton</u> with questions or comments.  $\blacklozenge$ 



#### **RESEARCH IN BRIEF**

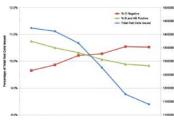
In a small pilot study, untested leukoreduced blood components showed no transmission by transfusion of cytomegalovirus (CMV) to premature infants. For preterm babies with very low birth weights, CMV can pose a significant risk. There is no consensus strategy for preventing transfusion transmission CMV (TTCMV) to these newborns. Various combinations of donor serologic testing, leukoreduction, and their combination, are used. In a prospective observational comparative effectiveness pilot study of 20 prematurely born infants (average gestational period of 28.4 weeks) with low birthweights of an average 1031 grams (2.27 pounds), 40 percent of them received a leukoreduction-only transfusion. Five of those eight infants were transfused with one or more CMV-seropositive blood components. While the authors look at this pilot study as a basis for a larger study before a reliable strategy can be determined, in a commentary, Ronald Strauss, MD, professor emeritus at the University of Iowa in pathology and pediatrics (where leukoreduced components have been used exclusively for this indication for years), considers leukoreduced blood components processed to current standards <u>as optimally reduced and run relatively no risk</u> of TTCMV.

**Citations**: Delaney M., Mayock D., Norby-Slycord C., *et al.* Postnatal cytomegalovirus infection: a pilot comparative effectiveness study of transfusion safety using leukoreduced-only transfusion strategy. *Transfusion*. August 8, 2016. DOI: 10.1111/trf.13605.

Strauss R. Optimal prevention of transfusion-transmitted cytomegalovirus (TTCMV) infection by modern leukocyte reduction alone: CMV sero/antibody-negative donors needed only for leukocyte products. *Transfusion*. August 8, 2016. DOI: 10.1111/trf.13683.

A novel recombinant VIII (rFVIII) molecule has been shown to achieve hemostasis in nearly 94 percent of severe hemophilia patients. An open-label, nonrandomized, multicenter study recruited males with severe hemophilia A, previously treated with FVIII. Of the 175 patients meeting study eligibility criteria, 173 were treated with rVIII-SingleChain, prophylactically (n = 146), or on-demand in the treatment of bleeding episodes (n = 27). Hemostatic efficacy was rated by the investigator as excellent or good in 93.8 percent of the 835 bleeds treated and assessed and in 100 percent of the major surgeries, with a median annual spontaneous bleeding rate of 0.0.

**Citation**: Mahlangu J.,Kuliczkowski K., Abdul Karim F., *et al.* Efficacy and safety of rVIII-SingleChain: results of a phase 1/3 multicenter clinical trial in severe hemophilia A. *Blood*. 2016. DOI: 10.1182/blood-2016-01-687434.



Shows the decline, in blue, of overall red blood cell usage as well as a decrease in B and AB+ blood, green, but an increase, in red, of O - usage.

Blood centers may need to specialize in targeted recruitment strategies to entice red blood cell (RBC) specific donors, including those with O D negative type. While the demand for RBC units has declined overall, one blood profile continues to remain as in demand as ever—O D negative red blood cells. In a study of five American blood centers and records from the Australian Red Cross from 2010 to 2015, while the overall demand of RBC units dropped dramatically, the demand for O negative units significantly increased.

**Citation**: Beckman N., Yazer M., Land K., *et al.* Blood banks meet the paradox of Gabriel's Horn: what are the options to maintain supply as demand decreases? *Transfusion Medicine*. June 2016. DOI: 10.1111/tme.12310.

A study into a secreted protein from dengue virus (DENV)-infected cells showed non-structural protein 1 (NS1) can trigger increased vascular leakage both in human and mouse cells. While most DENV



<u>RESEARCH IN BRIEF</u> (continued from page 9)

infections do not result in acute cases of vascular leakage, severe DENV infections can. NS1-activated receptors on blood mononuclear cells are known to contribute to vascular leakage, but what mechanism triggers these proteins to cause hyperpermeability is unknown. Researchers in this study found that contracting DENV for a second time with a different serotype could lead to an increased risk for severe disease with endothelial permeability and vascular leakage.

