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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #8 **February 28, 2020**

INSIDE:

Congressional Members Ask FDA BPAC to Convene Another MSM Meeting to Address 'Discriminatory, Outdated, & Scientifically Obsolete' Deferral Policy

BREAKING NEWS

The FDA has granted South Texas Blood & Tissue Center approval to produce licensed cold-stored platelets making them the first blood center in the U.S. to receive this license. We will cover this story in more detail next week.

Members of the House of Representatives sent a letter this week to the U.S. Food and Drug Administration (FDA) asking the agency to revise the current blood donor deferral policy regarding men who have sex with other men (MSM). The letter from Reps. Chris Pappas (D-N.H.), Mike Quigley (D-Ill.), and Barbara Lee (D-Calif.) was addressed to FDA Commissioner Stephen Hahn, MD and cosigned by 30 members of Congress.

"We should no longer allow outdated, discriminatory bans on blood donation to remain in place that stigmatize members of the LGBTQ community," said Rep. Pappas in a news release, who serves as co-chair of the Congressional Equality Caucus. "The FDA needs to urgently reexamine these guidelines and implement new policies, consistent with modern science and research, that will permit willing and healthy Americans to donate blood, regardless of sexual orientation."

The letter describes the U.S. MSM deferral as "discriminatory," "outdated," and "scientifically obsolete" due to the fact that in their opinion it, "because the one-year deferral period ignores the modem science of HIV-testing technology. HIV testing on blood donated in the U.S. is currently implemented in a variety of ways, including nucleic acid testing. Using this testing method, the presence of the virus can be determined with high precision within 11-12 days after infection. Based on this, we do not believe that a one-year deferral period for MSM makes sense."

It also cites international MSM deferral policy changes in Canada, France, England, Scotland, and Wales as examples of other nations reducing their deferrals from 12 months, the current MSM deferral policy in the U.S., to three or four months, "most of these countries have also announced that this was only temporary as they plan on switching to a risk-based approach rather than a population-based approach when it comes to deferrals for blood donations." Rep. Quigley added "[t]he United States is currently in the midst of a nationwide blood shortage and yet the FDA continues to maintain biased, homophobic regulations that no longer have any basis in scientific

(continued on page 2)

MSM Congressional Letter to FDA (continued from page 1)

reality. The FDA must revise their guidelines to end the outdated practice of discriminating against healthy, willing gay and bisexual men. I will continue this fight until the policy is inclusive and scientifically sound."

The letter requests that the FDA "reconvene" a meeting of the Blood Products Advisory Committee (BPAC) to discuss data from England since they implemented a three month deferral. "The last meeting of the BPAC on blood donation policies regarding MSM was held on March 21, 2019. The BPAC was notably asked to 'comment on what has been learned from implementing other MSM policies internationally.' Unfortunately, at the time of this meeting, the data collected by the British authorities following their policy change had not yet been released and, as such, was not available to BPAC's members for review. No vote on the issue was held at this meeting either. We ask that you reconvene the BPAC so that its member can review the new data available and vote on reducing the current one-year deferral criteria for MSM."

America's Blood Centers (ABC) position remains the same, "[ABC] and its members are committed to maintaining a safe and available blood supply and treating all potential donors with fairness, equality, and respect. To that end, we strongly support ongoing research initiatives designed to determine if donor-screening alternatives based on individual behaviors, not based on sexual or gender identity, will provide equivalent or superior transfusion safety. We encourage the Food and Drug Administration (FDA) to continue its examination of deferral criteria for men who have had sex with men (MSM) to ensure the use of rational, science-based deferral periods that are applied fairly and consistently among blood donors." ABC member blood centers can find updated talking points on MSM on the ABC Member website.

The Congressional letter also makes reference to the revised position statement issued by the American Red Cross (ARC) in November 2019 which indicated support for the FDA revising the U.S. MSM blood donor deferral policy to three months as a " scientifically-based interim step" while "further options are evaluated." This MSM position change for ARC better aligned the organization's MSM position more directly to its humanitarian mission.

(Sources: Congressional News Release, 2/27/20; Congressional Letter, 2/19/20; ABC MSM Talking Points, 11/21/19; ARC Announcement, 11/21/19)

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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OUR SPACE

Ruth Sylvester, MS, MT(ASCP)SBB, Director, Regulatory Services

What Do We Do?

Here we are — facing another threat to the blood supply. The name is different, as is "the feel", but is it really different? So, what do we do? My answer is simple. We put on our disaster hats and respond the way we always do. The blood community has planned, practiced, and responded to a variety of events in the past. Now is no different. Think of this as Hurricane COVID-19. We know its name, but we are unsure of the size it will become or track it will take, but we know the potential of a worst-case scenario.

