America's Blood Centers®
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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2016 #21 **June 17, 2016**

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Please Note: The *Newsletter* will be getting a new look! Please expect to see some layout and formatting changes coming soon.

AABB Symposium Highlights Numerous Unknowns with Zika

AABB sponsored a symposium for blood industry professionals to discuss the state of the Zika virus outbreak in the U.S., the Food and Drug Administration (FDA) recommendations for blood safety and donor tissues, the public health and blood community responses, and Zika research initiatives, on June 10 in Washington, D.C.

The medical community needs to remain proactive if Zika is going to remain a relatively low threat to the blood supply within the continental U.S., noted Susan Stramer, PhD, vice president of scientific affairs at the American Red Cross. The speakers noted that remaining proactive will be a challenge as there are still so many unknowns in regards to Zika. Having an adaptable plan that balances safety and deferrals during critical summer months, and works in coordination and partnership with public health officials, is key, said Rita Reik, MD, chief medical officer from OneBlood in Orlando, Florida.

"We need a plan," said Dr. Reik. "Otherwise it's like hitting a mosquito with a club rather than a laser beam."

Following an introduction to the virology and clinical complications of Zika by Richard Kaufman, MD, medical director of Brigham and Women's Hospital in Boston, Dr. Stramer reviewed the epidemiological features of the epidemic in the Americas, with an emphasis on implications for transfusion medicine. She noted there have been four alleged transfusion-transmitted infections from three donors in Brazil, none of which produced apparent clinical illness in the recipients.

Marc Germain, MD, PhD, vice president of Medical Affairs at Héma-Québec presented models used by the Canadian blood operators to arrive at a 21-day travel deferral, with a high degree of confidence that would be adequate. In the U.S. the requirement is 28 days. Application of their Monte Carlo modelling technique to U.S.-specific parameters suggested that a similar deferral would result in a risk of one Zika transmission from 66.7 million donations here. He very briefly reviewed modeling suggesting a similarly low risk to the blood supply from sexually transmitted Zika infections.

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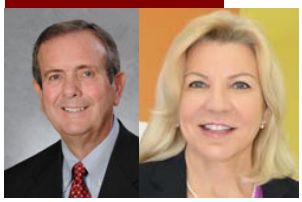
OUR SPACE



OneBlood CEO Don Doddridge
OneBlood CMO Rita Reik, MD

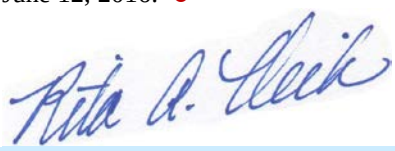
Some Thoughts About Orlando

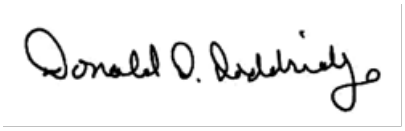
OneBlood in Orlando, ABC members from Florida to Hawaii and from Texas to Alaska extend condolences to all touched by the horror of the attack at Pulse last Sunday. We owe thanks to the blood donors whose willingness to extend their arms before, during, and after these events saved and will continue to support the lives of the victims. These words are a faint reflection of what is in our hearts, but if the survivors and their families and friends can know that it's from our hearts that we speak, that will be enough.

There are uniquely difficult circumstances associated with this attack on a gathering place for our LGBT friends. We are hearing expressions of the irony that allows gay men to become the targets of this horror, and then refuses them the solace of the most powerfully symbolic act of kindness available—giving blood. Members of the LGBT community have expressed a longstanding sense of discrimination against gay men with the historic lifetime deferral of men who have sex with men (MSM). We are said to act without medical and scientific justification. This is not hard to understand. However, that sentiment discounts the incredible precautionism and complexity that characterizes policies around transfusion safety that the American public demands and the Food and Drug Administration requires. Nothing we do can be seen as decreasing transfusion safety. First steps, the permanent deferral is being replaced with a one-year deferral following almost 15 years of our advocacy for change and based on data collected by the blood community. Data from ongoing blood community research initiatives will inform future revisions.