**Citation**: Puerta-Guardo H., Glasner D.R., and Harris E. Dengue Virus NS1 Disrupts the Endothelial Glycocalyx, Leading to Hyperpermeability. *PLoS Pathogens*. July 14, 2016. DOI: 10.1371/journal.ppat.1005738. ●

#### **BRIEFLY NOTED**

Just as Jennifer Andrews, MD, clinical assistant professor of pathology and pediatrics at Stanford University, had discussed at the ABC Summer Meeting, pediatric clinical trials are few and far between. A new retrospective analysis of 559 pediatric trials registered in <u>ClinicalTrials.gov</u> from 2008 to 2010 found that nearly half of all these types of trials are discontinued early (19 percent) or never published (30 percent). Industry-funded trials were more than twice as likely to result in nonpublication at 24 and 36 months (odds ratio [OR] 2.21, 95 percent, confidence interval [CI] 1.35–3.64; OR 3.12, 95 percent, CI 1.6–6.08, respectively) and had a longer mean time to publication compared with trials sponsored by academia (33 vs 24 months, P < .001).

**Citation**: Pica N., and Bourgeois F. <u>Discontinuation and Nonpublication of Randomized Clinical Trials Conducted in Children</u>. *Pediatrics*, August 2016.

With the increase worry of contracting Zika, a deluge of Zika products and homeopathic remedies claiming to do everything from cure to prevent Zika have hit the market. Some of the products include mosquito-shield bands, chemical-free bug sprays, and homeopathic remedies including eating dirt and drinking more vitamin C. (Source: <u>Gizmodo</u>, June 23, 2016.)

As reported in <u>Newsletter #16</u>, a California-startup company named Zipline has been delivering blood and medicine via drones in Rwanda. The company now is looking to deliver blood and medical supplies to remote and rural communities in the United States in the same manner. The company's focus is currently on Maryland's Smith Island, Native American reservations in Nevada, and the San Juan islands off Washington state. (Source: <u>Popular Mechanics</u>, August 2, 2016.)

**The National Institutes of Health (NIH) announced a draft policy that could result in acceleration of chimera research.** The agency is calling for public comment to the policy which highlights a case-by-case process to allow research of two kinds: 1) human pluripotent cells being introduced into non-human vertebrate embryos, up through the end of gastrulation stage, with the exception of non-human primates, which would only be considered after the blastocyst stage, or 2) human cells are introduced into post-gastrulation non-human mammals (excluding rodents), where there could be either a substantial contribution or a substantial functional modification to the animal brain by the human cells. The move comes on the heels of a recent update to the guidelines from the International Society for Stem Cell Research, which includes wording on how certain types of chimera research are appropriate. (Source: NIH, August 4, 2016.)



#### INFECTIOUS DISEASE UPDATES



The Florida Department of Health continues to update a map showing the areas with local vector-borne Zika transmission. While Miami-Dade County is the only county listed on the CDC website as having active Zika transmissions, an enormous effort on the Florida Department of Health, County officials and blood centers across the state are ensuring safety to the blood supply and aiding in the containment of the outbreak. OneBlood, LifeSouth Community Blood Centers, SunCoast Blood Bank, and the American Red Cross in Florida continue to test each donors' blood for Zika virus RNA, while County officials have diverted funds into mosquito control methods, such as elimination of

breeding sites and insecticide spraying the area for the pests. (Source: <u>CDC</u>, August 10, 2016.)

**Zika syndrome may cause joint contractures (arthrogryposis) in utero.** In a Brazilian retrospective study of seven children born with arthrogryposis, all of the newborns' brain scans showed characteristics of congenital infection. All the infants had malformations of cortical development, brain calcifications, reduced brain volume, ventriculomegaly, and hypoplasia of the brainstem and cerebellum—many of which are associated with active Zika infections in utero. Authors conclude that the arthrogryposis was likely a result of fixed posture within the womb due to neurological damage to central and peripheral motor neurons that kept the fetuses from moving normally. They suggested two possible mechanisms: viral "tropism of neurones, with involvement of peripheral and central motor neurones, or a relation with vascular disorders."