This hurricane has the potential to impact our operations. The largest potential impact of a pandemic on our industry is to collections. First there is donor fear of getting sick either from the donation itself or exposure to others. As an industry, we must educate our donors now about the need for them today, tomorrow, and during a pandemic. This is especially true for your platelet donors. While red blood cell demand could decrease during a full-blown pandemic as hospital beds are occupied by pandemic patients, chemo patients will still need their platelets. I urge you to begin the discussion with your donors if you have not already. America's Blood Centers and Blood Centers of America, Inc. are working with our colleagues at AABB, the American Red Cross, and the Department of Defense to develop unified messaging to assist blood centers when talking with donors using a consistent voice supported by facts. These communication tools should be available next week. I would also encourage you to proactively connect with your local media and request their assistance in getting the word out. The media has focused on the austere public health measures other countries have taken to contain the virus. Measures such as social distancing and bans on mass gathering can have a chilling effect on blood collections. Not only will they make it harder for a donor to get to a collection point, but operations will need to be modified to comply with public health requirements. It is imperative that member blood centers engage their local public health authorities so that they understand the need for continued donations to ensure an adequate blood supply. Additionally, it is important to begin thinking now about ways to modify your collections to ensure adequate infection control during a pandemic.

Last week, I participated on a U.S. Department of Health and Human Services conference call hosted primarily for hospitals and their suppliers. They too are working their way through their pandemic plans. While there was much discussion of surgical masks and gloves, blood was never mentioned. At some point, you should be discussing the potential for reduced blood supplies with hospitals so that they can be included in their triage considerations. Speaking of suppliers, you should be coordinating with your group purchasing organizations and vendor partners about supply chain. All are working diligently to keep you informed on the status and anticipated impacts of your essential supplies. Lastly, but certainly not least, do not forget your staff and the potential impact of a pandemic on them. How will your operations be impacted by reduced staff either because of illness, exposure, or family care concerns? Your staff are just like the public, they are being barraged by the media with dire predictions. They need information and reassurance of what the current situation is, what your organization's plans are for the future, and that their safety is a top priority. You have heard me say multiple times that it is not the plan but the planning process that is important to successfully respond to a disaster. We have all experienced a variety of disasters over the years including new virus outbreaks. The experience gained through those responses have prepared you to respond once again. Tools are available to help you with the specifics of responding to a pandemic, but the most important part of the plan...is YOU.

Ruth Sylvester, MS, MT(ASCP)SBB
Director of Regulatory Services

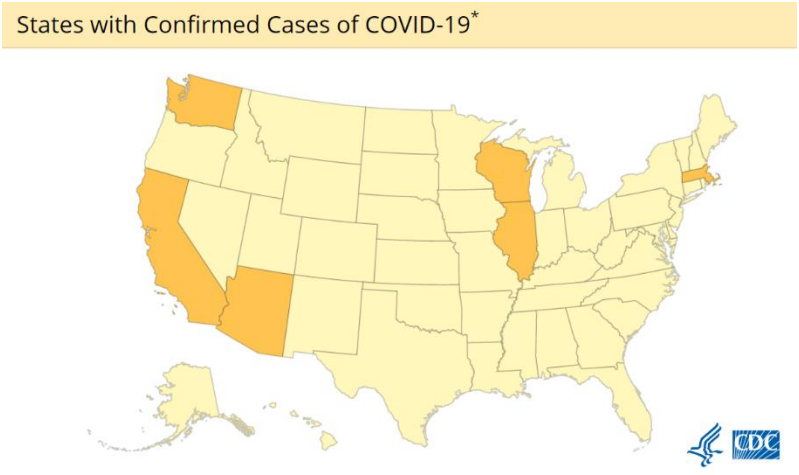
INFECTIOUS DISEASE UPDATES

CORONAVIRUS

The U.S. Food and Drug Administration (FDA) issued a "Supply Chain Update" this week regarding the impact of the COVID-19 outbreak. It references biologics and the U.S. blood supply as the agency states, "FDA is not aware of any cellular or gene therapies that are made in China for the U.S. market. There are no shortages of biologics to report at this time. The potential for transmission of COVID-19 by blood and blood components is unknown at this time; however, respiratory viruses, in general, are not known to be transmitted by blood transfusion. Further, there have been no reported cases of transfusion-transmitted COVID-19. The FDA has made information available to blood establishments and to establishments that manufacture human cells, tissues, or cellular or tissue-based products that may wish to consider additional donor screening measures in response to the COVID-19 outbreak."

This week President Trump announced that he has placed Vice President Pence in charge of leading the nation's response to COVID-19 and the coordination efforts among government agencies. The Vice President emphasized the Administration's top priority is the health and safety of Americans. "I'm bringing together all the members of the [Coronavirus] Task Force that [the President] established: HHS, CDC DHS, the Department of Transportation, and State. This team has been, at your direction, Mr. President, meeting every day since it was established. My role will be to continue to bring that team together; to bring to the President the best options for action; to see to the safety and wellbeing and health of the American people." The CDC announced this week that the number of total confirmed cases is 15 out of 451 tested in the U.S. excluding the cases among persons repatriated to the U.S. The newest case confirmed on February 26th was in California in an individual "who reportedly did not have relevant travel history or exposure to another known patient with COVID-19...It's possible this could be an instance of community spread of COVID-19, which would be the first time this has happened in the United States," according to the FDA.