An alternative to deferral based on sexual identity—sensitive tests backed by explicit sexual behavioral screening and shorter deferral times—is proposed in the absence of an experience adequate to assure the FDA the result will be stable or improved transfusion safety. The emerging experience with behavioral screening, as opposed to sexual orientation, comes from environments far different from U.S. donor rooms and may not be generalizable. Short deferrals moving closer to the window periods seen with contemporary tests need validation from the study of large numbers of donors (millions) and are difficult to do. We are responding with limited resources to many issues of donor and recipient safety—donor reactions, donor iron depletion, and mitigating risk from non-infectious transfusion complications that are orders of magnitude more frequent than the current risk from HIV—we need to engage our stakeholders in evaluating novel approaches and to arrive at the most effective ways to select safe donors.

These are difficult issues, and no single answer satisfies us all. At the end of the day, the blood community can only ask for understanding and engagement. Those of you who cannot donate under current regulations will recognize that every qualified donor you find and send to your local blood center provides the same gift of life that saved lives on June 12, 2016.





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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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AABB Symposium Highlights Numerous Unknowns with Zika (continued from page 1)

Jay Epstein, MD, director of the Center for Biologics Evaluation and Research's Office of Blood Research and Review described the agency's final guidance for protecting the blood supply from the virus.

Michelle McClure, PhD, biologist within the FDA's Office of Cellular, Tissue, and Gene Therapies in the Division of Human Tissues, noted the apparent persistence of Zika in many tissues, e.g. semen, compared to blood while discussing FDA's HCT/P guidance. Scott Koepsell, MD, PhD, from the University of Nebraska, suggested that hematopoietic stem cells should be treated like blood and components, using a 28-day deferral in contrast to the six month time-frame required in the guidance. A shortened deferral time-frame would avoid unnecessary restrictions on the use of these often critical cells for often urgent medical indications. Both FDA speakers emphasized these guidance dockets, although issued as final, remain open for comment from affected constituencies as "gaps in knowledge," said Dr. McClure, persist.

Dr. Reik and Danielle Stanek, DVM, program manager with the Florida Department of Health's Division of Disease Control and Health Protection, described their intensely collaborative relationship, dating back several years and established to mitigate dengue and chikungunya risks to blood in Florida and how it has influenced—and benefited—their responses to Zika. ABC President Susan Rossmann, MD, PhD, chief medical officer at Gulf Coast Regional Blood Center in Texas, described her center's decision to proactively implement investigational new drug (IND) testing for Zika nucleic acid donor testing with the Roche Molecular Systems platform, and their negative results since testing began on May 23. David Gruber, assistant commissioner with the Texas Department of State Health Services, described the capacity of his department to mitigate Zika risk and the critical importance of collaboration with blood centers, recognizing that the importance of a public health-blood community interface had not been an obvious priority before the Zika threat was recognized.

The 14th International Cord Blood Symposium in San Francisco, on June 9 to 11.

By Rebecca Haley, MD, Medical director of cord blood services at Bloodworks Northwest.

A special emphasis in the earlier part of the conference, sponsored by the AABB and the Cord Blood Association, was on public and private cord blood banking issues and interactive sessions. Brian Freed, PhD, DABHI, from Clinimmune Labs, Aurora, Colo., introduced some effects resulting from the expectation of Food and Drug Administration (FDA) licensure of cord blood units and the current status of units collected under Investigational New Drug Applications. The consensus is that the quality and reliability of units has probably gone up with the licensing, but pre-licensure units are continuing to be used and there is no discernible difference in transplant outcomes seen as long as validated, current methods are used for processing and quality release.

Dr. Yong Fan from the FDA described the licensing of cord blood banks from her agency's perspective. She emphasized the cord blood licensure is a hybrid program, not strictly a biological pharmaceutical approval and that the agency would work with applicants to give them guidance with their application. The size of cord blood units being banked and the inventory in storage now is dominated by smaller cord blood units, but the demand is for larger units in the public cord blood inventory.

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INSIDE ABC

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

AABB Advancing Transfusion and Cellular Therapies Worldwide

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American Red Cross

Joint Statement Addressing Outpouring of Support from Blood Donors June, 2016

AABB, America's Blood Centers and the American Red Cross issued the following joint statement regarding the outpouring of support following the tragic shooting in Orlando, Florida:

"As we celebrate World Blood Donor Day on June 14, AABB, America's Blood Centers and the American Red Cross want to express our sincere thanks and appreciation for the generous outpouring of support from blood donors in the wake of the tragedy in Orlando.

Not only in Florida, but across the country, the American public has come out to blood donation sites to provide help for patients in need and stand in solidarity, sometimes in long lines, for those affected by this horrific situation. We want to assure you that all blood needs from this event have been met.