**Citation**: van der Linden V., Rolim Filho E.L., Gomes Lins O., et al. Congenital Zika syndrome with arthrogryposis: retrospective case series study. *BMJ*. 2016;354:i3899. ●

#### **Registration is Open**

#### ABC Government Affairs Webinar "Advocacy Update"

Join us as ABC CEO Christine Zambricki DNAP, CRNA, FAAN, provides an update of ABC's ongoing advocacy efforts.

#### **Conference Details**

Date: August 15, 2016 Time: 4:00 PM Eastern Time Topic: Advocacy Update

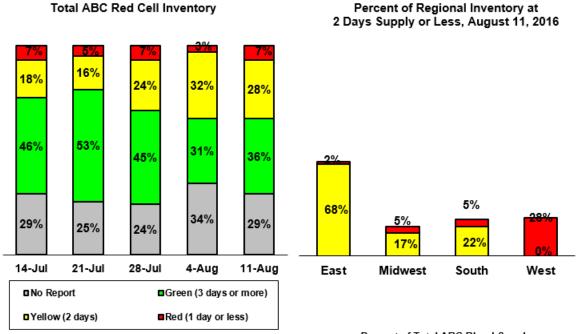
#### Click here to register now

If you have not used Adobe Connect before, please test your computer in advance of these events

You will be prompted to enter the following information: e-mail address, name, company name, title and asked to create a password. After all of the information has been entered, click submit. A confirmation e-mail will be sent to you with login details and an Outlook appointment.

*Note*: Registration will now be required for all ABC webinars. There is **no fee** for members to register. We look forward to your participation. Please contact <u>Mack Benton</u> at with any questions or concerns. Thank you!





STOPLIGHT®: Status of the ABC Blood Supply

Daily updates are available at: www.AmericasBlood.org Percent of Total ABC Blood Supply Contributed by Each Region East: 20%; Midwest: 25%; South: 24%; West: 31%



#### **REGULATORY NEWS**

The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) have issued a joint draft guidance titled, "Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs." Essentially a checklist for IRB written procedures, the guidance includes guidelines for "how the IRB assesses the informed consent process and determines that informed consent is sought and documented in accordance with other applicable regulations." The guidance is directed at IRB administrators, chairpersons and other institutional officials responsible for preparing and maintaining written procedures for the IRB. Public comments can be made until October 3, 2016. (Source: FDA, August 2, 2016.)

The Food and Drug Administration (FDA) issued a final guidance titled, "Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma." The guidance recognizes version 2.0 of the Plasma Protein Therapeutics Association (PPTA) standardized full-length and abbreviated donor history questionnaires and accompanying materials (SPDHQ). The guidance can be implemented immediately. The SPDHQ documents are available on the PPTA website. PPTA's SPDHQ version 2.0 implements changes included in the Final Rule that went into effect on 23 May 2016. While not mandatory to use, FDA indicates that PPTA's SPDHQ documents is one method of determining the suitability of a donor of source plasma consistent with 21 CFR 630.10 and 630.15. The FDA notes, however, that the PPTA SPDHQ documents includes a donor acknowledgement statement which does not meet the requirements of 21 CFR 630.10(g)(2) for donor acknowledgement. Hence, local procedures must be developed to comply with these requirements. For more on this final guidance, click here.

The Food and Drug Administration (FDA) established a public docket for comment on the blood donor deferral recommendations for reducing the risk of human immunodeficiency virus (HIV) transmission. Comments to the document are invited, based on, and with, scientific evidence attached. One possible policy change the FDA listed in their document was to alter the men who have sex with men (MSM) 12-month deferral policy to an individual risk assessment. The agency is accepting comments until November 25, 2016. (Source: FDA, July 26, 2016.) ●



The Centers for Disease Control and Prevention (CDC) awarded more than \$16 million to 40 states and territories-between \$200,000 and \$720,000 each—to help detect and fight microcephaly from Zika virus infections. "These awards are a stopgap diverted from other public health resources until Zika funds are provided by Congress," wrote the CDC in their press statement. They hope to gather real-time data on microcephaly cases and other Zikarelated birth defects as well as provide referrals and resources for at-risk families. Funds were appropriated depending on the risk level per state and are in addition to the \$25 million awarded by the CDC on July 1 for atrisk Zika areas. (Source: CDC, August 2, 2016.)