The AABB Interorganizational Task Force on Domestic Disasters Critical Events Assessment Group (CEAG) met on February 27th. They determined that since there continues to be no evidence that COVID-19 is transmitted through transfusion, with the far greater concern stemming from the potential for a prolonged, and potentially wide-spread impact to collections, the full Task Force did not need to be convened. However, they have asked the CEAG Public Relations Subgroup to develop communications tools such as a statement and talking points that aligns messaging across the blood community. These documents should be ready next week, and America's Blood Centers (ABC) will notify members when these tools are approved and made available for use by CEAG. ABC's February 6th public statement on the coronavirus outbreak remains current and emphasized that the blood donation process is safe and encouraged all donors and sponsors of blood drives to schedule appointments and keep commitments to donate blood. ABC will continue to monitor the outbreak and provide timely updates to member blood centers.



(Sources: FDA Statement, 2/27/20; White House Statement, 2/26/20 CDC Update 2/26/20; ABC Statement 2/6/20)

AMERICA'S BLOOD CENTERS'
58TH ANNUAL MEETING
March 9-11 | Washington, DC

"Join us in Washington, D.C. for the only industry meeting dedicated solely to advocacy as decisionmakers, thought leaders, experts, and industry partners discuss trends and issues that impact community blood centers. Value exists for professionals of all experience levels with the opportunity to let your voice be heard in policy discussions with your peers, regulators, and legislators as we work collaboratively with all stakeholders to develop solutions that advance the industry."

Kate Fry, Chief Executive Officer
America's Blood Centers

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2020 ANNUAL MEETING SCHEDULE

March 9 General Sessions, SMT Forum, Celso Bianco, MD Lectureship

March 10 ABC Members Meeting, Public Awareness Forum, Advocacy Forum, 23rd Annual Awards of Excellence

March 11 Capitol Hill Congressional Visits

Hotel Information
Ritz-Carlton (Pentagon City)
Hotel room rate: $259

For registration information, visit http://bit.ly/abc_am20

For sponsorship opportunities, please contact Mack Benton at mbenton@americasblood.org.

RESEARCH IN BRIEF

The unpredictable nature of demand for red blood cells (RBCs) presents several challenges for managing the collection and supply of RBCs for blood centers and the blood industry. One strategy for predicting usage is time-series methods. These are a "general set of techniques for predicting future values of a series of data that have some relationship to each other, specifically, where [it]can [be] assume[d] that the data values in the near future are related to the value of time points in the recent past." An article recently published in *Transfusion* examined this approach using four different time-series methods to forecast RBC usage between four and 24 weeks. The study used "daily aggregates of RBC units issued from 2005 to 2011 from [NHS Blood and Transplant]" in the United Kingdom. The authors generated "a new set of nonoverlapping weekly data by summing the daily data over seven days" and derived the average amount

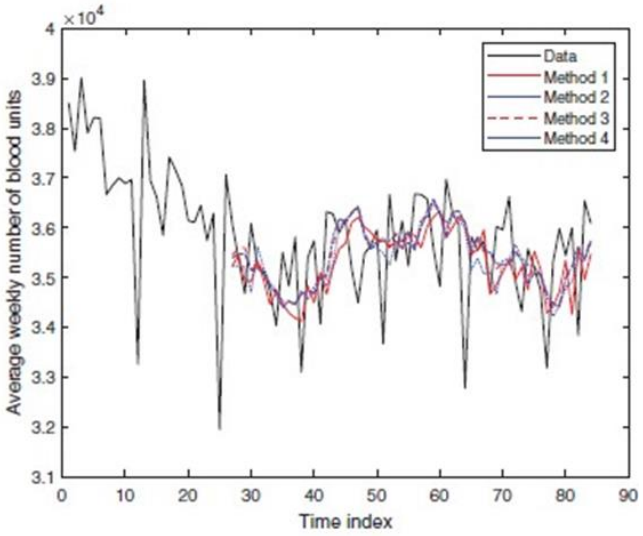

Figure 1: Courtesy of Transfusion

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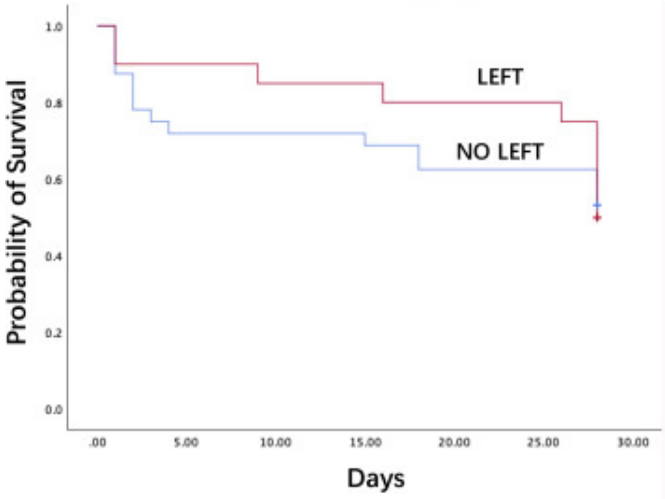
RESEARCH IN BRIEF (continued from page 5)

