



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #13

April 10, 2020

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FDA Issues COVID-19 Convalescent Plasma Guidance & Updates Protocol

The U.S. Food and Drug Administration (FDA) has updated its [Recommendations for Investigational COVID-19 Convalescent Plasma](#) (CCP) and published a guidance entitled “[Investigational COVID-19 Convalescent Plasma Guidance for Industry](#).” The guidance consolidates guidelines from the agency regarding CCP into a single document and adds clarity to the collection and labeling processes for CCP and considerations for donor/patient eligibility criteria.

The guidance recommendations specifically include the following:

- [pathways for use of investigational CCP](#);
- [patient eligibility](#);
- [collection of CCP, including donor eligibility and donor qualifications](#);
- [labeling](#); and
- [record keeping](#).

Nearly all U.S. blood centers are mobilizing to assist with the collection of CCP. America's Blood Centers (ABC) reports that 44 of 46-member blood centers have begun collecting or will begin shortly, which when added to the participation of the American Red Cross and hospital-based collectors means close to 100 percent of the blood supply will be part of this national response effort to COVID-19.

Hospitals can obtain CCP from any FDA-licensed blood collector but should check first with their regular blood provider. Administration of CCP must take place under one of the FDA-approved pathways for this investigational new drug (IND). There are currently several different IND pathways, designed to meet the needs of different patient populations and different hospitals, at different times. This framework is intended to provide wide flexibility to hospitals. General information is [available](#) from FDA. Hospitals may currently use one of three pathways:

- National Expanded Access Treatment Protocol IND available through the Mayo Clinic;
- Emergency IND (eIND); or
- clinical trials.

Additional [information](#) on these current pathways can be found on the CCP website [launched](#) by AABB last week “as an educational resource to inform the public, blood collectors, and clinicians about CCP”.

(continued on page 2)



FDA CCP Guidance & Recommendations (continued from page 1)

Currently, the blood community is working with FDA and the Biomedical Advanced Research and Development Authority (BARDA) to establish a resource sharing “clearinghouse” for blood centers to share any excess CCP intended for patient use at a hospital registered as part of the Mayo expanded access protocol. These national resource sharing effort(s) will attempt to fill any requests for CCP at a registered Mayo expanded access protocol hospital that is not available to a hospital via their normal blood provider.

Interested donors should contact their local blood provider to determine their eligibility. Blood collectors participating in the program can be found at: www.covidplasma.org. Additional resources regarding the CCP National Program including a [Questions & Answers document](#) are now available on the ABC member site [COVID-19 Resource Hub](#).

(Sources: ABC National CCP Program [Questions and Answers](#), 4/9/20; FDA CCP Draft [Guidance](#), 4/8/20; FDA CCP [Recommendations](#), 4/8/20; AABB Website News [Release](#), 4/3/20) ♦

ABC Issues National Press Release Regarding CCP as Blood Community Aligns with Joint CCP Statement

America’s Blood Centers (ABC) distributed a [news release](#) on Monday, April 6th regarding the role that community blood centers are playing in the collection of CCP as part of the nation’s response efforts to COVID-19. “Community blood centers are at the forefront of delivering convalescent plasma to patients in critical need,” said ABC CEO Kate Fry, MBA, CAE in the news release. “This promising investigational product must get to patients without delay, and blood centers across the country have mobilized in response...Community blood centers are the backbone of the nation’s blood supply and help facilitate the gift of life for patients in need every day. This effort is an extension of that mission.”

Additionally, ABC, AABB, and the American Red Cross developed a [joint statement](#) on CCP to align messaging at a national level, “the U.S. blood community has joined the U.S. Food and Drug Administration and Biomedical Advanced Research and Development Authority in a national effort to support the collection and distribution of convalescent plasma, a potentially life-saving treatment for critically ill COVID-19 patients...The safety of collection employees, donors and ultimate recipients remains our top priority. Only those individuals who have recovered fully from COVID-19 are eligible to donate convalescent plasma. Individuals cannot be tested for COVID-19 at a blood center.”