The secretary of the Health and Human Services, Sylvia Burwell, wrote a letter to Congress stating that the Centers for Disease Control and Prevention (CDC) will have exhausted the \$222 million available for helping the states and territories fight and prevent the spread of Zika. Ms. Burwell also spelled out that the National Institutes of Health (NIH) will also run their vaccine resources dry by the end of August without an additional funding. As reported in previous newsletter editions, Congress was deadlocked after Republicans shot down Obama's \$1.9 billion Zika plan and Democrats refused to sign a bi-partisan Senate bill allowing for \$1.1 billion in funding because of restrictions on funding Planned Parenthood. (Source: Associated Press, August 3, 2016.)



#### PEOPLE



**Bonfils Blood Center CEO Bryan Krueger to step down at end of year.** The announcement comes just after Bonfils and Blood Systems merger was declared. Mr. Krueger joined Bonfils in 2012 as CEO after more than 25 years of leadership experience in healthcare, including within the medical device, pharmaceutical and blood management industries. He declined other positions with Blood Systems after the merger is completed. During his time with Bonfils, the blood center grew its donor base and collections. Mr. Krueger will step down at the end of 2016 following a six-month transition period. He plans on spending more time with his wife of 35 years and family as well as continue his extensive community involvement.

**AABB announced Leah Mendelsohn Stone, JD, as their new director of Public Policy and Advocacy.** Ms. Stone will be designing and implementing the blood agency's advocacy agenda; directing the legislative and public policy initiatives; and advocating on AABB's behalf to Congress and other federal and state government agencies and committees. Prior to joining AABB, Ms. Stone spent a decade in private practice as a health care policy and advocacy attorney and was a research regulations specialist at the Johns Hopkins Bloomberg School of Public Health. (Source: AABB Weekly Report, July 29, 2016.)





Elizabeth Holmes, CEO of notorious lab startup company Theranos, introduced her company's latest product, the miniLab. She largely avoided the controversy surrounding the Edison product, the company's signature test that can supposedly test for blood-borne pathogens with just a few drops of blood. Critics want to analyze the device's capabilities and design, however, the company has remained steadfast in its secrecy. Holmes announced the new product at the American Association for Clinical Chemistry (AACC) Annual Scientific Meeting & Clinical Lab Expo in Philadelphia. The minilab will work in conjunction with the Theranos Virtual Laboratory, a cloud-based laboratory informatics system that will

analyze and report the data performed by each remote miniLab. Centers for Medicare & Medicaid Services (CMS) announced in July that they <u>barred Elizabeth Holmes from operating a medical laboratory for two</u> years. (Source: *Vanity Fair*, <u>Elizabeth Holmes's First Public Presentation of Theranos Data Falls Short</u>, August 1, 2016; <u>Theranos Press Release</u>, August 1, 2016.)

Governor Bruce Rauner of Illinois proclaimed July 2016 as Illinois' Blood Drive Coordinator Month. The governor encouraged all Illinoisans to help coordinate a blood drive in their community as well as asking blood centers and local government entities and people to encourage and praise those coordinating the blood drives. (Source: The Illinois Coalition of Community Blood Centers, July 29, 2016.) ●



#### **Save-the-Date**

ABC Quality Education Webinar "ZIKA and ABC Blood Centers Update" on August 16, 3:00-4:30 p.m. EDT.

To register click here.



MEMBER NEWS

**ABC** Newsletter



The San Diego City Council declared August 2016 as the San Diego Blood Bank (SDBB) month. "We are proud to work with the San Diego City Council to save lives in our community" said David Wellis, PhD, CEO of the San Diego Blood Bank. "We are truly honored to receive this proclamation." The City of San Diego has hosted blood drives with SDBB since 2004, collecting over 250 pints of blood over the years.