of blood issued per week over four-week periods. They used four methods for linear prediction of blood demand by computing the coefficients with the minimum mean squared error and weighted least squares error algorithms. They discovered that "the four time-series methods, essentially using different weightings to data points, gave very similar results and predicted mean RBC issued with a standard deviation of the percentage error of 3 percent for four weeks ahead and 4 percent for 24 weeks ahead." (Figure 1) The authors also state that "this was the first published report of predictions of blood demand using time-series data." Based on the results of their assessment, they conclude that the "application of these methods and more reliable forecasts would allow for better matching of the resources needed to collect blood, [and] there could be savings in marginal costs. Indeed, the improved predictions with reduced errors would allow greater efficiency in the recruitment of donors, scheduling of donor collections, manufacturing, and supply of RBCs to match demand."

Citation: Nandi, As. K., Roberts, D.J., Nandi An., K. Prediction paradigm involving time series applied to total blood issues data from England. *Transfusion*. 2020. Doi.10.1111/trf.15705.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

FFP to treat severe TBI? Research published in *World Neurosurgery* examined the efficacy of fresh frozen plasma (FFP) to treat patients that had suffered a severe traumatic brain injury (TBI). Investigators conducted a "prospective single-center, parallel-group, randomized trial" that featured 63 TBI patients admitted to the hospital that had undergone craniotomy evacuation of hematomas between January and November 2018. The low-dose early FFP Transfusion (LEFT) group received treatments of FFP (5mL/kg body weight) "infused (over 20–30 minutes) to patients in the LEFT group upon admission in the operating room. In the No LEFT group, normal saline (5 mL/kg of body weight) was infused (over 20–30 minutes) at the start of surgery." Eleven patients were excluded from the study for multiple reasons including not receiving a FFP transfusion, withdrew consent for follow-up, or incomplete/misclassified data. Twenty of the remaining 52 (38.5 percent) were in the LEFT group, while the other 32 were in the No LEFT group (61.5 percent). The investigators reported that the mortality rate was 48.1 percent, and the most common cause of death was postoperative cerebral hernia. At six months, 10 of 20 patients in the LEFT group (50.0 percent) had died compared with 15 of 32 patients in the saline group (46.9 percent) (relative risk, 1.133; 95 percent CI, 0.370–3.467; P = 1.000)…Among patients with LEFT treatment, 7 of 20 patients (35.0%) developed new delayed traumatic intracranial hematoma (DTICH) after surgery compared with 3 of 32 patients in the No LEFT group (9.4%) (relative risk, 5.205; 95% CI, 1.159–23.384; P = 0.023). Adjustment for baseline covariates, including RBC transfusion and Glasgow Coma Scale score on admission, did not change the study findings. Comparing the LEFT group with the No LEFT group, the adjusted odds ratio of DTICH was 5.493 (95 percent CI, 1.053–28.652; P = 0.043)." Additionally, patients from the LEFT group spent a longer amount of time in the hospital (45.2 ± 39.4 days) versus individuals in the No LEFT group (25.9 ± 23.6 days) and exhibited lower platelet counts the day after surgery (86.2 ± 36.3 × 10^9/L) versus (122.5 ± 40.7 × 10^9/L) (P = 0.008). The authors state that their findings reveal "poor efficacy of early, low-dose FFP



Courtesy of World Neurosurgery

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RESEARCH IN BRIEF (continued from page 6)

therapy in limiting red blood cell transfusion or preventing coagulopathy (i.e., DTICH), a finding that is in agreement with results of several studies using FFP." They conclude that "[i]n our study comparing LEFT with No LEFT treatment for coagulation during surgery, DTICH and prolonged length of antibiotic administration were observed in patients with severe TBI. These findings suggest that a restricted FFP transfusion protocol in the right clinical setting may be more appropriate in patients with severe TBIs".

Citation: Zhang, L.M., Li, R., Sun, W.B., *et al*. Low-dose, early fresh frozen plasma transfusion therapy after severe trauma brain injury: A clinical, prospective, randomized, controlled study. *World Neurosurgery*. December 2019. Doi: 10.1016/j.wneu.2019.09.024.