It is important to note that, while we have met the needs of this mass casualty event, every two seconds someone in the U.S. needs a blood transfusion. Volunteer blood donors are needed each and every day to help save lives. This weekend's tragedy illustrates that it's the blood already on the shelves that helps during an emergency – that's why it is so critical that eligible donors give on a regular basis to ensure we have a readily available blood supply.

Contrary to circulating rumors, all U.S. Food and Drug Administration donation eligibility requirements remain in place to give blood. All blood collectors in the U.S. are required to follow the rules and guidance issued by the FDA, including blood donation eligibility.

Blood centers often see blood and platelet donations decline during the summer months. AABB, America's Blood Centers and the American Red Cross encourage eligible individuals to schedule an appointment for the weeks and months ahead – particularly the challenging months of July and August. Visit redcrossblood.org or americasblood.org to make an appointment to donate."

The 14th International Cord Blood Symposium (continued from page 3)

Discussions on the current state of cord blood transplantation included very favorable outcomes of sibling cord blood transplants. The advantage for sibling transplants is in the very low incidence of graft-versus-host disease. Of particular interest was a report on cord blood transplantation in malignancies facilitating better control of minimal residual disease.

Workshop sessions included presentations on characteristics of cord blood units in bank inventories, selection of the appropriate cord blood unit for transplant or expansion, and methods used for potency testing. In the newer area of placental tissue preservation, workshops highlighted the wide number of approaches and different expectations of the various operators in this area.

Dr. Joanne Kurtzberg led the session where presenters discussed regenerative medicine applications, especially trials using cord blood in hypoxic ischemic encephalopathy and cerebral palsy. While promising, the young age and high natural variability in recovery of these conditions make results difficult to evaluate. Potential future uses of mesenchymal cells from birth tissues were presented. Since regenerative medicine indications often use stored autologous cord blood, there was a call for minimum standards for units stored in private cord blood banks.

A section was devoted to cord blood collection, led by obstetrician Joanie Hare, MD. She outlined the debate over late umbilical cord clamping from an obstetrician's point of view, noting she is very careful to give the premature infants the benefit of additional cord blood. After the equilibration of circulation in the full term newborn, there is no evidence that later clamping provides advantages.

The outlook of presenters was that cord blood transplantation is a very good method for patients lacking a related donor, but even more uses are being investigated in the autologous and regenerative medicine areas.

LETTERS TO THE EDITOR

The following emails were sent to ABC's CEO Christine Zambricki this week in response to the Orlando shooting. We would like to thank our international colleagues for their letters of support during this traumatic time.

Safe Blood for Europe

"Please pass my and EBA's condolences to all the colleagues, especially those in Orange county, regarding yesterday's terrorist attack in Orlando. We need to stand together to address all kinds of terrorism and also ensure that we can at our part support the aftercare and provide appropriate blood supply in disaster management." – Kari Aranko, MD, PhD, Executive Director, European Blood Alliance.

"We were deeply shocked and saddened to see the events that occurred today in Orlando. The Secretariat's thoughts are with you and all our American colleagues at this difficult time. Please let us know if the ABO community can provide support in any way." – Sally, Sandra, Alexis and Tracey, on behalf of the Alliance of Blood Operators Secretariat.

RESEARCH IN BRIEF

Irish study confirms high frequency of iron depletion in platelet donors. Frequent male platelet donors have lower iron stores than male first time blood donors (9 percent vs. 3 percent at a ferritin level of <20µg/L), according to a study from the Irish Blood Transfusion Service. The authors speculated that the findings resulted from the non-trivial RBC loss associated with plateletpheresis as well as the high frequency with which these donors can donate.

This data is consistent with those presented for ABC at a Blood Products Advisory Committee in 2011, during discussions of changing the male hemoglobin thresholds, as has been finalized in the recently implemented donor final rule. A 4 percent hemoglobin deferral rate for male whole blood donors was forecast compared to a 6 percent male plateletpheresis rate. Speculation then was that platelet donors are recruited from successful whole blood donors who are already documented to be acceptable donors with negative test results. These donors would have decreased iron stores from their whole blood activity, and would likely have relatively high platelet counts as a direct result of their iron depletion from baseline and continued RBC loss during apheresis. ABC CMO, Dr. Louis Katz asks if the impact of iron replacement on such donors' ability to provide double and triple collections needs to be considered as these programs proliferate.

