



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #23

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INSIDE:

CBER Updates 2020 Guidance Agenda.....	2
ABC Submits Recommendations on Maintaining a Robust Blood Supply to HHS....	3
Upcoming ABC Webinars – Don't Miss Out!.....	3
2020 Virtual ABC MD Workshop and Summer Summit Registration Launches.....	4
RESEARCH IN BRIEF	5
Register Today for Session Three of ABC's Ignite Rounds: "Nimble Is the New Normal"	6
MEMBER NEWS.....	7
CALENDAR.....	8
POSITIONS.....	9

Please Note: The ABC Newsletter will not be published on July 3rd. We will resume regular publication on July 10th. Thank you for your continued interest.

FDA Commissioner Is Encouraged By Preliminary Efficacy Data of Convalescent Plasma as a COVID-19 Therapy

This week, U.S. Food and Drug Administration (FDA) Commissioner Stephen Hahn, MD testified in a [hearing](#) on Capitol Hill examining the response of the Administration to the COVID-19 pandemic. He mentioned the [findings](#) of a Mayo Clinic convalescent plasma safety [study](#), covered in [ABC Newsletter Issue #22](#), that determined “investigational COVID-19 convalescent plasma to be safe following transfusion in a diverse group of 20,000 patients.” When asked about the “status of the research into the effectiveness of convalescent plasma to fight COVID-19” by Ranking Member Rep. Greg Walden (R-Ore.), Dr. Hahn testified that “[The FDA] has partnered with the Biomedical Advanced Research and Development Authority, HHS, and Mayo Clinic to develop an expanded access program (EAP). We have safety data from over 20,000 patients that shows [convalescent plasma] is a very safe therapy and our preliminary assessment of the effectiveness of this plasma is quite encouraging. We continue to look at the information. If those data hold, we potentially have another weapon in the armamentarium against COVID-19 pending those final results.”

The commissioner’s optimism echoes the sentiments expressed by Mayo Clinic Principal Investigator of the EAP and lead author of the study Michael Joyner, MD in a news release last week that, “[investigators are] optimistic but must remain objective as we assess increasing amounts of data.” Furthermore, Dr. Hahn explained to congressional members that “This will also allow us to have information that will feed the development of monoclonal antibodies and something else called hyperimmune globulin...It’s a good news story right now, but we have to wait for the final data to come in and we should know very shortly about that. There are also several randomized trials that are looking into this as well that are ongoing across the country.”

The hearing also featured leaders of other U.S. regulatory agencies that continue to play an integral role in the nation’s efforts to combat the disease including the Assistant Secretary for Health at the U.S. Department of Health and Human Services, Admiral Brett Giroir, MD, Centers for Disease Control and Prevention Director, Robert Redfield, MD, and the National Institutes of Health’s (NIH)

(continued on page 2)



FDA Commissioner Discusses CCP at Congressional Hearing (continued from page 1)

National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony Fauci, MD. In prepared remarks submitted to the committee prior to the hearing by NIAID, additional research into the efficacy of convalescent plasma was mentioned. “[National Heart, Lung, and Blood Institute] NHLBI is leveraging the NIH-funded ‘Strategies to Innovate Emergency Care Clinical Trials Network’ (SIREN) to study whether convalescent plasma, or blood plasma from individuals who have recovered from COVID-19, can help reduce the progression of COVID-19 in patients with mild symptoms.”

Dr. Hahn was also asked by Rep. Bob Latta (R-Ohio) if the FDA anticipated issuing additional emergency use authorizations (EUAs) later this year in the form of potential therapies to treat COVID-19. The commissioner indicated in his response that convalescent plasma therapies could potentially be granted an EUA if the research data supports such a decision. “I anticipate that we will receive data regarding several therapies in the future, plasma being one of them....[plasma and other potential therapeutic candidates] are being accelerated through the pipeline right now...[we cannot] prejudge the EUA process because we have to see the data, but I do anticipate that we will be receiving data.”