RECENT REVIEWS

Authors in *Transfusion Medicine Reviews* published a review that summarized the history of coronaviruses, their impact on blood safety, and the potential future implications for COVID-19 regarding blood safety. They also outline the current state of pathogen inactivation as an intervention for coronaviruses in blood products. "After the outbreak of SARS and MERS, a few studies investigated pathogen inactivation/reduction technologies (PRTs) based on in-house or commercial methods with the aim to decrease or completely eradicate the potential risk of transmission of coronaviruses via blood products or blood derivatives… These commercial systems could reduce the activities of SARS and MERS virus in plasma or platelet concentrates to different degrees." The review identifies costs as a prohibitive factor to the implementation of PRT in general and suggests that consideration of PRT " in response to SARS-CoV-2 depends on the severity and prevalence of COVID-19 in different regions and on the actual risk of transfusion transmission of SARS-CoV-2." The authors conclude by enumerating the interventions adopted by blood providers in China to mitigate the risk of the potential for transmission by transfusion as of February 10th. "[G]iven the differences between SARS-CoV, MERS-CoV, and SARS-CoV-2, it is not known if the prior recommendations used for SARS and MERS are sufficient. We are facing many unknowns, and careful monitoring and further studies should continue…Meanwhile, because coronaviruses RNA could be detected in plasma or lymphocytes, staff in blood centers and laboratories should improve biosafety protection during the epidemic. The coming months will provide an enormous amount of new information on SARS-CoV-2 and COVID-19—information which will allow us to make decisions regarding this new virus and public safety."

Citation: L. Chang, Y. Yan, and, L. Wang. Coronavirus Disease 2019: Coronaviruses and Blood Safety. *Transfusion Medicine Reviews.* 2020.

Upcoming ABC Webinars – Don't Miss Out!

- **ABC SMT Journal Club Webinar** – March 30th from 2 – 3 p.m. (EDT) More information coming soon.
- **ABC QA Education Webinar: FDA and the 356h Application Process** – May 19th from 3 – 4:30 p.m. (EDT) More information coming soon.

MEMBER NEWS

Héma-Québec has been ranked the best healthcare employer in Quebec by *Forbes.* "The current effervescent labor market in Quebec means that all employers have to compete in imaginative ways to attract the best talent," said Héma-Québec CEO Nathalie Fagnan in a news release. "Héma-Québec's unique mission, focused on the gift of life, has always contributed to giving our organization a strong identity and has had an attractive effect on job seekers. Our organization has worked hard to distinguish itself as a quality employer. It's always appreciated when recognition comes from the outside and especially from a reference such as *Forbes*." The honor was based on polling of 8,000 full-and part-time workers at Canadian companies that have more than 500 employees. It factored in the likelihood of survey participants to recommend employers to other individuals and considered the evaluations of other employers.

(Source: Héma-Québec News Release, 2/25/20)

OneBlood announced that the young cancer patient with an extremely rare blood type that inspired a global search for blood donors in December 2018 is now in remission. The organization produced a video chronicling Zainab's battle with cancer and the international search for donors. Her blood is very rare due to missing a common antigen, the Indian B. Thanks to the collective efforts of the entire worldwide blood community lead by OneBlood and the American Rare Donor Program, five total compatible donors were found in the U.S., United Kingdom, and Australia. "Zainab's story has brought unprecedented global attention to the need for a diverse blood supply," said OneBlood's Senior Vice President of Corporate Communications and Public Relations Susan Forbes in the news release. "There are many other patients, just like Zainab who have extraordinarily rare blood needs. Finding compatible blood for these patients comes down to genetics. The only way to find specially matched blood for these patients is to increase the diversity of the donor population." More information on Zainab, who recently, turned four years old, and her story is available on OneBlood's website which contains a landing page created specifically for updates on Zainab.

(Source: OneBlood News Release, 2/25/20)

PEOPLE

Gulf Coast Regional Blood Center President and CEO **Brian Gannon, MBA** has been named chair of the AABB Interorganizational Disaster Task Force. He succeeds Dennis Todd. Mr. Gannon has many years of experience as an administrator and executive in the healthcare sector and disaster preparedness operations/planning. He joined Gulf Coast Regional Blood Center in February 2006 after serving as The Blood Center (New Orleans, La.) President and CEO from 1991 to 2006. Also, Leo DeBandi will fill the newly created role of vice chair for the Interorganizational Disaster Task Force. He is the vice president of Production Planning and Logistics Management for the American Red Cross (ARC). He has more than 20 years of experience in securing blood products as a part of disaster response operations and has been participated on the Interorganizational Disaster Task Force since its formation in 2002.