(Sources: ABC News [Release](#), 4/6/20; ABC, AABB, American Red Cross Joint [Statement](#), 4/6/20) ♦

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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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HHS PAHPAIA Comment Period Extended

The U.S. Department of Health and Human Services (HHS) announced this week an extension, until July 21st, to the comment period for the [Request for Information \(RFI\) for section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act \(PAHPAIA\)](#). The previous deadline was April 22nd. The announcement follows in the wake of a joint [request](#) from America's Blood Centers (ABC), AABB, and the American Red Cross. In the request, the organizations asked HHS to extend the comment period by at least 90 days due to the blood community being actively involved in the nation's response efforts to COVID-19.

In late March, the Office of the Assistant Secretary for Health in HHS solicited feedback and comments regarding section 209 of PAHPAIA which passed Congress in June 2019. Section 209 of this legislation states that the Secretary of 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.

America's Blood Centers (ABC) and its members continuously supported PAHPAIA by signing onto multiple coalition [letters](#) and advocating on Capitol Hill to congressional leadership encouraging the bill's passage.

(Source: ABC, AABB, American Red Cross [Request](#), 3/27/20; *Federal Register* [Notice](#), 3/23/20)

Upcoming ABC Webinars – Don't Miss Out!

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

RESEARCH BRIEFS

America's Blood Centers welcomes contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing a brief for potential publication please contact us [here](#).





ADRP Conference to Take Place in November

ADRP, an International Division of America's Blood Centers (ABC), recently announced that its annual conference has been postponed from May 19th-21st to November 22nd-24th in Phoenix, Ariz. [Registration](#) is open for the meeting which will take place at the Hyatt Regency. This year's theme is "Charting the Course to Excellence" as the conference will explore all aspects of the blood donor journey and provide insights for individuals of all experience levels who work in:

- donor recruitment;
- collections;
- communications;
- marketing; and
- public relations.

Additional information including a preliminary [program](#), exhibitor [information](#) and [sponsorship](#) opportunities, and [hotel](#) accommodations are available on the ADRP [website](#). Please contact info@adrp.org with questions.

(Source: ADRP Annual [Conference](#)) 💧

RESEARCH IN BRIEF

No Evidence of Transfusion-Transmission of SARS-CoV-2. "To mitigate the theoretical risk of transfusion-transmission of SARS-CoV-2 via blood donation from pre-symptomatic COVID-19 cases", the Korean Red Cross Blood Services' (KRCBS) enhanced precautionary measures and requested donors "to report any illness or close contact with a confirmed case prior to donation, or being classified as a suspect case or diagnosed as COVID-19 [post-donation]". An article published in *Vox Sanguinis* studied seven donors who were identified as COVID-19 confirmed cases post-donation (six whole blood and one source plasma). The KRCBS quarantined blood products in inventory from confirmed cases and retrieved those that had been issued to hospitals including the source plasma unit. "All six platelet units were transfused to six patients" and "three red blood cell units had also been transfused to three recipients." One recipient died due to causes unrelated to COVID-19. The eight other recipients did not develop any symptoms related to COVID-19 (19 to 29 days post-transfusion). As "the KRCBS keeps repository samples of all blood donations for ten years," once the six COVID-19 donor cases were identified, these samples were sent to the Korea Centers for Disease Control & Prevention (KCDC) for "further investigation." All tested negative for SARS-CoV-2 RNA. Since all donors tested negative, "the Korean health authorities decided not to perform further investigation in recipients. Independent from the health authority's decision, three recipients were tested for SARS-CoV-2 RNA in nasopharyngeal samples and all tested negative." The authors concluded that transfusion transmission of SARS-CoV-2 to recipients did not occur as no recipients of platelets or red blood cell transfusions from donors diagnosed with SARS-CoV-2 infection post-donation developed COVID-19 related symptoms or tested positive for SARS-CoV-2 RNA. They suggested that it would be "optimal for blood services to receive the details of all confirmed COVID-19 cases from their health authorities and not solely rely on post-donation information." Currently, "the KRCBS is receiving the list of all COVID-19 cases identified in Korea for cross referencing to donors to trace recipients or recall any blood products not transfused and to apply a three-month deferral for future donations."