(Sources: House Energy and Commerce Committee [Hearing](#), 6/23/20; Mayo Clinic News [Release](#), 6/18/20)

CBER Updates 2020 Guidance Agenda

The U.S. Food and Drug Administration’s (FDA) Center for Biologics Evaluation and Research (CBER) has [published](#) an update to its guidance calendar for 2020. This agenda outlines the guidance and draft guidance documents that CBER plans to issue throughout the year. Topics of note that the agency still intends to address include:

- Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry;
- Blood Pressure and Pulse Donor Eligibility Requirements; Draft Guidance for Industry;
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry;
- Collection of Platelets by Automated Methods; Guidance for the Industry; and
- Recommendations for Screening, Testing, and Management of Blood Donors and Blood and
- Blood Components Based on Screening Tests for Syphilis, Guidance for Industry.

The topics listed for Tissue and Advanced Therapies all involved gene therapy and chimeric antigen receptor T cell (CAR-T) therapies. The agency still intends to publish a draft guidance that addresses “Consideration for the Development of [CAR-T] Cell Therapies.”

ABC has been advocating to the FDA on several of these issues and is pleased to see CBER addressing these topics of concern to our membership. A complete listing of the potential guidances is available on the FDA’s [website](#).

(Source: FDA [Announcement](#), 6/24/20) 💧





ABC Submits Recommendations on Maintaining a Robust Blood Supply to HHS

America's Blood Centers (ABC) submitted recommendations regarding the [Request for Information \(RFI\) for Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act \(PAHPAIA\)](#). Section 209 of this legislation states that the Secretary of the U.S. Department of Health and Human Services (HHS) shall submit to Congress a report containing recommendations related to maintaining an adequate national blood supply, specifically:

- challenges associated with the continuous recruitment of blood donors (including those newly eligible to donate);
- ensuring the adequacy of the blood supply in the case of public health emergencies;
- implementation of the transfusion transmission monitoring system; and
- other measures to promote safety and innovation, such as the development, use, or implementation of new technologies, processes, and procedures to improve the safety and reliability of the blood supply.

In [recommendations](#) suggested by ABC, the association highlights the challenges faced by blood centers to recruit and retain donors, especially young and diverse donors, and the amplification of these challenges in wake of the pandemic. ABC notes “[b]lood donation is no longer a part of the public consciousness as it once was and overall, younger generations do not comprehend the scope of the need or their role in ensuring a robust blood supply. Furthermore, diversity is essential in the blood supply, especially for frequently transfused patients that require precisely matched blood components because of rare blood types... National encouragement of blood donation as a necessary prosocial behavior must be advanced with a focus on ethnic diversity and, in particular, the ability to recruit group O Rh negative donors. To be successful, this message cannot only come from blood centers but must include government, the entire healthcare community, and the local communities themselves through civic organizations.”

ABC also discusses lessons learned during this pandemic and identifies areas where federal action is necessary to support a blood supply able to withstand the unknown challenges of disasters including this or another pandemic. It specifically outlines ways the federal government can support the nation's blood supply during a disaster including the need for a national data and monitoring system, disaster planning, the inclusion of blood as an essential supply in the supply chain, the national stockpile, and the need for blood center staff to have access to appropriate personal protective equipment. The recommendations highlight the need for financial stability in order to ensure blood centers can withstand a pandemic and notes regulatory changes to support blood centers moving forward including options for regulatory flexibilities established for use in future disasters.

ABC will continue to work with HHS on the development of the report to Congress including participation on the steering committee and the multiple committees created by HHS to develop this report, which is expected to be sent to Congress later this year. Both ABC and its members previously supported PAHPAIA by signing onto multiple coalition [letters](#) and advocating on Capitol Hill to congressional leadership encouraging the bill's passage.

(Source: ABC Recommendations Regarding PAHPAIA Section 209 [RFI](#), 6/19/20) ♦

Upcoming ABC Webinars – Don't Miss Out!