(Source: AABB Announcement, 2/25/20)

COMPANY NEWS

QualTex Laboratories has added automated testing capability via an automated track system in its San Antonio, Texas lab. According to the news release issued this week, the new system is the second to be installed in a QualTex Laboratories testing lab and only the third overall in the U.S. "The track system will help us further improve testing turnaround times, so blood and plasma centers will get their results even faster" said Ward Carter, chief operating officer of QualTex Laboratories. "It also helps us maintain our high standards for testing quality. This is critically important, as we test about 9 million donors annually. "Our laboratory personnel will be doing fewer routine tasks, like loading and unloading centrifuges. Instead, they're going to work on more technical aspects of the preanalytical processes such as customer order exceptions, result release, and analytical review of test results." QualTex Laboratories previously implemented the track system in its Norcross, Ga. facility. This new addition provides the organization with the "largest automated testing setup in the country," states the release.

(Source: QualTex Laboratories News Release, 2/26/20)

BioMarin Pharmaceutical, Inc. recently announced that the U.S. Food and Drug Administration (FDA) has granted priority review status of the biologics license application (BLA) submitted to the agency for its investigational AAV5 gene therapy to treat hemophilia A in adults. The gene therapy named valoctocogene roxaparvovec is the first FDA-approved marketing application for any hemophilia gene therapy treatments in the U.S. according to the news release. "Valoctocogene roxaparvovec has the potential to be the first gene therapy approved in any type of hemophilia and the acceptance of this application and its priority review status marks a significant milestone for gene therapies in general and for the hemophilia community specifically," said Hank Fuchs, MD, president of Global Research and Development at BioMarin Pharmaceutical, Inc. Doris Quon MD, medical director of the Orthopaedic Hemophilia Treatment Center at The Orthopaedic Institute for Children added "[t]he hemophilia community has been waiting for decades for gene therapies. The FDA acceptance of the filing and initiation of review for the first gene therapy for hemophilia A builds on years of scientific achievements in improving the standard of care for people with bleeding disorders." Currently, the gene therapy is in a "phase three interim analysis of study participants treated with investigational product."

(Source: BioMarin Pharmaceutical, Inc. News Release, 2/20/20)

Grifols is expanding its plasma operations to Saudi Arabia thanks to a partnership with the Public Investment Fund of Saudi Arabia according to a recent news release. The partnership will allow Grifols to open plasma collection centers production facilities for plasma therapeutics. "We are very satisfied to form part of the collaboration which will contribute to the development of the Saudi Arabian health system and will allow more people to have access to our treatments," stated Grifols Co-CEO Víctor Grífols Deu in the news release. Grifols will be the supplier of plasma-derived production for Saudi Arabia using its current "supply, manufacturing, and distribution" network while the new facilities are being built.

(Source: Grifols News Release, 2/18/20) ♦

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INSIDE ABC

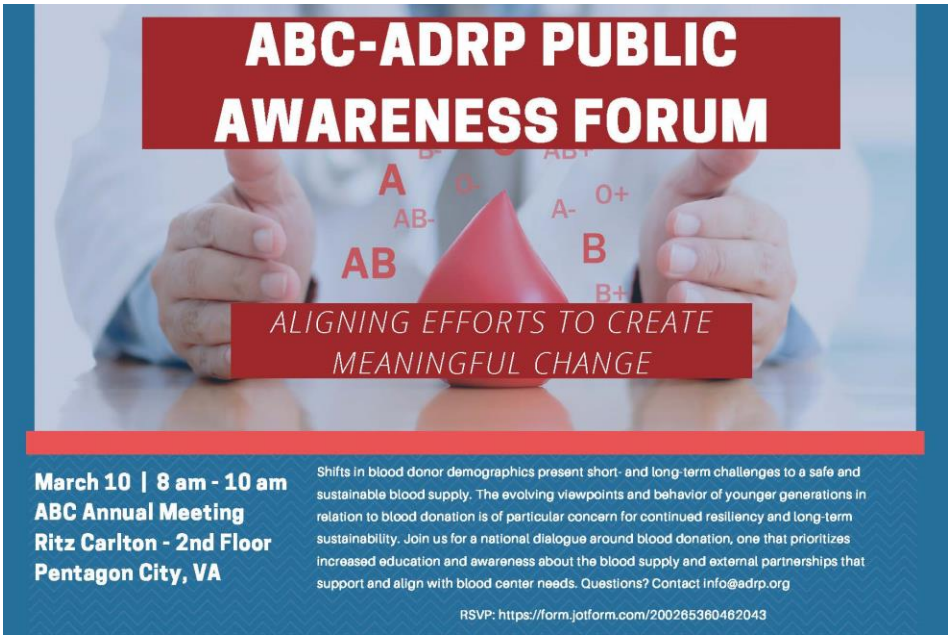
The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