**Community Blood Center of the Ozarks hosted its 12th annual Bleed Red Blood Drive.** The drive celebrates the area's love of baseball, especially the Springfield Cardinals, the double A affiliate of the St. Louis Cardinals and blood donors. This year, 995 blood donors took part in the event, establishing a new participation record. For participation in the blood drive, donors received a team logo t-shirt and two general admission tickets to a Cardinals game. The Bleed Red Blood Drive occurs at just the right time of the summer, when blood donations can and often do become



scarce. "Up to 40 percent of our total blood donations come from high school and college students," Pilgrim said. "When school is out, we are challenged to get people to give at sustaining levels. The Bleed Red Blood Drive is a significant tool that helps us with our summer collection efforts."

The Illinois Coalition of Community Blood Centers (ICCBC) held its annual statewide competition honoring blood drive coordinators. The named three awards: "Most Innovative," "Best School Drive," and "Most Dedicated" and based on nominations from blood centers across the state. Most Innovative Blood Drive Coordinator Award goes to Arnie Diedrich of McHenry County who has produced quarterly blood drives for the Knights of Columbus for 13 years. Bill Puhse and Amy Heath, co-sponsors of Granite City High School's Honor Society, are the winners of the Best School Drive Coordinator Award and have organized 26 blood drives since 2009. The Most Dedicated Blood Drive Coordinator will be presented to Father Donald J. Nevins, who has been organizing blood drives for over 16 years at his local parishes. The winners will be presented with their awards during their next blood drives and invited to the Illinois State Capitol when the legislature is in session for a press conference and special reception. The ICCBC is comprised of a number of ABC member centers, including Heartland Blood Center, Mississippi Valley Regional Blood Center, LifeSource—a part of ITxM, and Rock River Valley Blood Center. (Source: ICCBC, July 29, 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 <u>newsletter@americasblood.org</u>. You will be sent a writer's guide that provides information on style conventions, story structure, deadlines, etc.



### COMPANY NEWS

AABB is looking for new committee members. AABB's Professional Engagement Program is looking for up to four members interested in serving on the 2016 to 2017 AABB Nominating Committee. The Nominating Committee members must be willing to attend a face-to-face meeting in the early spring 2017 and take part in two or three phone conferences. If interested or if you want to nominate someone, please do so by September 30, 2016. The Association will also have an additional five openings on their <u>CT Section Coordinating Committee</u> (CTSCC), which spots will open as current members complete their term.





GlaxoSmithKline (GSK) announced a new joint venture with Verily, formerly Google Life Sciences, a division of the semi-secretive GoogleX, to form Galvani Bioelectronics. Verily is known for their bioelectric medicines and devices, e.g., development of a contact lens that monitors glucose sugar levels, and whose leaders have expressed interest in the immunotherapy field. Galvani will be gaining a seven-year investment spread of an estimated \$702 million and be headquartered in the United

Kingdom. (Source: <u>GSK press release</u>, August 1, 2016)

#### **GLOBAL NEWS**



**Sanquin released a new video called "Journey of Blood."** In this 90second video from Sanquin, the sole Netherlands-based blood and transfusion operator, the viewer follows the journey of a donor's blood from time of donation, through testing, and transportation, separation and donation. The video has seen much success over social media channels and the website Mashable and has been viewed over 29,000 times on YouTube. (Source: EBA newsletter, August 1, 2016.)

Genetically modified mosquitoes were let loose in the Cayman Islands two weeks ago in an effort to prevent Zika from spreading on the islands. The operation is being carried out on the Grand Cayman island by MRCU and biotechnology company Oxitec, who manufacturers the mosquitoes. The Oxitec mosquitoes have a self-limiting gene that is passed on to the insect's offspring, so when a male Oxitec engineered mosquitoes mates with a wild Aedes aegypti female mosquito, their off-



spring inherit the self-limiting trait and die before reaching adulthood. Roll-outs for the genetically selflimiting mosquito has been tested before on the East End of Grand Cayman in the past and was recently used in Brazil as well, Oxitec wrote on their site. (Source: <u>Oxitec press release</u>, July 28, 2016.) •

#### 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 <u>newsletter@americasblood.org</u> 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.



#### MEETINGS

#### Sept. 8 FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.

This free, first-come-first serve, public workshop titled the <u>Scientific Evidence in</u> the Development of Human Cells, <u>Tissues</u>, and <u>Cellular and Tissue-Based Products Subject to Premarket Approval</u> 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 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.