Citations: Duggan F., O'Sullivan K., Power J.P., *et al*. Serum ferritin in plateletpheresis and whole blood donors. *Transfusion and Apheresis Science*. 2016. Accepted manuscript. DOI: dx.doi.org/10.1016/j.transci.2016.06.004.

The Food and Drug Administration (FDA) estimates the increase in transfusion transmission of HIV with ineffective individual donor risk assessment in worst-case modeling exercise. Using conservative assumptions about the effect of replacing time-based deferral for various HIV risk behaviors, FDA investigators estimated that an additional 39 (95 percent confidence interval, 35-43) HIV infected units would escape detection during the NAT-negative window period, and potentially expose an additional 68 recipients (95 percent CI, 61-75).

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RESEARCH IN BRIEF (continued from page 6)

The authors of the study, published in May, concluded "(D)espite some inherent uncertainty, the worst-case scenario of completely ineffective individual risk assessment, absence of donor self-selection and increased reliance on NAT for blood screening is estimated to be associated with an approximately four-fold increase in the risk of HIV exposure through transfusion in the U.S."

However, some have already identified potential limitations in the study's design. "This worst-case scenario model of an 'ineffective' behavioral deferral may end up aligning with previous modelling efforts, which were overly pessimistic about the consequence of changing the indefinite deferral of MSM to a time-based deferral. The recent publication by Dr. Marc Germain in *Transfusion* has shown several different models over-estimated the rates of HIV that would be found in donors following the change to a time-based MSM deferral in Australia, Canada, and the United Kingdom. No one would advocate for a 'completely ineffective' individual risk assessment behavioral deferral. I think this article begs the question, how do we assess appropriate individual risk assessment approaches rather than ineffective ones?" asked Brian Custer, PhD, MPH, Associate Director at Blood Systems Research Institute in San Francisco.

Citation: Yan H., Anderson S.A., Forshee R., *et al*. Modeling complete removal of risk assessment questions in the USA predicts the risk of HIV exposure in blood recipients could increase despite the use of nucleic acid testing. *Vox Sanguinis*. May 2016. DOI: 10.1111/vox.12375.

BRIEFLY NOTED

The drug Inotuzumab ozogamicin (CMC-544), is associated with complete cancer remission rate for 80 percent of participants with acute lymphoblastic leukemia (ALL). In a randomized phase III study of 326 adult patients, 109 with relapse after standard therapies, were randomized and 218 included in the intention to treat analysis of complete remission. Standard therapies for adults with newly diagnosed B-cell ALL resulted in complete remission rates of 60 to 90 percent; however, many of them relapse and only about 30 to 50 percent will achieve long-term, disease-free survival lasting more than three years. This study reports complete remission rates of nearly 81 percent and a median 4.6 month remission period, versus 1.8 months with standard therapies, and a median 7.7 month median overall survival, versus 6.7 months.

Citation: Hagop M., Kantarjian H., DeAngelo D., et al. Inotuzumab Ozogamicin versus Standard Therapy for Acute Lymphoblastic Leukemia. *New England Journal of Medicine.* June 12, 2016. DOI: 10.1056/NEJMoa1509277.

REGULATORY NEWS

The International Council for Commonality in Blood Banking Automation (ICCBBA) announced updates to ISBT 128, the international identification, labeling, and information processing system for products of human origin. Version 6.17.0 of the ISBT 128 Product Description Code Database is now available to licensed facilities. The new database can be downloaded as a Microsoft Access database and all updates are listed on the version control sheet. The **Standard Terminology for Medical Products of Human Origin v6.17 has also been** released**.** It provides definitions to all ISBT 128 terminology and should be used in conjunction with the ISBT 128 Product Description Code Database. (Source: ICCBBA, June 13, 2016.)

(continued on page 8)

REGULATORY NEWS (continued from page 7)

For the third year in a row, the total number of Blood Product Deviation (BPD) reports submitted to the Food and Drug Administration (FDA) has decreased overall and specifically for licensed blood established. The FDA has released the Biological Product and HCT/P Deviation Reports – Annual Summary for Fiscal Year 2015. However, as acknowledged by the FDA, they do not collect denominator data which would enable proper interpretation of the results. As has been the case, Post Donation Information (PDI) dominates the reporting, accounting for 72 percent of the 18,660 BPDs reported by Licensed Blood Establishments and 45,773 reports from all establishments. The remaining distribution of BPD reports remains consistent over time as one would expect given the dominance of PDIs in the reporting. Like blood product reports, deviation reports for 361 Human Cellular, Tissues and Tissue-based Products has declined for the third year in a row. As with blood, it is not possible to accurately interpret the results definitively given the lack of denominator data.