Register for the 2020 ABC Annual Meeting

Registration is open for America's Blood Centers' (ABC) 58th Annual Meeting in Washington, D.C. March 9th – 11th, 2020 at the Ritz-Carlton (Pentagon City). Join us for the premiere blood community meeting that brings blood center, regulatory, legislative, and medical leadership together to focus on key issues which will ultimately impact blood center bottom-lines. From implementation challenges for the new bacterial guidance to the operational complexities entailed in gender identification, the ABC Annual Meeting will provide you with the latest updates on these topics and more, along with the opportunity to help shape the association's advocacy and policy efforts. Additionally, attendees will have the chance to work collaboratively with their peers and ABC leadership in developing solutions that address internal and external needs ranging from health policy to donor motivations. This meeting also includes a day on Capitol Hill to let our voices be heard. Contact Jeanette Brown for available sponsorship opportunities and to see if hotel availability still exists at the group rate. Registrant substitutions are accepted any time at no charge. Registrations cancelled after February 16 will be refunded, less $200. No refunds after March 8. CME and P.A.C.E.® credits will be offered. Schedule at a glance:

- ABC Board Meeting (**open to ABC Members only*) (March 8th)
- General Sessions & SMT Forum & Celso Bianco Lectureship (March 9th)
- ABC Members' Meeting *(*open to ABC Members only*) & Public Awareness Forum & Advocacy Forum (March 10th)
- 23rd Annual *Awards of Excellence* (March 10th)
- Advocacy Day – Capitol Hill Visits (March 11th)

(Source: MCN 19-086, 12/18/19)



CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2020

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** Registration is open.

Mar. 25-26. **IPFA 5th Asia Workshop on Plasma Quality and Supply, Chonburi, Thailand.** More details available here.

April 1. **U.S. Food and Drug Administration (FDA) Public Meeting on FDA's Communications About the Safety of Medical Devices.** Silver Spring, Md. More details available here.

April 2-3. **U.S. Food and Drug Administration (FDA) Blood Products Advisory Committee Meeting.** Silver Spring, Md. More details available here.

April 14-15. **16th Annual FDA and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** More details available here.

April 17-18. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details available here.

April 23-24. **13th Annual FDA/AdvaMed Medical Devices and Diagnostics Statistical Issues Conference, Washington D.C.** More details available here.

May 12-13. **AABB and Mayo Clinic Laboratories Transfuse 2020, Rochester, Minn.** More details available here.

May 13-14. **IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available here.

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details available here.

July 21-23. **2020 ABC Medical Directors Workshop and Summer Summit, Cleveland, Ohio.** More details coming soon.

Sept. 23-25. **4th European Conference on Donor Health and Management.** Hamburg, Germany. More details available here.

Oct. 3-6. **2020 AABB Annual Meeting, Baltimore, Md.** More information available here.

ABC 2020 Meetings & Workshops

Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9th-11th	Washington, D.C.	Ritz-Carlton (Pentagon City)	Registration open!
ADRP 2020 Conference	May 19th-21st	Phoenix, Ariz.	Hyatt Regency	Registration open!
2020 ABC Medical Directors Workshop and Summer Summit	July 21st-23rd	Cleveland, Ohio	Westin Downtown	More details coming soon!

Notes: For the most up-to-date information on all events, members of ABC may check the calendar on ABC's Member Site. Non-members may attend all events; information will be updated on ABC's Public Site.

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, e-mail: newsletter@americasblood.org

POSITIONS

Director of Donor Recruitment. Do you have a passion for community service, leadership and sales? Are you a goal-oriented people person? Arkansas Blood Institute is seeking qualified candidates for Director of Donor Recruitment in the Little Rock area. This is a vital and rewarding position that will play a key role in expanding our footprint and sharing our lifesaving mission in Central Arkansas. Arkansas Blood Institute is part of one of the fastest-growing independent blood centers in the U.S., providing blood to more than 30 hospitals in Arkansas, including four major hospitals in Little Rock. Arkansas is home to 52 state parks set on gorgeous mountains, lakes, streams and forests. Little Rock is beautifully located along the Arkansas River and has more than fifteen miles of scenic riverfront, cultural and historic attractions, entertainment and world-class dining. Qualifications: Three to five years of work experience directly related to blood banking. Associate's degree is required, bachelor's degree preferred. Benefits: Arkansas Blood Institute offers a competitive salary, excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and a relocation package for candidates who do not reside in the Little Rock area. Apply online only at http://arkbi.org/careers/. EEO M/F/D/V/Drug Free Work Environment

Hematologist/Medical Director. OneBlood is expanding its clinical practice offerings in the areas of outpatient transfusion medicine, therapeutic apheresis & phlebotomy, pre-op anemia management, cell therapy, treatment of blood disorders. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking/transfusion medicine, hematology and outpatient clinical services, IRL, therapeutic apheresis, cellular therapy, research, consider joining our medical team as a regional Medical Director. This position includes a highly competitive salary, benefits package, including the option of free medical coverage, retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, etc. The position is based out of the Ft. Lauderdale, Florida area. Qualified candidates should possess: minimum of three years' experience, M.D. or D.O. degree with board certification in Internal Medicine/Hematology and sub-specialty board certification in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Candidates must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. For more detailed information, visit OneBlood's ***Careers*** page at www.oneblood.org. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.