- **ABC SMT Journal Club Webinar** – August 10th from 2 – 3 p.m. (EDT). Additional details coming soon.
- **ABC QA Education Webinar** – August 18th from 3 – 4:30 p.m. (EDT). Additional details coming soon.



Reimagined Virtual Experiences



Summer Summit

July 14 & 16



Medical Directors Workshop

July 21 & 22

AmericasBlood.org



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2020 Virtual ABC MD Workshop and Summer Summit Registration Launches

[Registration](#) is now open for the 2020 Virtual America's Blood Centers (ABC) [Medical Directors \(MD\) Workshop](#) and [Summer Summit](#). Reimagined as a virtual experience with two separate events taking place over four days total, ABC envisions this format providing flexibility for attendees' schedules without sacrificing the knowledge sharing and benefits of peer to peer discussions that are a hallmark of in-person meetings. The Summer Summit (July 14th and 16th) will convene thought leaders from across the industry to focus on the future of blood centers and the transfusion medicine community. Sessions will feature case studies, engaging discussions, and an update from Peter Marks, MD, PhD, director of the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research.

(continued on page 5)

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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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ABC Summer Summit & MD Workshop Registration Launches (continued from page 4)

The MD Workshop (July 21st-22nd) will provide attendees with an additional two days of timely, content-rich presentations that explore updates on COVID-19 testing, utilization of whole blood in hospitals, blood center experiences in lowering the platelet component dosage, along with interactive case study rounds. CMEs/PACE credits will be offered. ABC invites you to [register](#) to attend both events as we have reduced the registration fees from our traditional “face to face” meetings. A group rate has also been included for the Summer Summit along with a discount if you register for both events. Thank you for your patience throughout this process, and for your continued support of ABC.

(Source: [MCN 20-067](#), 6/24/20)

RESEARCH IN BRIEF

Plasma Exchange Plays a Role Treating Severe COVID-19. In an article published in the *British Journal of Haematology* the authors “[reported] the efficacy of therapeutic plasma exchange (TPE) in three severe COVID-19 patients with acute respiratory distress syndrome.” They describe “[t]hree patients (male, aged 44, 55 and 64)...[who] were receiving TPE.” Each of the patients also “had received various antiviral treatments...However, despite initial antiviral treatment and other therapeutic interventions, all three patients developed respiratory distress with respiratory frequency ≥ 30 /min, pulse oximeter oxygen saturation ≤ 93 percent at rest, or oxygenation index (PaO₂/FiO₂) ≤ 300 mm Hg. The lymphocyte counts of the patients were lower than the normal range in adults. In contrast the levels of C-reactive protein (CRP), neutrophil count, lactate dehydrogenase, and interleukin 6 (IL-6) were significantly higher than the normal reference ranges.” The investigators explain that “TPE was used as an emergency treatment for these three severe COVID-19 patients. TPE was performed with a plasma separator multi-filtration system, and about 3,000 ml of normal fresh-frozen plasma was exchanged for one person. Each patient received one treatment of TPE.” They note that PaO₂/FiO₂ “improved for all three patients within 24 hours after TPE...One day after the treatment, the values of [C-reactive protein] CRP decreased more than >70 percent, and the levels of IL-6 also declined to the normal reference range. After treatment, the values of the neutrophil to lymphocyte ratio (NLR) were significantly decreased. Four or five days after treatment, the patients were all changed from high-flow oxygen to receive low-flow oxygen. After one day with low-flow oxygen, all patients could breathe ambient air without requiring oxygen supplementation. About ten days after TPE, all three patients met the discharge criteria...The lengths of hospital stay were 14, 15, and 22 days, respectively. The time from symptom onset to recovery ranged from 18 to 25 days.” The authors suggest that “the main reason for the severity and continuous progress of COVID-19 might be cytokine storm.” They also note that “[TPE] is effective for cytokine storm and is widely used in the treatment of a variety of severe and critical patients, such as pneumonia and respiratory failure from H1N1 influenza A virus.” The authors conclude that “TPE had an immediate effect on the treatment of the cytokine storm... [and] might be a rescue therapy in severe COVID-19 patients with acute respiratory distress syndrome and cytokine storm.”