Haemonetics Corporation announced a recall on Leukotrap RC System with RC2D Filter. The leukotraps are causing a higher than expected residual white blood cell count with lot numbers 1656076 (129-62) and 1656083 (129-63), lot 1656084 may also be affected by the issue and is being recalled as well. For more information, visit this FDA recall page.

THE WORD IN WASHINGTON

The National Institutes of Health (NIH) were granted $2 billion in funding when the House of Representatives passed the 2017 Labor, Health and Human Services, Education and Related Agencies Appropriations bill last week. The $2 billion increase in budget (from $30 billion to $32 billion) is the largest increase the NIH has seen since 2003. About $230 million is allocated toward President Obama's Precision Medicine Initiative Cohort Program, which aims to help individualize disease prevention and treatment by mapping people's genomes and taking into account their individual environments and lifestyles, which includes leukemia patients. And another $680 million is designated toward Vice President Biden's cancer moonshot program.

INFECTIOUS DISEASE UPDATES

The Center for Disease Control and Prevention (CDC) released the Zika Draft Interim Response Plan outlining the agency's response plan during the first local-vector borne Zika infections in the continental U.S. The plan details measures the CDC will take during pre-incident local-vector borne infections, during a single incident of suspected or confirmed infection, and during local and widespread multiple infections. Read the full interim plan.