Vice President, Donor Services (RN). Kentucky Blood Center, located in Lexington, Kentucky, seeks a dynamic professional to direct the activities of the Blood Collections departm3ents in accomplishing collection goals. Responsibilities will include the development of strategic plans, budgeting, and oversight of employee training, processes, and procedures in compliance with equipment manufacturer, FDA, AABB and EU guidelines/regulations. The position has oversight of employees at multiple locations throughout Kentucky, in addition to mobile blood drive operation. Qualified applicants must have a minimum of a four-year degree, Registered Nurse (RN), with a minimum of five years management experience. Must be knowledgeable of industry regulations including FDA, AABB, and EU. Must be proficient with MS Office, Outlook and Adobe with the ability to navigate web-based applications and other internal systems. Should possess proven data analysis skills and be highly organized, reliable, and have outstanding interpersonal skills. Strong written and oral communication skills, a do-what-it-takes work ethic, and a team player attitude are required. All resumes must contain a cover letter. To be considered, candidate must reside in or be willing to relocate within 1 hour of the Lexington area. Relocation assistance available. Competitive salary and benefits package. Click here to apply.

Vice President of Technical Operations (Oklahoma City, OK). The Vice President of Technical Operations provides planning, operational management, budgeting and leadership to the Oklahoma Blood Institute. It will oversee and direct the operational and quality systems in the Testing Laboratory, Manufacturing Laboratory, Quality Control Laboratory, Logistic & Distribution, and Client Relations & Contracting departments. He/She will develop and administer capital expense budgets and operating budgets. This position requires a thorough understanding of regulations and laws applying to Oklahoma Blood Institute. Qualifications: Requires a Bachelor of Science degree in Medical Technology, master's degree strongly preferred, minimum of eight years progressive management in a related medical industry. Salary Range: Competitive salary and excellent benefits package including health, dental, vision, life insurance, long term disability, 401(k), paid time off, etc. How to apply: http://obi.org/careers/.

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POSITIONS (continued from page 12)

Assistant Director of Quality Assurance. This position at Shepeard Community Blood Center assists the Director of QA in management and implementation of organizational Quality Plan. Monitors regulatory compliance in all areas of operation and reviews new and revised regulations, standards and other compliance documents. Assists in management of corrective and preventative action, change control, document control, record storage, equipment and validation. Coordinates and facilitates center training and competency programs. Serves as resource for quality and compliance issues for staff. Qualifications: bachelor's in laboratory science or related discipline required; three to five years' experience in blood bank or transfusion service, management experience, working knowledge of PC software using Windows, Microsoft Word, Excel and other software programs as required, familiarity with FDA/AABB Regulations/Standards, OSHA and CLIA requirements; working knowledge of regulations and standards for biologics to include blood and blood products. Working knowledge of donor suitability criteria and infectious disease testing. Must maintain knowledge of and perform according to Standard Operating Procedures (SOPs) and policies. Must maintain knowledge of cGMP, CLIA regulations, applicable OSHA rules, and current industry standards. Licenses/Certifications: MT or MLT with appropriate certification preferred or BS-RN acceptable with appropriate work experience. Please upload cover letter, resume, relevant documentation and complete an application at www.shepeardblood.org.

Director, Regulatory Affairs. America's Blood Centers (ABC), North America's largest network of community-based, independent blood programs, is seeking a Director, Regulatory Affairs. The position will be actively involved and accountable for the development, implementation, execution and advancement of the ABC regulatory agenda before federal agencies and other stakeholders. In addition, the position will assist in the facilitation of member education, evaluation and coalescing of member input in the development of industry positions, data collection from internal and external sources, and primary and secondary research. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on regulatory affairs and public policy issues pertaining to the nation's blood supply. A bachelor's degree is required for the position, which is based in Washington, D.C. This individual should: have a thorough understanding of the federal regulatory processes and landscape, particularly with the FDA; have knowledge of and experience in health policy; blood industry knowledge preferably (but not required); be able to collect, analyze, and synthesize information from varied sources; have strong critical thinking, analytical, and problem-solving skills; be self-motivated and goal oriented; have the ability to multitask and determine priorities; be able to network and collaborate effectively with colleagues and volunteers; have strong communication skills - verbal, written, and presentation; and be able to travel, sometimes at short notice. ABC offers a salary commensurate with experience as well as an excellent benefit package including medical, dental, LTD, and 401k contribution. We are a hybrid virtual office that promotes a flexible work environment. This is a full-time staff position including benefits and a stipend for internet and telephone services. ABC prohibits discrimination and provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws. The full job description is available here. Interested applicants should send a cover letter and resume to careers@americasblood.org.