Citation: Kwon, S.Y., Kim, E.J., Jung, Y.S., *et al.* Post-donation COVID-19 Identification in Blood Donors. *Vox Sanguinis*. 2020. Doi. [10.1111/vox.12925](https://doi.org/10.1111/vox.12925).

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

REGULATORY NEWS

The Joint Commission’s updated 2020 National Patient Safety Goals for laboratory services is scheduled to take effect on July 1st. The first goal for laboratory services aims to make improvements to the accurate identification of patients through the use of “at least two patient identifiers” for services in the lab:

- Use at least two patient identifiers when administering blood or blood components; when collecting blood samples and other specimens for clinical testing; and when providing other treatments or procedures. The patient’s room number or physical location is not used as an identifier. *Note: An example of “other procedures” includes bone marrow aspirates.*
- Label containers used for blood and other specimens in the presence of the patient.

The Joint Commission is an independent non-profit organization that accredits and certifies more than 22,000 health care organizations and programs in the U.S. Goals for laboratory services include improving the accuracy of patient identification once again, as in previous years, along with improving the effectiveness of communication among caregivers and reducing the risk of healthcare-associated infections. Both a [simplified version](#) and [full chapter version](#) are available. Additional information on the 2020 National Patient Safety Goals for other programs such as hospital or ambulatory services can be found on The Joint Commission [website](#).

(Source: The Joint Commission [NPS 2020](#), 4/4/20)

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 April 27th from 9 a.m. to 12:30 p.m. EDT. This meeting “will review the work of the Public Comment and Federal Inventory Subcommittees and the chapters being developed for the 2020 report to Congress on federal tick-borne activities and research.” The meeting is open to the public and [registration](#) is open. Additional meeting materials and information will be available on the working group’s [website](#). Individuals that would like to make verbal or written comments must notify the agency prior to midnight April 19th.

(Source: *Federal Register* [Announcement](#), 4/9/20) 💧

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.

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!



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

INSIDE ABC

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

ABC Releases Thank You Video for Donors

To recognize the extraordinary response by blood donors across the country to ensure the availability of the nation's blood supply during the COVID-19 pandemic, ABC has created a [thank you video](#). It acknowledges donors and encourages them to make future appointments to meet the nation's ongoing blood needs. ABC commends the work of the blood community during this unprecedented time to keep the blood supply safe and ready for patients in need.

(Source: ABC [Video](#), 4/10/20)

ABC Partners with Paintball Community to Promote Blood Donation

America's Blood Centers (ABC) and the paintball community are collaborating to help amplify awareness for the ongoing need for blood donations. Organizer and YouTuber Lars Hindsley, AKA "DangerMan", is encouraging paintballers across the country to schedule appointments to donate, starting the week of April 20th. They have launched a website, [Paintball Cares](#), to support this initiative which includes a link to the ABC zip code locator to assist potential blood donors in finding their local donor center. Mr. Hindsley has more than 50,000 YouTube subscribers with over 500,000 monthly views.

(Source: Paintball Cares [Announcement](#), 4/10/20)

Presentations Available from 2020 ABC Annual Meeting

ABC has uploaded [presentations](#) from the 2020 ABC Annual meeting to the member website. Access to the presentations is available to all member blood centers. Please note that only presentations for which speakers provided permission to share can be accessed. For any questions or issues, please contact [Member Services](#).

(Source: [MCN 20-041](#), 4/9/20)

ABC and ADRP Unveil New Strategic Plan for 2020-23

America's Blood Centers (ABC) and ADRP, an International Division of ABC, have developed a new strategic plan as both organizations continue to move forward anticipating how to exceed member expectations while providing maximum value to ABC members and ADRP subscribers. Using the acronym PACE, the plan is the organizations' vision for creating an association nimble and innovative enough to change with blood centers in the rapidly evolving healthcare environment. It is centered around four strategic pillars with the tagline "keeping pace with the change around us:"

- Promote;
- Advance;
- Champion; and
- Elevate.

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Additional information about the plan is available on the ABC public [website](#).