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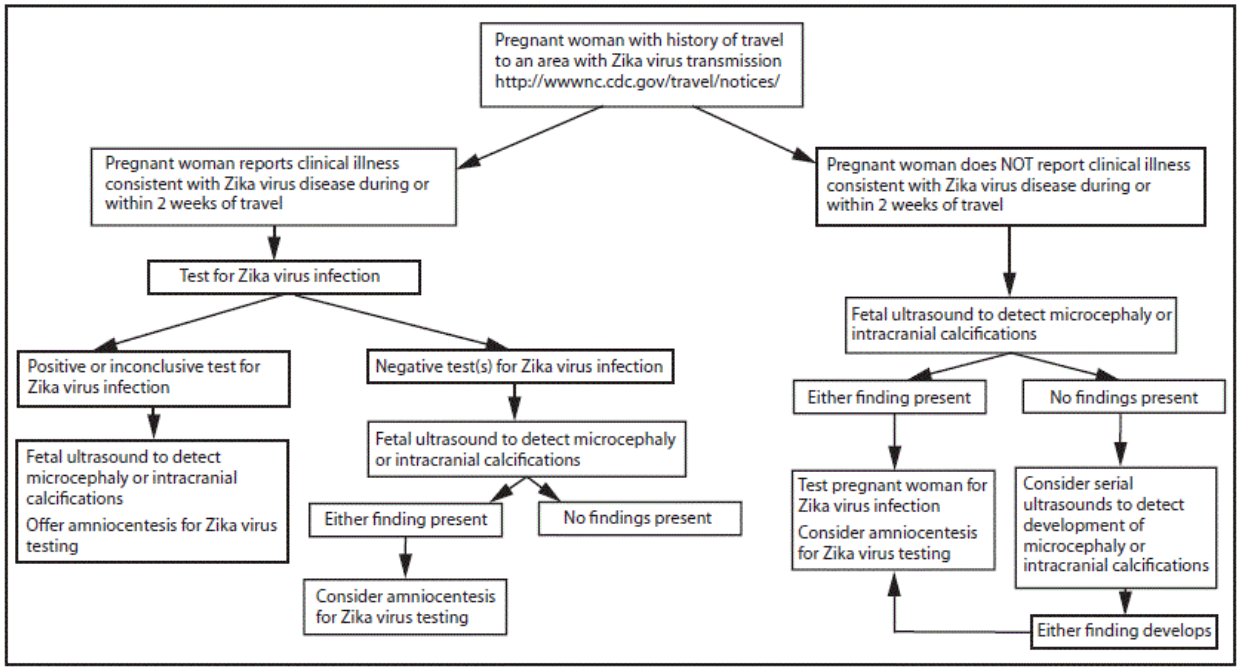
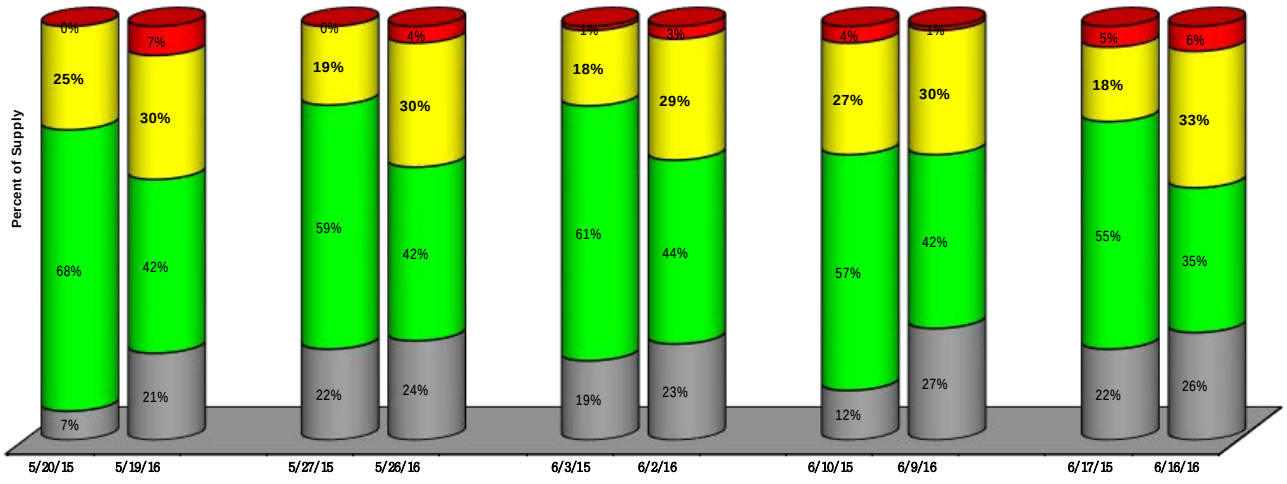
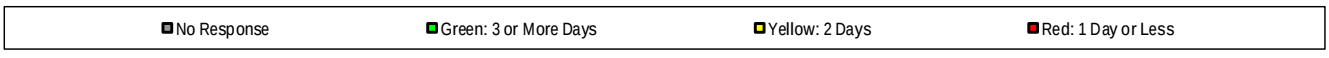
INFECTIOUS DISEASE UPDATES (continued from page 8)



Interim guidelines from the CDC on how to handle pregnant women with a history of travel to an area with Zika.

STOPLIGHT®: Status of the ABC Blood Supply, 2015 vs. 2016





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MEMBER NEWS

The San Diego Blood Bank is revitalizing their newsletter. A quarterly publication, the newsletter will feature blood drives, blood center news, and local events aimed at increasing donor recruitment and awareness for the blood center. Formerly a mailed newsletter, the new publication will be digitally optimized as well as printable.

Lifeblood celebrated its 7th annual Donor Fest by encouraging donors to continue donating blood or platelets throughout the critical summer months. The non-profit blood center set a goal to increase donations during the week of June 6 to 11. During Donor Fest week Lifeblood collected enough blood from local blood donors to help save 2,500 lives. The week ended with a celebration event designed to thank Lifeblood donors on Saturday, June 11 at a local high school.

OneBlood, Inc. has adopted the OrSense hemoglobin measuring system in an effort to make the donor experience more comfortable. The Florida-based blood center is the first in the country to introduce the non-invasive occlusion spectroscopy device that measures hemoglobin and pulse rate without pricking a donor's finger. "Blood donors often cite the finger prick as the most unpleasant part of the blood donation experience," said Don Doddridge, president and CEO for OneBlood. "The new OrSense system makes the finger prick a thing of the past. Click here to view a video about OrSense and how the new technology works.