Citations: Zhang, L., Zhai, H., Ma, S., *et al.* Efficacy of therapeutic plasma exchange in sever COVID-19 patients. *British Journal of Haematology*. 2020: Doi: [10.1011/bjh.16890](https://doi.org/10.1011/bjh.16890).

Contributed by Richard Gammon, MD, Medical Director at OneBlood 💧

ABC Calendar of Events

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



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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 Today for Session Three of ABC's Ignite Rounds: "Nimble Is the New Normal"

America's Blood Centers (ABC) has opened [registration](#) for the last of its series of three member-only Ignite Rounds. The July 8th Ignite Round will focus on "Increasing Donor Availability." This series of virtual events are designed to be open forum discussions to assist member blood centers through the challenges created by the COVID-19 pandemic with the theme "Nimble Is the New Normal." [Registration](#) is free to ABC member blood centers and its vendor partners. With these sessions occurring ahead of the [Medical Directors \(MD\) Workshop](#) and [Summer Summit](#), ABC intends for the series to be a way to ignite conversation and spark new ideas for operating in the new reality of COVID-19. We envision the conversations and ideas being the catalyst for change, while serving as a primer aimed at helping our member blood centers navigate these challenging times through the development of content and resources that lead to impactful solutions discussed in further detail during the 2020 MD Workshop and Summer Summit.

The "Ignite Rounds" are open to all blood center employees to ensure a cross-functional lens. Please mark your calendars and plan on joining the conversation. Come prepared to think creatively and share ideas that could potentially help your blood center and the industry pivot to not only survive COVID-19 but to thrive in the new reality.

ABC Ignite Rounds: Increasing Donor Availability

July 8, 2020 | 4:00 pm EDT

Registration link available to ABC members in [MCN 20-065](#).

(Source: [MCN 20-065](#), 6/18/20) ♦

BRIEFLY NOTED

The U.S. Department of Health and Human Services (HHS) Tick-borne Disease Working Group [announced](#) that it will host its next meeting online via webcast on July 8th from 9 a.m. to 5:30 p.m. EDT. At this meeting, the committee will discuss "the draft 2020 report to the HHS Secretary and Congress and review and approve graphics and images for the report. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; federal activities related to tick-borne diseases; and gaps in tick-borne disease research." The meeting is open to the public and [registration](#) is open. Additional meeting materials and the agenda are available on the working group's [website](#). Another meeting is scheduled to take place August 14th with additional information to be made available closer to the meeting date.

(Source: *Federal Register* [Announcement](#), 6/9/20)

(continued on page 7)



BRIEFLY NOTED (continued from page 6)

Facebook has updated its blood donation tool with a new scheduling feature. Facebook recently announced the feature to help simplify the process for blood center page followers to schedule an appointment. “We are making it even easier for you to engage and recruit donors by adding a scheduling button to posts,” stated Facebook. “Now you can post to your ‘Page’ to share compelling content and prompt ‘Page’ followers and nearby donors to make an appointment to donate. You will no longer need ‘Page Created Requests’ to reach donors and specify blood types”. Blood centers can now create a ‘Page’ post with a scheduling button, which prompts donors to call or click through to the blood center’s website to schedule an appointment. Facebook continues to send automatic notifications to nearby registered donors to remind them to donate at their local blood centers for those organizations which are using the blood donation tool. These notifications will reach donors on an ongoing basis. Please visit the Facebook help center for more information. Additionally more information on the blood donation tool and training videos are available [here](#).