(Source: ABC [Website](#), 4/1/20)

Member Value Report Now Available

ABC has published the fiscal year 2020 (April 1st, 2019 – March 31st, 2020) member value [report](#). It provides a snapshot of the progress being made to further ABC's [advocacy agenda](#), prioritize new organizational initiatives, and prepare the association for the future. ABC encourages members to review the report and actively engage with us by providing [feedback](#) in the form of questions, comments, and ideas for the future.

(Source: ABC Member Value [Report](#), 4/1/20) ♦

WORD IN WASHINGTON

Congressman Raul Ruiz, MD (D-Calif.) of the 36th District visited **LifeStream** on April 2nd to help underscore the importance of blood donation during the COVID-19 pandemic. "We are grateful for Congressman Ruiz' support of voluntary blood donation at this unprecedented time," said Rick Axelrod, MD, LifeStream's president/CEO and medical director. "As a licensed physician, he is fully aware of both the goodness of blood donation and the resulting benefit of helping save a life. We appreciate that he took time from his busy schedule to 'BLead by Example' for community leadership and caring for local patients in need." Rep. Ruiz also went on Facebook Live during and after his blood donation and answered constituents' questions about the donation process and safety protocols taken amid COVID-19 concerns. "I was glad to assist our local blood bank to help patients in need during this public health crisis and appreciate coronavirus precautions LifeStream is taking to protect donors," said Rep. Ruiz.



Rep. Raul Ruiz donates blood and discusses the state of the local blood supply amid the COVID-19 pandemic with Rick Axelrod, MD, president/CEO and medical director of LifeStream.

(Source: LifeStream Announcement, 4/6/20) ♦

BRIEFLY NOTED

AABB has issued its call for abstracts to be presented at the 2020 AABB Annual Meeting in Baltimore, Md. from Oct. 3rd to 6th. AABB encourages individuals to [submit](#) abstracts online to share knowledge with colleagues by completing submissions on or prior to April 24th. Acceptance notifications are expected to be distributed in July. A guide to assist with preparation and submission guidelines is available for [download](#). More information and submission instructions can be found [here](#).

(Source: AABB [Announcement](#)) ♦

COMPANY NEWS

An international alliance of plasma companies has formed to expedite the development of plasma therapies aimed at treating COVID-19. The collaboration, led by **Takeda Pharmaceutical** and **CSL Behring**, recently announced the addition of four new organizations to the alliance:

- Biotest;
- Bio Products Laboratory;
- LFB; and
- Octapharma.

“Unprecedented times call for bold moves,” said Julie Kim, president of Plasma-Derived Therapies Business Unit at Takeda in a news [release](#). “We collectively agree that by collaborating and bringing industry resources together, we could accelerate bringing a potential therapy to market as well as increase the potential supply. We invite companies and institutions focusing on plasma to support or join our alliance.” Bill Mezzanotte, CSL Behring’s Executive Vice President and Head of Research and Development added, “[t]here is no question that we are all experiencing the impact of COVID-19. This effort aims to accelerate a reliable, scalable and sustainable option for caregivers to treat patients suffering from the impact of COVID-19. In addition to pooling industry resources, we will also collaborate with government and academic efforts as a single alliance whenever we can, including important activities like clinical trials. This will make it more efficient in these hectic times for these stakeholders as well.” The alliance is working to develop an anti-SARS-CoV-2 polyclonal hyperimmune immunoglobulin.

(Source: Joint Press [Release](#), 4/6/20) ♦

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) 899-2621. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)*

POSTPONED

April 14-15. **16th Annual FDA and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** 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](#).

2020

April 27. **U.S. Department of Health and Human Services Tick-borne Disease Working Group Meeting (Teleconference).** More details available [here](#).

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CALENDAR (continued from page 8)

May 8. **U.S. Food and Drug Administration (FDA) Cellular, Tissue and Gene Therapies Advisory Committee Meeting, Teleconference.** More details available [here](#).

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

Aug. 28-29. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details 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](#).

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](#).

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

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A 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, 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.

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

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POSITIONS (continued from page 9)

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 3 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. ♦