PEOPLE

Jeffrey Chell, MD, National Marrow Donor Program (NMDP) Executive Director and chief executive officer with Be the Match campaign, has announced his retirement, effective November 2017 after what will be 17 years with the organization. Under Dr. Chell, The Be The Match Registry ® has more than doubled to more than 12 million and the number of transplants facilitated has grown four-fold to over 6,400 annually. During his tenure, the emerging use of umbilical cord blood for transplant has established the NMDP as the global leader in facilitating cord blood transplants. Prior to joining the NMDP, he served as president, Allina Medical Clinics; was a private-practice physician of Internal Medicine in Minneapolis; and before that served in the U.S. Air Force Medical Corps. He is currently the Vice-Chair on the board of directors of the Make-A-Wish Foundation ® of Minnesota, the nation's largest wish-granting organization.

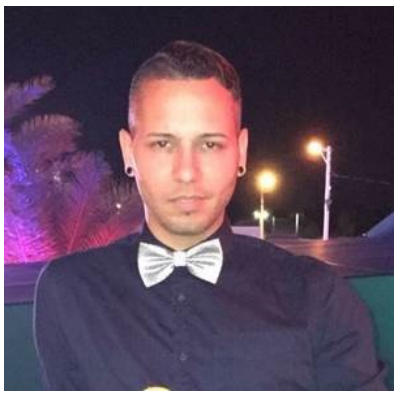
Robert Coutts, Jr. became LifeStream's 10th donor to reach the 100-gallon milestone in lifetime blood donations when he donated platelets on Wednesday, June 8. Sharing in the occasion during a chairside ceremony commemorating the achievement were Mr. Coutts'

(continued on page 11)

PEOPLE (continued from page 10)

mother, Jean; his brother, Steve; his wife, Lynnette; fellow blood donors; LifeStream staff; and representatives of local county, state and federal elected officials. Dr. Rick Axelrod, LifeStream's president, CEO and medical director, noted that Mr. Coutts first donated in 1979 as a tribute to his soon-to-be-born first child and that the theme became one of continuity and dedication. "Once he was told a few years later he had 'baby-friendly' blood and that his donations were safe for use in pediatric cases, his response was, 'How can you say no to that?'" Dr. Axelrod said. For his part, Mr. Coutts told the gathering he felt the ability to give blood is a gift, and that to waste a gift is "simply not right."

In Memoriam



Tragically, one of our own ABC member center employees is one of the victims of the Orlando, Florida, shooting. OneBlood's Rodolfo Ayala-Ayala, who went by Rody, was a highly respected member of the OneBlood family. He was passionate about saving lives and took great pride in the lifesaving work he performed. He began his career with OneBlood in December of 2011 as a Biologics Assistant and assumed the role of Team Lead in 2015. From there, Mr. Ayala-Ayala became the Platelet Supervisor in the Orlando laboratory. "He was a caring, loving individual. He wanted to help everybody as much as possible," said Adam Colon, one of Mr. Ayala-Ayala's coworkers. "We fought through tears and cried while we worked. We used Kleenexes and changed our gloves to do what we had to do. We're still doing it now," said coworker Matt Simons. "He instilled within us everything we ever needed to know to get the job done." While the team is devastated, they are even more motivated to continue to save lives in Mr. Ayala-Ayala's honor.

COMPANY NEWS

The Food and Drug Administration has approved an investigational new drug (IND) for Prolong Pharmaceutical's SANGUINATE, a medication for severely anemic patients who cannot receive red blood cell transfusions. SANGUINATE focuses on *treating the comorbidities of sickle cell disease* and other disorders caused by anemia or hypoxia/ischemia. Clinical research for the phase II trial is now underway testing the reduction or prevention of delayed cerebral ischemia following subarachnoid hemorrhage, the transfer of oxygen to oxygen-deprived cells and tissues. To be considered for the trial, contact Richard Prince, vice president of Prolong.

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 Lisa Spinelli at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

MEETINGS

August 1 - 4 **ABC 54th Summer Meeting and 6th Annual Links for Life Golf Tournament, Honolulu, Hawaii**

Registration has begun for the ABC 54th Summer Meeting in Honolulu, Hawaii, hosted by Blood Bank of Hawaii, to take place August 1 to 4 at the Hilton Waikiki Beach on Kuhio Ave. It will feature the ABC Medical Directors Workshop and the Foundation for America's Blood Centers Links for Life Golf Tournament. Contact Lori Beaston for more information.

Sept. 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.

Sept. 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.

Sept. 13-14. **IT Workshop, America's Blood Centers, Minneapolis, Minn.**

Member center experts in the field will gather in Minneapolis to discuss the implications of corporate mergers as well as cost saving initiatives among many other pressing IT topics at this ABC workshop. To register or learn more about this workshop, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.