MEMBER NEWS

A team of researchers at **New York Blood Center** recently published findings from a study examining antibody levels in recovered COVID-19 patients. The results announced in a June 10th [news release](#) and [featured](#) in *TIME* revealed a “wide range of antibody levels” that the researchers believe suggests “varying levels of immunity” to limit potential infections in the future. “There was a very significant group of people who had essentially no neutralizing activity [against the virus],” said Larry Luchsinger, PhD, the lead author of the paper, to *TIME*. “What we found was that surprisingly, across all tests, there was a very wide deviation or range of antibody results that people were experiencing.” New York Blood Center President and CEO Christopher D. Hillyer, MD, added in the news release, “New York Blood Center is proud to leverage our expertise in virology, immunology and test and device development to offer major and rapid contributions to the fight against COVID-19. This research has important implications for public policy as we navigate our way through this pandemic. Restarting the economy based on inaccurate serology testing or poorly understood results could have devastating consequences. There is no room for error.” For the study, researchers examined seven different COVID-19 assays “measuring antibody levels and the performance characteristics of each test to show a wide range of antibody values from convalescent plasma donors. The study also shows that neutralizing antibody levels, which indicate the ability for antibody to prevent infection, strongly correlated with some antibody tests. These data will be helpful to estimate the level of immunity in patients and may be critical for interpreting antibody results as early evidence of vaccine efficacy. Thus, the study may help establish a valuable ‘roadmap’ for clinicians to interpret COVID-19 antibody tests results.”

(Sources: New York Blood Center [News Release](#), 6/10/20; *TIME*, [Antibody tests don't mean a ton right now. But that could change soon](#), 6/16/20)

Mississippi Valley Regional Blood Center announced that it is expanding its partnership with Branch Consulting + Analytics following successful results in increasing its base of platelet donors by 20 percent over a six-month period in 2019. “We could tell pretty quickly that the program was making an impact when we saw the high donor connect and conversion rates for our callers,” said Mississippi Valley Regional Blood Center Donor Recruitment Manager Tara Matheson in a news release. “And about half of all new donors are 49 or younger which is helping us to build our base for the future.” As part of the continued partnership, the blood center will look to increase conversion of mobile drive donors to fixed-site collection facilities. “Getting more of our donors into fixed site donor centers has been a priority during the COVID-19 pandemic,” added Ms. Matheson. “Our mobile blood drive calendar has been decimated with blood drive cancellations, so we have an opportunity to recoup those units by getting donors into our centers.”

(Source: Mississippi Valley Regional Blood Center News Release, 6/22/20)



CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2020

July 8. **U.S. Department of Health and Human Services (HHS) Tick-borne Disease Working Group Meeting (Virtual)**. More details and registration available [here](#).

July 14 & 16. **ABC Summer Summit (Virtual)**. More details coming soon.

July 21-22. **ABC Medical Directors Workshop (Virtual)**. More details and registration available [here](#).

Aug. 14. **HHS Tick-borne Disease Working Group Meeting (Virtual)**. More details and registration available [here](#).

Sept. 9. **10th Annual Symposium Red Cell Genotyping 2020: Visionary Solutions, Bethesda, Md.** More details available [here](#).

Sept. 10. **39th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** More details available [here](#).

Oct. 3-6. **2020 AABB Annual Meeting, Baltimore, Md.** More information available [here](#).

Nov. 22-24. **2020 ADRP Conference, Phoenix, Ariz.** More details available [here](#).

2021

June 25-26. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details available [here](#).

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany.** More details available [here](#).

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 and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. 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.

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

Chief Medical Officer [Associate Professor, Full Professor]. The University of Washington, Department of Laboratory Medicine and Pathology is accepting applications for Chief Medical Officer [Associate Professor, Full Professor]. This position involves overall responsibilities for providing medical direction and support for all aspects of Bloodworks' activities. The position requires licensure as a physician (M.D. or D.O.) and board certification in Blood Banking/Transfusion Medicine. In lieu of board certification, candidates who meet the requirements for CLIA laboratory director with 3 years' experience in blood collections, immunohematology, apheresis, and cellular therapy will also be considered. University of Washington faculty engage in teaching, research, and service. Please apply at <https://usr57.dayforcehcm.com/CandidatePortal/en-US/bloodworks/>. EO employer – M/F/Vets/Disabled 💧