#### Sept. 12 - 13 **FDA Public Hearing on HCT/Ps, Bethesda, Md.**

This public hearing was created to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found <u>here</u>.

#### Sept. 13 – 14 ABC IT/Workshop, Minneapolis, Minn.

Experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more, contact the ABC Meetings Department at (202) 654-2901 or e-mail: <u>meetings@americasblood.org</u>.

#### Sept. 21 Red Cell Genotyping 2016: Clinical Steps, Bethesda. Md.

The BloodCenter of Wisconsin (BCW) and the Department of Transfusion Medicine at the National Institutes of Health (NIH) Clinical Center, are co-hosting the 6th Annual Red Cell Genotyping Symposium at Lister Center Auditorium, National Library of Medicine, NIH Building 38A, 8600 Rockville Pike, Bethesda, Md., from 8:25 a.m. to 4:15 p.m. This symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. For information, program fee and advance registration visit BCW's <u>website</u> or contact Phyllis Kirchner <u>phyllis.kirchner@bcw.edu</u>.

#### Oct. 31 – Nov. 1 FDA 510(k) Submissions Workshop, Washington, D.C.

AdvaMed hosts FDA and industry experts to teach the basics of 510(k) submissions. Learn about the FDA's updates to the 510(k) process, considerations for determining a product's regulatory route to market, factors to consider when planning and assembling a 510(k) submission. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register <u>here</u>.

#### Nov. 2 FDA IDE Submissions Workshop, Washington, D.C.

Learn the regulatory and practical guidelines governing when an investigational device exemption is required during this interactive AdvaMed workshop. The workshop will take place at Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register <u>here</u>.

#### **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 Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: <a href="mailto:lmaundy@americasblood.org">lmaundy@americasblood.org</a>.

#### **POSITIONS**

Medical Director (Denver-based). - Blood Systems is one of the nation's oldest and largest comprehensive transfusion medicine organizations. We serve blood centers, hospitals and health systems, offering shared management and support services, quality excellence and effective contracting. Knowledge/Education: MD or DO or equivalent degree required. Licenses/Certifications: Medical license in the state(s) of work within six months required. Transfusion Medicine board certification (or eligibility followed by certification within two years of employment) OR board certification in Hematology required. Board certification in Clinical Pathology, Internal Medicine, or Pediatrics preferred. Experience: Fellowship training or equivalent experience in blood banking/transfusion medicine required. Experience at a blood center and/or hospital transfusion service including provision of education, clinical consultations, and some combination of therapeutic apheresis, cell therapy, laboratory, immunohematology, etc. experience required. Two years of experience in the field of Transfusion medicine preferred. Blood Systems, Inc. is an Equal Opportunity Employer. Apply at: http://www.bloodsystems.org/careers.html/ Req. 16000321. EOE/Minority/Female/Disability/Vets

Technical Director. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a nonprofit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Technical Director. Under the direction of the Administrator and Medical Director, the Technical Director has overall 24-hour responsibility for the Laboratory and all activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Technical Director oversees component production, inventory, product distribution, reference immunohematological testing, and compliance with regulatory and standard-setting agencies. Experience, Education and Licensure: Four-year degree from an accredited college or university in science, medical technology or a related field. Valid current CA license as a Clinical Laboratory Scientist. Experience as a technologist performing high complexity testing in a clinical laboratory and familiarity with standard laboratory methods and techniques. Demonstrated ability to perform standardized routine testing, specialized testing in blood donor processing, and immunohematology is preferred. Must meet the CLIA

defined General supervisor qualifications (42 CFR 493.1461). To Apply: Contact Tom Schallert (<u>TomSchall@aol.com</u>; Northern California Community Blood Bank, 2524 Harrison Avenue, Eureka, CA 95501; (707) 443-8004).