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

The FDA and industry experts are coming together 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) submissions. 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 here.

POSITIONS

Director of Marketing. Mississippi Blood Services has been meeting patient needs for high quality blood products in Mississippi for over 36 years. We are currently seeking a strategic leader for the critical departments tasked with ensuring we achieve our donor recruitment team goals, including field recruitment, Telerecruitment and PR/Communications. As an experienced sales leader, you will provide leadership and expertise to the donor recruitment efforts. You'll develop strategies and systems to ensure we meet our established recruitment goals. You will utilize strong analytical and planning skills, helping grow and develop recruitment territories. You'll provide leadership and assistance in helping your team improve communications, and enhance community relationships to encourage donors and donor groups. Additionally: a proven track record in sales leadership, field sales, call center and customer service. A bachelor's degree with an emphasis in business/marketing preferred, with three to five years of related experience with proven success in meeting critical goals. Previous supervisory experience is essential. Strong creative, strategic, analytical and personal sales skills. Ability to visualize opportunities in the short and long term future. Must be committed to working with shared leadership and in cross-functional teams. Ability to successfully manage multiple projects simultaneously. Experience in blood donor recruitment a plus. Apply at https://msblood.applicantpro.com/jobs/.

Laboratory Manager. OneBlood in Tallahassee, FL is looking for a Lab Manager to manage the day-to-day activities in the Compatibility Testing Lab including the testing performed, staff scheduling, training and quality activities. The Lab Manager has the responsibility for performance, interpretation, recording of tests and accurate, timely reporting of results and issuance of blood from the laboratories. Applicants must have a bachelor's degree in medical technology, healthcare, chemistry, biology, biotechnology or related field from an accredited college or university with five or more years' experience in a related field or an equivalent combination of education, certification, training and/or experience. Must have a valid and current Florida Clinical Laboratory Supervisor license in Immunohematology or Blood Banking. SBB certification preferred. To see a complete job description and apply, visit the OneBlood Careers page at www.oneblood.org/careers.

Manager, Donor Services – Mobiles. The Donor Services Manager, Mobiles is fully trained as a Donor Services Technician (Phlebotomist); this includes the collection of whole blood on mobiles, as well as center environments, autologous and therapeutic collections and technologies of automated equipment. Carries out supervisory/managerial responsibilities either directly or indirectly in accordance with the organization's policies and applicable laws. Ability to delegate and ensure accountability of job performance; provides documentation of performance/disciplinary issues as needed and/or positive reinforcement. Ensures training courses are developed and executed in a timely manner. Analyzes departmental measurements/metrics such as deferral rates, QNS rates, split rates, errors, staff turnover, etc. Develops and executes process improvement plans to meet and maintain compliance and quality standards. Implements direct process improvement plans to meet annual collection goals, to enhance quality, to enhance the donor experience and encourages donors to support their community blood program. Oversees mobile collections problem trends and supports corrective actions required to sustain continuous improvement across the organization. Assures effective internal and external communication between all department levels and functions to foster teamwork and enhances operational success. Continually develops, mentors and supports staff to reach their full potential; in achieving independent and efficient work status. Assists in mobile collections as needed. Apply online at www.cbcc.us/careers.

Marketing Manager. Since 1948, BloodSource has proudly served as a leader in our industry. We are a globally-recognized leader in blood transfusion medicine! With Donor Center locations throughout Northern and Central California, more than 2,200 community blood drives every year and a dedicated donor base, we are the source of nearly every unit of blood used by more than 40 hospitals in approximately 25 counties. Our reputation is one of excellence, quality and service. We recognize our most valuable asset – our employee with excellent benefits, competitive salaries and an environment based on respect, collaboration, and teamwork. We are looking for a Marketing Manager to join our leadership team at BloodSource! The Marketing Manager is responsible for overseeing the development of marketing and communication strategies that reflect and support organizational goals to ensure that community blood needs are effectively communicated and operational goals are consistently achieved. This individual will be responsible for developing, executing and measuring the effectiveness of all strategic marketing, public relations and special events to support attainment of BloodSource Collections goals in multi-site locations and our newly forming Pacific Region (Northern California, Sacramento, San Francisco and North-West Nevada). Link to Apply: http://www.bloodsource.org/About-Us/Employment.