Outside Sales Representative/Event Planner (Amarillo, Texas). This position must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain their support in meeting community needs for volunteer blood donors. Responsibilities will include providing service excellence in organizing and promoting mobile and donor center blood programs and blood donation events; assessing, developing and implementing strategic and tactical plans to achieve blood donor recruitment objectives and goals. They are expected to develop a customer-focused culture that will result in successful community partnerships and blood donor awareness. Job duties include scheduling blood drives in established territory to meet established goals, including major and minor holidays. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Solicit and recruit new groups and organizations for mobile drives within established territory/region. Rebook recurring blood drives for the following year. Develop and maintain collaborative working relationships with key accounts. Give presentations and represent Coffee Memorial Blood Center in order to promote blood collection. Qualifications: Associate's or bachelor's degree preferred, one to three years sales experience, and valid driver's license. Salary: Competitive salary, commission plan, and excellent benefits package. To apply, please visit https://obi.org/careers.

**Director of Accounting/Controller.** We have an opportunity for an experienced Director of Accounting/Controller who would be responsible for the financial operations of Bloodworks including accounts payable, billing, payroll, cash management and external reporting functions. Requirements for this position include: Bachelor's degree in Finance or Accounting; CPA or Master's degree preferred. Five or more years' experience in a Controller or Assistant Controller role. Five or more years supervising and developing staff.



#### POSITIONS (continued from page 17)

Healthcare/not for profit experience preferred. This is a full-time exempt position based at our Central location in Seattle's First Hill Neighborhood. Salary is DOE, DOQ. Application Deadline: Open Until Filled. Interested Applicants should send their application materials to HumanResources@bloodworksnw.org or fax to (866) 286-8495. All correspondence must reference job number 7885. The application can be found at: http://www.bloodworksnw.org/careers/employment.pdf. Bloodworks Northwest is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law. Should you have a disability that requires assistance and /or reasonable accommodation with the job application process, please contact the Human Resources department at HumanResources@bloodworksnw.org, or at (206) 292-6500, or at 921 Terry Avenue, Seattle, WA 98104.

Lab Quality Specialists. Currently, Cleveland Clinic is seeking Lab Quality Specialists for our East, West and South Regions. These positions are responsible for driving operational standardization throughout our laboratories and ensuring daily activities comply with regulatory and accrediting agencies. This will involve the collection and review of quality metrics, the evaluation of compliance gaps, and the continuous implementation of process improvements. Qualifications: Bachelor's degree in Clinical Laboratory Science or a chemical, physical or biological science; Three or more years of experience in quality systems development, implementation and assessment, or in regulatory affairs focused on the manufacturing of biologics or pharmaceuticals; At least three years of experience as a Medical Technologist; A minimum of three years' experience within a blood bank/transfusion service/blood center; and data management experience. To apply, please visit www.ecentralmetrics.com/url/?u=22906184778-215.

Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

Lead Laboratory Technologist – Blood Bank. The Lead Laboratory Technologist performs various duties



that drive the continued success of our Blood Bank and other areas of our lab. From basic to advanced patient and donor testing, to the interpretation and validation of results, your work will determine donor-recipient compatibility as well as solutions for identified irregularities. You'll also be responsible for conducting instrument and equipment qualifications, managing reagent inventory, tracking quality metrics, recommending improvements, and serving as an educational resource for employees, residents and students. Qualifications: Associate's degree in Medical Laboratory Technology or another laboratory science, or a bachelor's degree in Medical Technology or a relevant chemical, physical, biological or clinical laboratory science; two years of blood bank experience; and one year of supervisory or quality assurance experience. To apply, please visit www.ecentralmetrics.com/url/?u=64006184865-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

Supervisor - Blood Bank. Currently, Cleveland Clinic is seeking Blood Bank Supervisors. In this highly visible role, you'll be responsible for supervising blood bank staff at multiple hospitals for our East, West and South Regions. This will involve overseeing the performance of basic and advanced patient and donor tests, helping train new employees, tracking and reporting on quality metrics, and leading performance improvement initiatives. Through these and many other contributions, you'll build on the continued success of our blood banks while moving forward in your career. Qualifications: Bachelor's degree in Medical Technology or a chemical, physical, biological or clinical laboratory science; Three years of blood bank experience; At least one year of management experience; and Working knowledge of Quality System Essentials. To apply, please visit www.ecentralmetrics.com/url/?u=32946184866-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE.