**AABB’s Regulatory Updates for COVID-19**

**Last updated October 16, 2020**

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**09/25/20 Hospitalized COVID-19 Patients Require Fewer Blood Transfusions**

**Hospitalized COVID-19 Patients Require Fewer Blood Transfusions**

Hospitalized COVID-19 patients required many fewer blood transfusions than other hospitalized patients, according to findings published in the September issue of *Transfusion*. The findings may inform planning and preparation of blood resource utilization during the pandemic.

Investigators at Northwestern Memorial Hospital in Chicago performed a retrospective observational study of blood component transfusions in the first 4 weeks of COVID-19 ward admissions at their facility, beginning 14 days before the first COVID-19 cohort wards opened in the hospital and ending 28 days afterward. They tabulated the number of patients and blood components transfused in the COVID-19 ward and compared transfusion rates of each blood component in COVID-19 wards with all other inpatient wards.

Forty-one of 305 hospitalized COVID-19 patients (13.4%) received transfusions, with 11.1% receiving red blood cells (RBCs), 1.6% platelets, 1% plasma and 1% cryoprecipitate. The COVID-19 wards accounted for 12.3% of all inpatient-days during the study period but received 4% of all inpatient blood components during that time. The COVID-19 intensive care unit (ICU) wards transfused 51-62% of the COVID-19-ward RBCs, platelets and cryoprecipitate, along with all COVID-19 ward plasma units.

COVID-19 wards had significantly lower transfusion rates compared to non-COVID wards for RBCs (0.03 versus 0.08 units/patient-day), platelets (0.003 versus 0.033) and plasma (0.002 versus 0.018). Rates of cryoprecipitate transfusion were similar (0.008 versus 0.009). Data indicated that COVID-19 ICU wards had significantly higher rates than COVID-19 non-ICU wards for RBCs (0.045 versus 0.022 units/patient-day) and plasma (0.006 versus 0.000), but not for platelets (0.006 versus 0.002) or cryoprecipitate (0.014 versus 0.004).

Readers who complete a short activity about the report can earn continuing medical education (CME) credit. Those who correctly answer at least 70% of the post-test items can also earn Self-Assessment Module (SAM) credit toward Maintenance of Certification (MOC).

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**09/25/20 COVID-19 Antibodies Detected in Nearly 2% of Blood Donors**

**COVID-19 Antibodies Detected in Nearly 2% of Blood Donors**

Approximately 2% of individuals who donated blood at American Red Cross (ARC) facilities between June 15 and Aug. 23 tested positive for SARS-CoV-2 antibodies, according to a research letter published in *JAMA*. Investigators Roger Y. Dodd, PhD; Meng Xu, MPH; and Susan L. Stramer, PhD, also
found that donations from younger and racial and ethnic minority donors were more likely to be reactive.

ARC began testing blood donations for SARS-CoV-2 antibodies on June 14. Of 953,926 donations tested during the study period, 17,336 (1.82%) were reactive. Of these, 4,786 (28%) were from first-time donors, while 12,550 (72%) were from repeat donors (reactive rates of 2.99% and 1.58%, respectively). Odds of reactivity were higher in donors ages 18-24 compared with donors 55 years and older; in African Americans and Hispanics compared with white donors; and in donors from the Northeast compared with donors in the West. Overall reactive rates increased from 1.18% to 2.58%, but investigators noted that this increase may be due to donors with higher rates of prior exposure donating to obtain antibody test results.

Dodd, Xu and Stramer also compared the change in first-time and repeat donors during the 2 weeks before ARC initiated antibody testing (June 1-14) with the period after testing began (June 15-Aug. 23). In the 2 weeks prior to initiation of testing, 11% of donors were first-time donors, compared with 17% after that time.

They reported that the distribution of anti–SARS-CoV-2 reactive test results was similar to results reported for patients with clinically diagnosed COVID-19, with higher rates among African American and Hispanic donors. They noted, however, that blood donors are not representative of the overall population and that some areas of the United States may not be served by an ARC collection site.

Similarly, Vitalant recently released data indicating that 2.26% of 250,000 blood donors who donated in Vitalant facilities in July were reactive for COVID-19 antibodies. This was an increase from June, when 1.37% of Vitalant donors were positive for COVID-19 antibodies.

09/25/20 FDA Updates Q&A Appendix in Medical Products Clinical Trial Guidance

FDA Updates Q&A Appendix in Medical Products Clinical Trial Guidance

FDA recently updated the Q&A appendix in its guidance titled “Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency.” The updated guidance includes a new Q&A regarding a clinical trial investigator’s responsibility to review all investigational new drug application safety reports, including reports that will not result in a change to the investigator brochure, informed consent or protocol.
Two NIH-Funded CCP Clinical Trials Expand

Two randomized, placebo-controlled clinical trials funded by the National Institutes of Health (NIH) are expanding enrollment to further evaluate CCP as a treatment for patients hospitalized with COVID-19. The trials are receiving $48 million in support through Operation Warp Speed, a collaborative initiative across federal agencies to advance the development, manufacturing and distribution of COVID-19 vaccines, therapeutics and diagnostics.

The Convalescent Plasma to Limit COVID-19 Complications in Hospitalized Patients trial expects to enroll approximately 1,000 hospitalized adult patients with respiratory symptoms of COVID-19. The trial will assess clinical improvement at 14 and 28 days and evaluate outcomes based on mortality, intensive care unit admission and patient antibody concentrations.

The Passive Immunity Trial of Our Nation for COVID-19 will expand to enroll about 1,000 participants. The trial will assess clinical improvement in adult patients with acute respiratory infection symptoms and laboratory-confirmed SARS-CoV-2 infection at 15 days. It will also evaluate ventilator use, supplemental oxygen use, acute kidney injury and cardiovascular events.

REGULATORY UPDATE: FDA Publishes Updated Evidence Supporting the CCP EUA

The Food and Drug Administration posted a review of updated evidence to support the emergency use of COVID-19 convalescent plasma (CCP) in the Daily Roundup this week. In the update, FDA stated it will continue to review the circumstances and appropriateness of the EUA and reemphasized that the issue of an EUA during a declared public health emergency does not require the same evidentiary standard as required for approval or licensure. “Instead, the FD&C Act requires that the product ‘may be effective’ for its intended use, and that the ‘potential benefits outweigh the known and potential risks,’” the report said.

FDA described four lines of evidence that continue to support the emergency use authorization (EUA) at this time. The first, as described in the EUA, is historical data regarding prior experience with the use of convalescent plasma in other outbreak settings, animal study data that indicates the administration of convalescent plasma can protect the animals against infection with SARS-CoV-2, emerging data in the literature and evidence based on the results from the Expanded Access Treatment Protocol (EAP). The EAP showed that in patients who were not intubated and treated within 72 hours of diagnosis, “there was a dose response of convalescent plasma evident, with higher antibody levels associated with better outcomes.”

FDA noted that none of the clinical trials that have appeared to date provide the level of evidence
needed to meet the effectiveness standard that FDA uses for drug and biological product approvals. "Generally, these publications note that the administration of COVID-19 convalescent plasma appears to be safe. Regarding efficacy, although some clinical trials have not shown any effect of COVID-19 Convalescent Plasma, others have indicated that it may be effective, particularly in certain settings,” FDA said. An example of an analysis from one of the larger published matched cohort studies “indicated that there was a statistically significant reduction in mortality at 28 days that was most notable in the 112 patients transfused within 72 hours of admission with plasma having a high anti-spike protein receptor binding domain titer of greater than or equal to 1:1350.”

Based on the totality of the four lines of evidence, FDA continues to “find that COVID-19 convalescent plasma has met the ‘may be effective’ standard for the EUA.” The agency noted that because the efficacy analysis of the EAP did not include an untreated control group for comparison, "FDA strongly encourages the continuation of randomized controlled clinical trials to more definitively evaluate the potential benefits of this therapy.”

09/18/20 Results of Small Study Suggest CCP Safe in Pediatric Patients

Results of Small Study Suggest CCP Safe in Pediatric Patients

Physicians at the Children’s Hospital of Philadelphia safely administered CCP to four pediatric patients with severe COVID-19. The study, published online in the Pediatric Blood and Cancer, is the first report of CCP in children with life-threatening COVID-19.

Investigators measured donor antibody levels and recipient antibody response prior to and following CCP infusion to determine whether there were any adverse reactions. CCP transfusion was not associated with antibody-dependent enhancement and did not suppress endogenous antibody response.

According to investigators, CCP may be of greatest benefit for patients who are early in their illness and have not yet generated endogenous antibodies. High-titer CCP may also be associated with improved outcomes.

“We believe that convalescent plasma may provide the greatest benefit for patients who are early into their illness and have not yet generated endogenous antibodies,” David Teachey, MD, senior author, said. “While the small sample size of our study does not allow us to draw any definitive conclusions, we believe this method is safe and future research should include randomized controlled trials to more definitively examine how effective convalescent plasma may be in treating children infected with COVID-19.”

09/18/20 September Issue of AABB News Highlights Challenges to Leadership

September Issue of AABB News Highlights Challenges to Leadership
The COVID-19 pandemic arrived amidst an ongoing trend of decreasing resources for blood services, including shortages in blood components and reduced staffing. One of the feature articles in the September issue of AABB News discusses strategies to address these challenges, such as increasing communication between donor centers and transfusion services, maximizing the use of automation and cross-training laboratory staff among departments. Another feature article provides an overview of emergency planning for transfusion services. Other articles describe some of the fun sessions and returning favorites among the education sessions planned for the upcoming 2020 AABB Virtual Annual Meeting — including the Wizardry School of Antibodies and Antigens and Essential Twitter for Blood Banking and Cellular Therapy Professionals — and list the 2020 National Blood Foundation early-career Scientific Research Grant awardees.

09/18/20 ACBTSA to Discuss Recommendations to Improve Blood Community’s Pandemic Response

ACBTSA to Discuss Recommendations to Improve Blood Community’s Pandemic Response

The Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will meet virtually Sept. 25 to discuss and vote on recommendations to improve the blood community’s response to future public health emergencies. ACBTSA members voted to establish work groups to develop recommendations to the Assistant Secretary of Health at a meeting last month. Members of the public will have the opportunity to present their views to the ACBTSA (orally or in writing), and instructions are available online. Registration information and a meeting agenda are also available online.

09/18/20 REGULATORY UPDATE: FDA Issues Updated 2020 Guidance Agenda

REGULATORY UPDATE: FDA Issues Updated 2020 Guidance Agenda

FDA’s Center for Biologics Evaluation and Research (CBER) issued a September update to the 2020 Guidance Agenda. In the “Blood and Blood Components” category, changes reflect the agency’s August updates to the April 2020 HIV and Creutzfeldt-Jakob disease guidance documents, as described in an Aug. 28 Weekly Report article. The agenda also includes the September issue of the investigational COVID-19 convalescent plasma guidance, which superseded a guidance of the same title issued in April and updated in May.

Notably, FDA added a guidance in the “Vaccines” category titled “Emergency Use Authorization for Vaccines to Prevent COVID-19,” with a footnote indicating that the agency “intends to issue a guidance to provide recommendations regarding the data and information needed to support the issuance of an EUA for vaccines to prevent COVID-19.”

FDA did not make changes in the categories of “Tissues and Advanced Therapies” or “Other.” AABB invites members to contact regulatory@aabb.org with questions.
AABB Releases Latest Findings From Hospital Transfusion Services Survey

AABB released a graphic summary of findings from the latest survey of AABB member hospital transfusion services on their actions in response to the COVID-19 pandemic. This week, 149 hospitals from 39 states completed the survey, conducted Sept. 14-16.

A total of 86.5% of hospitals transfused COVID-19 convalescent plasma (CCP) units; however, 14.1% reported delays in obtaining CCP units. A plurality of hospitals prioritized CCP to severely ill patients (43.3%). An upward trend is apparent in prioritization based on timing of diagnosis/admission. The observed trend relates to efforts made to shift CCP use to favor patients early in the course of disease. A total of 78.9% of hospitals used Emergency Use Authorization (EUA) to transfuse CCP units.

More hospitals (32.9%) were alerted by blood suppliers that they are unable to meet typical inventory need, compared to the last survey. Platelets and O-negative RBCs were the most affected components.

Select past survey results are available on the AABB Survey and Reports web page.

FDA Issues Temporary Guidance on Resuming Drug, Biologics Manufacturing

The Food and Drug Administration issued a new temporary guidance last week to help drug and biological product manufacturers during the COVID-19 public health emergency plan and prioritize current good manufacturing practice (CGMP) activities as they transition to normal manufacturing operations. The guidance describes how to evaluate and prioritize the remediation of CGMP activities that have been necessarily delayed, reduced or modified during the public health emergency. The guidance will remain in effect only for the duration of the COVID-19 pandemic.

AABB, ABC, ARC Urge Vaccine Authority to Prioritize Blood Center Employees

AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) urged the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus to prioritize blood centers by recognizing them as health care facilities for the purpose of vaccine allocation. In the Sept. 4 letter, the organizations highlighted the essential role that blood centers and their personnel play in protecting the health care system. They also emphasized blood centers’ role on the front lines of the national response to the pandemic, which places blood center personnel at higher risk for exposure to COVID-19. “To ensure a safe and robust blood supply remains available throughout the pandemic, it is
essential that blood centers be considered health care facilities for the purpose of the vaccine allocation framework and that their personnel be included as critical risk workers," the letter stated.

09/04/20 AABB Celebrates 15th Annual Blood Collectors Week

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AABB and Fresenius Kabi are collaborating to celebrate the 15th annual Blood Collectors Week, to be held Sept. 6-12. Blood Collectors Week honors blood collectors, the vital link between donors and patients in need of blood, and recognizes their efforts to keep blood products readily available. Blood Collectors Week also spotlights blood collectors’ efforts to make blood donation a positive experience for donors through personal stories.

“This year, Blood Collectors Week takes on a special meaning. The impacts of the ongoing COVID-19 pandemic remind us about the essential role that phlebotomists, apheresis operators and all those involved in blood collection play in the health care system,” said Debra BenAvram, CEO of AABB. “As they have done throughout the pandemic, these dedicated professionals continue to navigate unprecedented challenges to ensure that blood is available for patients in need. AABB is proud to partner again with Fresenius Kabi to honor their vital work this Blood Collectors Week.”

The Blood Collectors Week website provides materials to help participating blood centers recognize their blood collection staff, promote their events and view activities planned by centers across the country. To keep up to date with Blood Collectors Week activities, follow @bloodcollectors and use the hashtag #BloodCollectorsWeek on Twitter.

09/04/20 Blood Banks and Transfusion Services Standards Committee Issues New Guidance

Blood Banks and Transfusion Services Standards Committee Issues New Guidance

The Blood Banks and Transfusion Services Standards Committee (BB/TS SC) issued new guidance to Reference Standard 5.4.1A, Requirements for Allogeneic Donor Qualification, concerning the receipt of vaccines, including unlicensed SARS CoV-2 vaccines. Based on communications from FDA, the Standards Committee felt it was necessary to provide information in a question-and-answer format on how accredited facilities should manage the deferral of donors participating in vaccine trials.

Reference Standard 5.4.1A requires a 12-month deferral for recipients of unlicensed vaccines, subject to review by the medical director. Medical directors can consider a shorter deferral period (as short as 14 days from inoculation) for those receiving live attenuated vaccines. It should be noted that no deferral is necessary for blood donors who received non-replicating, inactivated or RNA-based vaccines, or the mRNA-1273 Moderna vaccine.
The guidance also discusses donor deferrals related to potential donors who have received the SARS CoV-2 vaccine and who have donated CCP and potential donors who have donated CCP.

The guidance can be found in the Standards Portal or in the Standards Library.

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**09/04/20 AABB Releases Latest Findings From Hospital Transfusion Services Survey**

**AABB Releases Latest Findings From Hospital Transfusion Services Survey**

AABB released a graphic summary of findings from the latest survey of AABB member hospital transfusion services on their actions in response to the COVID-19 pandemic. A total of 168 hospitals from 40 states completed the survey, conducted Aug. 31-Sept. 2.

The percentage of hospitals that transfused CCP units was 85% (comparable to the week of Aug. 17); 20.9% of respondents reported delays in obtaining CCP units (a decline compared to week of Aug. 17). A total of 70% of hospitals are using EUA to obtain CCP units. A total of 58% of hospitals would consider transfusing low-titer units (<S/CO of 12) if they encountered delays in obtaining high-titer CCP units, whereas 61% would consider transfusing more than one low-titer unit.

A plurality of hospitals prioritized CCP to severely ill patients (37.1%); however, a declining trend is apparent. Findings indicated an upward trend in efforts made to shift CCP use to favor patients early in the course of disease.

With regard to inventory, 25% of responding hospitals received notice from their blood supplier that they are unable to meet typical inventory need, compared to the last survey; 9.6% of respondents reported increases in product outdating due to pandemic-related changes.

Select past survey results are available on the AABB Survey and Reports web page.

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**09/04/20 VRBPAC Will Discuss COVID-19 Vaccine at Oct. 22 Meeting**

**VRBPAC Will Discuss COVID-19 Vaccine at Oct. 22 Meeting**

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) will discuss the development, authorization and/or licensure of vaccines indicated to prevent COVID-19 at its next public meeting. The meeting will be held virtually from 10 a.m. to 5 p.m. ET on Oct. 22. FDA intends to make background material available to the public no later than 2 business days before the meeting. Members of the public may present data, information, or views, orally or in writing, on issues pending before the Committee. Instructions and registration information are available online.
Comments on Recommendations for Early COVID-19 Vaccine Distribution Due Today


The discussion draft includes a phased framework for the allocation of a vaccine. Phase 1a would include “high-risk workers” in certain health care facilities (including hospitals, nursing homes or providing home care) and first responders. Phase 1b would include people with comorbid and underlying conditions that put them at significantly higher risk, as well as older adults living in congregate or overcrowded settings. Phase 2 includes several populations, including “critical risk workers,” defined as “workers who are both in industries essential to the functioning of society and at substantially high risk of exposure.”

An expedited, 3-day public comment period began on Wednesday, and comments are due today. AABB encourages members to submit comments to support blood centers being considered “health care facilities” for the purposes of the vaccine allocation framework and for blood center employees, at a minimum, to be classified as “critical risk workers.”


Congress may wish to consider further action to maintain the blood supply as part of its pandemic response, the Congressional Research Service (CRS) stated in a report on the U.S. blood supply. The Aug. 26 report provides a brief background of the regulatory framework for the U.S. blood supply and explains the federal response to the current crisis.

The report also addresses the potential treatment of COVID-19 using blood-derived products — CCP and hyperimmune globulin — and FDA’s use of its existing authorities to increase access to these unapproved products through expanded access and EUA. The report noted that some concern has been raised regarding FDA’s issuance of an EUA for CCP in the absence of evidence from randomized controlled trials. The report also states that it is unclear the extent to which an EUA will increase access to CCP, since its availability is limited by donations.

“If patients are more readily able to access CCP through the EUA, participation in clinical trials may be hindered, making it more difficult to generate data regarding the effectiveness of convalescent plasma for COVID-19,” the report stated. “Given the therapeutic potential of blood-derived therapies and that availability is limited based on donations, Congress may wish to consider further action regarding the maintenance of the U.S. blood supply as part of its efforts to respond to the COVID-19 pandemic.”
AABB Issues Statement on Benefits of Early CCP Transfusion

AABB issued a statement this week addressing the benefits of early CCP transfusion. The statement referenced recent findings that suggest the strongest benefit of CCP is associated with transfusion of high-titer units early in the course of the disease (within 72 hours of hospital admission). The Association will continue to monitor the state of knowledge and practice on CCP and will provide updates or recommendations as appropriate.

Regulatory Update: FDA Releases Final CCP Guidance; AABB Updates CCP Toolkit

FDA published a new final guidance on Wednesday containing recommendations for the collection and use of CCP for emergency use. This action was expected following the approval of the emergency use authorization (EUA) for CCP on Aug. 23.

The recommendations address:

- Pathways for use of investigational convalescent plasma.
- Collection of CCP under the EUA.
- Collection of CCP under an IND.
- Support of randomized clinical trials that will not be impacted by the release of the EUA.

Most notably, the guidance describes FDA’s authority to “exercise temporary enforcement discretion” which supports access to CCP transfusion for consenting patients by permitting the use of the current inventory of investigational CCP collected prior to the EUA, without retesting or relabeling.

“FDA intends to exercise this discretion with respect to the IND requirements for the collection, shipment, and administration of investigational convalescent plasma for a period of 90 days following the issuance of this guidance document,” the guidance stated.

On Wednesday, AABB hosted a call with Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research (CBER); and Nicole Verdun, MD, director of CBER’s Office of Blood Research and Review, to address questions from clinicians and transfusion services regarding CCP. In the hour-long call, Marks and Verdun answered questions from the AABB community relating to the updated CCP guidance released that afternoon, enforcement discretion, testing, special considerations, labeling, titer requirements, dosing and inventory management. AABB has updated its CCP Toolkit to reflect the new information in the CCP guidance and comments shared by FDA.
CMS Introduces New COVID-19 Reporting Requirements for CLIA Laboratories

The Centers for Medicare and Medicaid Services (CMS) published an interim final rule with comment period (IFC) on Wednesday that establishes requirements for CLIA laboratories to report all COVID-19 test results to the secretary of Health and Human Services during the COVID-19 public health emergency (PHE). The regulations took effect immediately and apply to all types of certificates, including certificates of waiver and certificates of accreditation.

AABB is continuing to work with CMS to obtain clarity around these new regulations and their impact on blood collectors and testing centers. At this time, the impact is unclear because blood collectors perform antibody tests to identify possible COVID-19 convalescent plasma (CCP) donors in the context of a biological manufacturing process. AABB brought this issue forward to the Food and Drug Administration, and FDA officials indicated their intent to address this with CMS. AABB is advocating for CMS to exclude donor qualification from this ruling; if this is not possible, AABB will advocate for the new requirements to be minimally burdensome. The Association will provide updates as soon as they become available.

The IFC notes that reporting of test results should follow the June 4 guidance from CMS. An FAQ document for that guidance provides that reporting “…should occur within 24 hours of results being known or determined, on a daily basis, to the appropriate state or local public health department based on the individual’s residence.” The IFC also makes the failure to submit COVID-19 test results a condition-level deficiency subject to $1,000 civil penalty for the first day of noncompliance and $500 for each subsequent day.

Facilities using AABB as their CLIA provider should note that these new regulations are being incorporated into the AABB assessment process. All AABB members should be aware that the IFC amends regulation 493.555, which now includes a paragraph (c)(6) requiring that, for the duration of the COVID-19 PHE, all accrediting organizations must notify CMS within 10 days after identifying a laboratory that fails to report COVID-19 test results as required.
AABB News Flash - Revised CLIA COVID-19 Reporting Requirements Effective Today; New FDA Final Guidance on CCP; and Recommendations for Early Vaccine Distribution

AABB is alerting member facilities to three important government actions with the potential to affect the transfusion medicine community.

Immediate Requirement of Reporting SARS-CoV-2 Test Results to CMS

The Centers for Medicare and Medicaid Services (CMS) today published an interim final rule with comment period (IFC) that takes effect immediately. The interim final rule establishes requirements for CLIA laboratories to report all COVID-19 test results to the secretary of Health and Human Services during the COVID-19 public health emergency (PHE). The regulations take effect immediately and apply to all types of certificates, including certificates or waiver, as well as certificates of accreditation. They also include antibody testing performed by blood centers, since that testing is intended to detect COVID-19.

In their current form, these regulations apply to COVID-19 testing performed by blood collectors, including antibody tests performed to identify possible COVID-19 convalescent plasma donors.

The rule also makes the failure to submit COVID-19 test results a condition-level deficiency subject to $1,000 civil money penalty for the first day of noncompliance and $500 for each subsequent day.

The IFC notes that reporting of test results should follow the June 4 guidance from CMS. An FAQ document for that guidance notes that reporting “...should occur within 24 hours of results being known or determined, on a daily basis, to the appropriate state or local public health department based on the individual’s residence.”

AABB is continuing to work with CMS to obtain clarity around these new regulations and on their impact on blood collectors and testing centers. At this time, the impact is unclear because blood collectors perform this testing in the context of a biological manufacturing process. AABB brought this issue forward to FDA, and FDA officials indicated their intent to address this with CMS. AABB is advocating with CMS to exclude blood centers from this ruling; if this is not possible, AABB will advocate for the new requirements to be minimally burdensome. The Association will provide updates as soon as they become available.

The impact on blood collectors is still unclear, since this testing is typically performed in the context of a biological manufacturing process. AABB brought the issue forward to FDA, and FDA officials indicated their intent to address this with CMS. In addition, AABB is advocating with CMS to exclude blood centers from this ruling. The Association will provide updates as soon as they become available.
For facilities using AABB as their CLIA provider, please note that these new regulations are being incorporated into the AABB assessment process. All AABB members should be aware that the IFC amends regulation 493.555, which now includes a paragraph (c)(6) requiring that, for the duration of the COVID-19 PHE, all accrediting organizations must notify CMS within 10 days after identifying a laboratory that fails to report COVID-19 test results as required.

**Final Guidance on COVID-19 Convalescent Plasma**

Today, the Food and Drug Administration published a new final guidance containing recommendations for the collection and use of COVID-19 convalescent plasma for emergency use. This action was expected following the approval of the emergency use authorization (EUA) for CCP on Aug. 23.

The recommendations address:
- Pathways for use of investigational convalescent plasma.
- Collection of CCP under the EUA.
- Collection of CCP under an IND.
- Support of randomized clinical trials that will not be impacted by the release of the EUA.

Most notably, the guidance addresses FDA’s approach to compliance that will support uninterrupted access to CCP for patients in need of treatment by permitting the use of the current inventory of investigational CCP collected prior to the EUA.

“FDA intends to exercise this discretion with respect to the IND requirements for the collection, shipment, and administration of investigational convalescent plasma for a period of 90 days following the issuance of this guidance document,” the guidance stated.

AABB will issue additional communication about this issue this week.

**Comments Open on Recommendations for Early Vaccine Distribution**

Additionally, AABB is alerting the blood community to a document from the National Academies released a document entitled, “Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine (2020).” The National Academies released the document in response to a request from the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC).

The discussion draft includes a phased framework for the allocation of a vaccine. Phase 1a would include “high-risk workers” in certain health care facilities (including hospitals, nursing homes or providing home care) and first responders. Phase 1b would include people with comorbid and underlying conditions that put them at significantly higher risk as well as older adults living in congregate or overcrowded settings. Phase 2 includes several populations, including “critical risk workers,” defined as “workers who are both in industries essential to the functioning of society and at substantially high risk of exposure.”

There is an expedited three-day public comment period, and comments are due Friday, Sept. 4.
Members are encouraged to submit comments to support blood centers being considered “health care facilities” for the purposes of the vaccine allocation framework, and for blood center employees, at a minimum to be classified as “critical risk workers.”

08/28/20 ACBTSA Meeting Examines Effect of COVID-19, Considerations for Future Pandemics

ACBTSA Meeting Examines Effect of COVID-19, Considerations for Future Pandemics

The Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) met virtually Wednesday and Thursday to examine the effect of the COVID-19 pandemic on the blood supply and to consider recommendations to improve the blood community’s response to public health emergencies. Speakers included government officials and private-sector stakeholders from throughout the vein-to-vein blood community.

Debra BenAvram, chief executive officer of AABB, presented the Association’s experience with the COVID-19 pandemic. She spoke about three strengths she observed during the pandemic that should be the foundation of future pandemic responses, including coordinated national messaging on the need for blood donation; collaboration related to changes in blood availability and utilization; and innovation facilitated by policymakers and a unique public-private partnership for CCP. She also discussed weaknesses that threatened, or could threaten, the safety and availability of the blood supply and patient care: lack of real-time data on the blood supply, utilization and hemovigilance; threats to the blood system supply chain; and risks related to blood collection activities.

BenAvram concluded by advancing policy solutions on behalf of the Association, recommending that HHS prioritize three recommendations through public-private partnerships to ensure that the solutions will support patients’ needs while also advancing the work done by organizations and individuals throughout the blood community. First, she reiterated AABB’s position that HHS should work with Congress to establish, implement and maintain a sustainable infrastructure that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes and hemovigilance. Next, HHS should develop and implement effective donor awareness and engagement activities. These efforts should be supplemented with other policies intended to increase the availability of blood components, such as FDA continually reassessing and updating donor deferral and testing requirements and HHS establishing a national red blood cell antigen typing patient database. Finally, BenAvram recommended that HHS invest in working with the private sector to proactively promote innovation, promote quality and efficiencies, and advance the continued safety and availability of the blood supply. AABB’s statement is available online.

The themes highlighted in AABB’s statement to the Advisory Committee were echoed by several speakers throughout the two-day meeting. Brian Gannon, chair of the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, presented the Task Force’s experience with responding to the COVID-19 pandemic. His statement highlighted strengths of the Task Force’s
response, including enabling the exchange of timely information about the blood supply and facilitating a rapid, organized response to the pandemic, and providing consistent messaging to the blood community and the public on the status of the blood supply during a pandemic or public health emergency.

Gannon shared several challenges: the absence of accurate, comprehensive, timely data on the blood supply; the lack of real-time data on blood utilization and inconsistent coordination between hospitals and blood centers on the evolving changes in the blood supply and utilization; ongoing challenges with effectively communicating the status of the blood supply to the public; and vulnerabilities throughout the blood supply chain. He also recommended that HHS improve preparedness by dedicating funding to modernize the system used to report the available blood supply, and maintain an automated system that includes real-time, comprehensive, accurate data on blood inventories; developing policies and investing resources to strengthen the resiliency of the entire blood supply chain; and dedicating funding to support the Task Force’s infrastructure.

The meeting concluded with a committee discussion. The Committee voted to form subgroups to formulate findings and recommendations to the Assistant Secretary of Health, which will be considered during an ACBTSsA meeting in the near-future.

08/28/20 OCR Adds Health Plans to Plasma Donation Guidance

**OCR Adds Health Plans to Plasma Donation Guidance**

The Office of Civil Rights (OCR) within the Department of Health and Human Services (HHS) added health plans to the June guidance that explains how the Health Insurance Portability and Accountability Act permits covered health care providers to identify, contact and inform their patients and beneficiaries who have recovered from COVID-19 that they can donate CCP. OCR issued the updated guidance to complement FDA’s EUA for CCP to treat COVID-19 in some hospitalized patients. The guidance emphasizes that, without individuals’ authorization, the providers and health plans cannot receive any payment from, or on behalf of, a plasma donation center in exchange for such communications with recovered individuals.
CBER Officials Answer Blood Community’s CCP EUA Questions

Peter Marks MD, PhD, director of the Center for Biologics Evaluation and Research (CBER); and Nicole Verdun, MD, director of CBER’s Office of Blood Research and Review, answered questions from the blood community regarding FDA’s recent EUA for CCP on Wednesday. In an hour-long call, Marks and Verdun addressed several operational areas related to the EUA in response to questions compiled by AABB, America’s Blood Centers and the American Red Cross. They also answered follow-up questions from call participants.

Several questions related to the transition from Mayo Clinic’s COVID-19 expanded access program (EAP), which ends today at midnight, to the EUA for CCP. Marks and Verdun confirmed that FDA is providing a transition period that permits blood centers and hospital transfusion services to continue to provide CCP from the current inventory without interruption in patient access to this treatment. They clarified that hospitals are permitted to administer CCP collected and labeled under the EAP with one additional requirement to inform patients using verbal consent and adding “investigational COVID-19 convalescent plasma” to their standard transfusion consent form. In addition, Marks emphasized that hospitals administering investigational plasma collected under the EAP do not need an investigational new drug (IND) application and are not out of compliance with FDA regulations for administering the product after the EAP closes. He also said that the agency would release additional communications in the near future to further clarify the agency’s expectations during this transition period.

Marks and Verdun answered additional questions about the new requirements for antibody assays necessary to label low- and high-titer CCP collections as described in the EUA, agreed to consider extending the outdate for frozen CCP and discussed the deferral of CCP donors who themselves received a CCP transfusion. AABB provided the agency’s Aug. 7 clarification on qualification of donors following receipt of an investigational vaccine for SARS-CoV-2.

AABB updated the toolkit for CCP use under the EUA to include responses to questions based on FDA answers from Wednesday’s call and will publish an updated version later today. Individuals may send additional questions to regulatory@aabb.org.

FDA Issues EUA for COVID-19 Convalescent Plasma; AABB Releases Toolkit

The Food and Drug Administration issued an emergency use authorization (EUA) on Sunday for COVID-19 convalescent plasma (CCP) as a treatment for patients battling COVID-19. Based on the scientific evidence available, FDA concluded that CCP may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks. The agency also announced plans to revise the May 2020 guidance, “Investigational COVID-19 Convalescent
Plasma; Guidance for Industry,” to reflect the issuance of the EUA.

AABB welcomes new therapeutic options in the fight against COVID-19, the Association said in a statement released Monday, reiterating that science must guide regulatory decisions. AABB urged “the continuation of clinical trials to better understand the efficacy and determine optimal treatment regimens for CCP as a therapeutic option” and said that more data will be useful to determine CCP’s full potential.

In response to the EUA, AABB developed a new toolkit for CCP to assist members in keeping updated on the changing regulatory environment. AABB will release an updated toolkit later today. Members with questions may email regulatory@aabb.org.

08/24/20 AABB News Flash - FDA Issues Emergency Use Authorization for COVID-19 Convalescent Plasma

AABB News Flash - FDA Issues Emergency Use Authorization for COVID-19 Convalescent Plasma

Yesterday, the Food and Drug Administration issued an emergency use authorization (EUA) for COVID-19 convalescent plasma (CCP) as a treatment for patients battling COVID-19. The announcement was made in a White House press briefing yesterday afternoon by President Donald Trump; Alex Azar, secretary of Health and Human Services; and Stephen Hahn, MD, FDA commissioner.

During the announcement, Hahn said researchers studying CCP treatment in patients with COVID-19 “have concluded that [CCP] is safe and shows promising efficacy, thereby meeting the criteria for an emergency use authorization.”

Azar noted that data show CCP’s efficacy may be correlated with the time during disease progression in which the treatment is given. “The data we gathered suggest that patients who were treated early in their disease course – within three days of being diagnosed – with [CCP] containing high levels of antibodies benefited the most from treatment,” he said.

AABB applauds the heroic work of the dedicated professionals of this community and throughout health care who have helped advance CCP as a treatment option. The Association welcomes new therapeutic options in the fight against COVID-19 but believes that science must guide regulatory decisions. In a new statement on CCP, AABB urges “the continuation of clinical trials to better understand the efficacy and determine optimal treatment regimens for CCP as a therapeutic option” and says “more data will be useful to determine CCP’s full potential.”

AABB developed a new toolkit for CCP under FDA’s EUA to assist members in keeping updated on the changing regulatory environment regarding CCP. AABB will update the toolkit based on additional updates to FDA guidance expected in the coming days.
As members make adjustments at their facilities to accommodate the new EUA, AABB anticipates many questions about the new information from FDA. In response to member questions, AABB will create additional resources to assist members with these changes. Please let AABB know what questions you have and what tools would be most beneficial by completing this survey.

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**08/21/20 SARS-CoV-2 Antibodies Vary Substantially in Patients with Mild COVID-19 Infection**

SARS-CoV-2 Antibodies Vary Substantially in Patients with Mild COVID-19 Infection

Neutralizing antibody titers to SARS-CoV-2 appeared to vary substantially in 175 patients with mild COVID-19 infection in Shanghai, China, according to findings published on Tuesday in *JAMA Internal Medicine*.

Investigators from Fudan University in Shanghai measured SARS-Cov-2–specific neutralizing antibodies (NAbs) in plasma from patients at Shanghai Public Health Clinical Center with laboratory-confirmed SARS-CoV-2 infection who had been hospitalized with mild symptoms. The research team also recruited 13 healthy volunteers who did not have a history of exposure to SARS-CoV-2 and had negative tests on two occasions for SARS-CoV-2 viral RNA as controls. Investigators then examined the association between clinical characteristics and the level of NAbs at discharge and 2 weeks after discharge.

Investigators detected NAbs were in patients from day 4 to 6, and they reached peak levels from day 10 to 15 after disease onset. Of the 175 patients, 165 developed significantly higher SARS-CoV-2–specific NAbs at the time of discharge compared with 13 uninfected controls. There were 10 patients whose NAb titers were less than the detectable level of the assay and two patients who showed very high titers of NAbs.

NAb titer levels in 82 men (1,417) were significantly higher than those in 93 women (905) at the time of discharge. Older patients and patients with a stronger inflammatory response also developed higher titers of NAbs.

In the 117 patients available for follow-up at 2 weeks post discharge, the median NAb titer in plasma at follow-up was 886, which investigators noted was significantly lower than at the median NAb titer at the time of discharge (1,110). The median levels of NAb titers were 1,049 in men and 751 in women. Patients who did not generate NAbs at the time of discharge did not develop detectable NAbs at the time of follow-up.

In an accompanying *editor’s note*, Mitchell H. Katz, MD, noted that investigators observed higher antibody levels in men, older patients and those with indicators of stronger immunologic response. However, men, older patients and those with stronger inflammatory response have generally fared...
worse. According to Katz, these findings suggest that the higher titers of antibodies may not necessarily lead to higher recovery rate.

In addition, Katz pointed out several additional questions that remain unanswered, such as whether higher levels of antibody production will result in greater protection against the virus and whether patients who did not develop NAbs are protected from future infection. The authors also concluded that further research is needed to understand the clinical implications of differing NAb titers for protection against future infection.

08/21/20 Big Data Is Focus of August Issue of AABB News

Big Data Is Focus of August Issue of AABB News

Big data and informatics are playing an increasingly significant role in health care. The August issue of AABB News focuses on the ways in which big data are being used to improve patient and donor outcomes in transfusion medicine. A feature article discusses how blood centers are utilizing large amounts of collected donor data to help donors manage their health, such as by providing them with information about their heart rate and blood pressure, and to help blood centers identify areas for operational improvement. Another feature article describes the process of developing a database — including data capture, processing and analysis — and examines the ways in which these data can be used to support best transfusion practices. In addition, the issue contains columns previewing some of the most anticipated education sessions scheduled for the 2020 AABB Virtual Annual Meeting and on contributions to COVID-19 research by National Blood Foundation early-career Scientific Research Grant Award recipients and data trends seen in AABB's weekly survey of hospital transfusion services.

08/21/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 22 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 139 respondents from 42 states completed survey, conducted Aug. 17-19.

The percentage of hospitals reporting delays greater than 24 hours in obtaining CCP units (24.6%) declined slightly this week; several hospitals (in states including California, Maryland, Mississippi, Ohio, Pennsylvania and Virginia) are reporting delays. The percentage of hospitals transfusing CCP (84.7%) was slightly lower compared to week 21. This week, 44.3% of hospitals reported prioritizing CCP to severely ill patients; but a declining trend is apparent since survey week 19. Among hospitals that made efforts to shift CCP use to favor patients early in the course of disease, 40.7% are doing so by providing information to ordering physicians and 30.6% are doing so by giving CCP as soon as O² needs rise above baseline.
Regarding CCP supply, 8% of responding hospitals reported an increase in product outdating due to pandemic-related changes. This is comparable to week 21. Of these hospitals, 54.5% reported that the product outdating was increased compared to last week. Furthermore, 2.2% of the responding hospitals that previously resumed elective surgeries put these procedures on hold, a declining trend that began during survey week 18 (week of July 20). A total of 18.1% (n=25) of responding hospitals received notice from their blood supplier that they will not be able to meet typical inventory needs, a slight increase compared to week 21. O-negative RBC was the most affected component this week.

In terms of in-patient census, 32.1% of responding hospitals are operating at 75-90% of pre-pandemic levels. Of the hospitals that resumed elective surgeries, 34.1% are operating their elective surgeries at 75-90% of pre-pandemic levels. Among the trigger points for canceling surgeries/procedures, the top three remain availability of ICU beds, availability of blood and COVID-19 caseload.

AABB will now conduct these surveys on alternating weeks. There will be no survey released next week. Past results are available on the AABB Survey and Reports web page.

08/21/20 OBI Hosts Governor for CCP Donation

**OBI Hosts Governor for CCP Donation**

Oklahoma Blood Institute (OBI) hosted Oklahoma Governor Kevin Stitt for a CCP donation at its Enid, Okla., donor center on Aug. 7. Stitt is the first governor in the United States to donate CCP. Following his donation, Stitt issued a call to government officials who have recovered from COVID-19 to donate as well. On Aug. 12, eight cabinet officials and Oklahoma state legislators answered Stitt’s call and donated CCP at the Oklahoma City Health and Innovation District donor center with Stitt in attendance. In total, Stitt, cabinet officials and Oklahoma legislators donated 26 blood products, receiving coverage on both local and national media.

08/21/20 CDC Announces Webinar on COVID-19-Associated VTE

**CDC Announces Webinar on COVID-19-Associated VTE**

CDC will [host a webinar](https://www.cdc.gov) on COVID-19 and thrombosis risk as part of the agency’s blood disorders public health webinar series. Peer-reviewed reports have raised concerns that the risk of venous thromboembolism (VTE) may be unusually high in patients with SARS-CoV-2 infection, even when standard pharmacologic prophylaxis is administered. In this program, speakers will summarize the evidence of COVID-19-associated VTE from research published in peer-reviewed publications, describe proposed mechanisms by which COVID-19 may increase the VTE risk and recount the latest guidelines for preventing VTE in patients who are hospitalized for COVID-19. The webinar will take place at 2 p.m. ET on Sept. 17. [Registration](https://www.cdc.gov) is complimentary, but attendees must register in advance.
FDA Warns of Risk of Inaccurate Results With Thermo Fisher Scientific TaqPath COVID-19 Combo Kit

FDA alerted clinical laboratory staff and health care providers to the risk of false results with the Thermo Fisher Scientific TaqPath COVID-19 Combo Kit. The alert, issued Monday, addresses two areas: instructions for vortexing and centrifugation of RT-PCR reaction plates, which Thermo Fisher Scientific has updated, and an issue related to the assay Internal Positive Control (IPC). This issue requires laboratory staff to upgrade software to resolve. The alert also includes the agency’s recommendations for individuals using the TaqPath COVID-19 Combo Kit.

FDA Officials Discuss Agency’s Response to COVID-19 in Health Affairs Blog

Anand Shah, MD, deputy commissioner for Medical and Scientific Affairs at FDA, and Stephen M. Hahn, MD, FDA commissioner, published a multi-part blog series outlining the regulatory landscape and key policy considerations for COVID-19. Shah and Hahn published the series this week on the Health Affairs blog to provide clarity to consumers, providers and policymakers on tests, therapeutics, vaccines and the agency’s response to COVID-19 during the first six months of the pandemic.

FDA Publishes Q&A Guidance on Inspections During COVID-19 Public Health Emergency

FDA announced the availability of a temporary guidance for industry, “Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers,” on Wednesday. The agency developed the guidance to answer frequently asked questions on regulatory and policy issues related to inspections, including an explanation of what the agency considers to be a “mission-critical” inspection; pending drug applications and changes in manufacturing facilities for approved pharmaceutical products. FDA intends for the guidance to remain in effect only for the duration of the COVID-19 public health emergency.

REGULATORY UPDATE: FDA Updates Investigational CCP Web Page

Patient Emergency IND” section includes updated instructions on how to enable, electronically complete and submit the Form FDA 3926. The Center for Biologics Evaluation and Research requests that all forms be completed electronically to facilitate a rapid review.

The agency now requests that age and gender be included in the patient’s brief clinical history, along with diagnosis, current therapy and rationale for requesting the investigational treatment in order to meet the expanded access use requirements in 21 CFR 312.305 and 312.310.

Updated information is included for requests made between 8 a.m. and 8 p.m. ET and for overnight emergency and non-critical requests. Also, when submitting the expanded access application form when the provider is unable to complete and submit Form FDA 3926 due to extenuating circumstances, the requestor is advised to indicate that the application is a follow-up to a previously granted emergency IND and to provide the IND number.

There agency did not revise the May 2020 Investigational COVID-19 Convalescent Plasma guidance.

Members may contact regulatory@aabb.org with questions.

08/21/20  FDA Pauses EUA Approval of CCP

**FDA Pauses EUA Approval of CCP**

The Food and Drug Administration put a hold on an emergency use authorization (EUA) for the use of COVID-19 convalescent plasma (CCP) to treat patients battling COVID-19, the *New York Times* reported on Wednesday. H. Clifford Lane, MD, the clinical director at the National Institute of Allergy and Infectious Diseases (NIAID), told the *Times* that the authorization is on hold as additional data is reviewed, but an emergency approval could be issued in the future.

The hold follows concerns from Lane and other health officials – including Francis S. Collins, MD, PhD, director of the National Institutes of Health; and Anthony S. Fauci, MD, director of NIAID – that recent data from Mayo Clinic’s COVID-19 expanded access program (EAP) and other studies was not strong enough to warrant an emergency approval.

Pre-print findings from Mayo Clinic published recently on medRxiv indicated that the mortality rate of patients who received plasma within three days of diagnosis was lower than it was for those who received plasma later (21.6% and 26.7%, respectively). Investigators also determined that the use of CCP with higher antibody levels was associated with reduced seven-day and 30-day mortality. Michael J. Joyner, MD, who is leading the EAP, discussed the findings last week in COVID-19 Clinician Call, which AABB co-hosted in partnership with the Infectious Diseases Society of America and Centers for Disease Control and Prevention (CDC).

Investigators from Houston Methodist recently published preliminary results from a trial of CCP in
the *American Journal of Pathology*. The research team found that transfusing patients who are critically ill with COVID-19 with high-antibody plasma early in their illness reduced the mortality rate. Data indicated that transfusion within 72 hours after hospitalization was most effective. The study was not randomized. Rather, every patient in the trial received CCP, and investigators compared their outcomes to similar patients with COVID-19 who did not receive CCP.

At least 10 randomized trials in the United States have collectively enrolled only a few hundred people, the *Times* reported. However, these trials have been stymied by the waning of the virus outbreak in many cities. This further complicates the ability of researchers to recruit patients, and some investigators worry that an emergency authorization could have the unintended effect of making it harder for rigorous clinical trials to demonstrate whether CCP is effective.

In a *statement* released today, AABB emphasized the importance of the preliminary findings from the Mayo Clinic EAP, which suggest that CCP can potentially be most effective when given early and that it may reduce mortality in some patients. AABB also reiterated its support for continuing research efforts on CCP through randomized controlled trials and encouraged those who have recovered to continue to donate CCP at their nearest blood center.

AABB continues to monitor ongoing communications from FDA regarding CCP and will update members as new information is available.

08/14/20 Early-Bird Registration for 2020 Virtual Annual Meeting Ends Aug. 19

Discounted early-bird registration for the 2020 Virtual Annual Meeting, to be held Oct. 3-5, ends Wednesday, Aug. 19. Individuals who register before the early-bird deadline can save $50 on the cost of registration. Although the meeting will take place virtually, AABB has ensured that this year’s program includes practice-changing information on the field’s critical topics, the latest scientific research and a plethora of professional development opportunities.

This year’s sessions address some of the most important topics currently facing the field, including sickle cell disease, pediatric transfusion medicine, therapeutic apheresis, alternatives to platelet transfusion, red cell genotyping, platelet inventory management, cellular and genetic therapies, blood collection and utilization, and much more. Several perennial favorite sessions – including “Ask the FDA” and “Ask the Standards” – will return this year as well. AABB will also add several hot topic sessions closer to the meeting, including some focusing on COVID-19.

Additional information, including the online program guide, is available online.
AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 21 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 143 respondents from 40 states completed the survey, conducted Aug. 10-12.

The percentage of hospitals reporting delays greater than 24 hours in obtaining CCP units increased this week (25.4%); several hospitals (in states including California, Maryland, North Carolina, New York and Ohio) reported delays. The percentage of hospitals transfusing CCP was higher compared to week 20 (85.2%). A plurality of the hospitals are prioritizing CCP to severely ill patients (46.4%).

With regard to blood utilization, 8.5% of respondents reported an increase in product outdating due to pandemic-related changes, a decline compared to week 20. Of these hospitals, 50% reported increased outdating compared to week 20. In addition, 2.1% of responding hospitals that previously resumed elective surgeries have put these procedures on hold, continuing a decline that began during week 18 (July 20).

Furthermore, 14.8% (n=21) of the respondents received notice that their blood supplier will not be able to meet typical inventory needs, a decline since survey week 16 (July 6). O-negative RBCs was the most affected component this week. A total of 48.6% of hospitals have implemented inventory management strategies to address product shortages.

In terms of inpatient census, 32.6% of responding hospitals are operating at 75-90% of pre-pandemic levels. Of the hospitals that resumed elective surgeries, 37.6% are operating their elective surgeries at 75-90% of pre-pandemic levels. Among the trigger points for canceling surgeries/procedures, the top three remain availability of ICU beds, availability of blood and COVID-19 caseload. The percentage of hospitals that considered availability of ICU bed increased this week.

Past results are available on the AABB Survey and Reports web page.

FDA Revokes EUA for Anti-SARS-CoV-2 Rapid Test

The Food and Drug Administration revoked the emergency use authorization (EUA) last week of the Autobio Diagnostics Co. Ltd.’s Anti-SARS-CoV-2 Rapid Tests for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human plasma from anticoagulated blood or serum 2. Based on the results of new testing, FDA concluded that it is unlikely that this test is effective in detecting SARS-COV-2 IgM antibodies and that the known and potential benefits of its use
do not outweigh the known and potential risks. “Therefore, the agency believes that the criteria for issuance of an authorization are no longer met and is revoking the EUA,” FDA said.

08/14/20 AABB CMO Claudia S. Cohn to Discuss CCP Efficacy, Supply on IDSA’s Weekly Clinician Call

AABB CMO Claudia S. Cohn to Discuss CCP Efficacy, Supply on IDSA’s Weekly Clinician Call

AABB’s Chief Medical Officer Claudia S. Cohn, MD, PhD, will present as part of a panel on the efficacy and supply of COVID-19 convalescent plasma (CCP) in an upcoming COVID-19 Clinician Call hosted in partnership with the Infectious Diseases Society of America (IDSA). IDSA and Centers for Disease Control and Prevention host the Clinician Call – a weekly one-hour teleconference – to explore timely issues relevant to clinicians. Each call features case presentations by experts in the field, synthesis of new data and an opportunity to engage with colleagues during Q&A and discussion.

The COVID-19 Clinician Call will take place at 3 p.m. ET on Saturday, Aug. 15. It will feature presentations from Cohn, who is the associate director of Laboratories and director of the Blood Bank Laboratory at the University of Minnesota in addition to her role at AABB; as well as Sean T. Liu, MD, PhD, of the Icahn School of Medicine at Mount Sinai in New York City; and Michael J. Joyner, MD, of the Mayo Clinic in Rochester, Minn. Dana S. Wollins, DrPH, MGC, IDSA’s vice president, Clinical Affairs & Practice Guidelines, will moderate the event.

Registration for the event is complimentary and available online.

08/14/20 NBF Announces Recipients of 2020 Scientific Research Grants

NBF Announces Recipients of 2020 Scientific Research Grants

AABB’s National Blood Foundation (NBF) recently announced the recipients of the 2020 early-career Scientific Research Grants. Annamaria Aprile, PhD; Agnieszka Czechowicz, MD, PhD; Areum Han, PhD; Robert H. Lee, PhD; Larry Luchsinger, PhD; Evan Orenstein, MD; David Roh, MD; and Kim Vanuytsel, PhD, will each receive a grant of up to $75,000 to further a one- or two-year research project. These are the latest researchers to receive funding from the NBF, which has fueled early-career research in the fields of transfusion medicine and cellular therapies for more than 30 years.

“Looking back on the NBF legacy, it is clear that the contributions of NBF recipients to the understanding and treatment of diseases that rely on transfusion medicine and biotherapies have been nothing short of remarkable,” said Jim Gorham, MD, PhD, chair of the NBF Scientific Research Grants Review Committee. “This is no more vividly illustrated than in 2020, as scientists supported by the NBF have made, and continue to make, highly impactful discoveries about COVID diagnosis and treatment to the benefit of all throughout the world. We are thrilled to welcome this new cadre of early-career scientists to the NBF family and look forward to seeing their impact on the understanding of disease and the delivery of life-saving transfusions to patients in need.”
AABB and the NBF congratulate this year’s awardees. This year, the grants will fund research in the following areas:

- Exploring the role of fibroblast growth factor 23 (FGF23) in beta thalassemia (Apile).
- Determining the genetic factors and mutations that regulate progression to bone marrow failure and myeloid neoplasia in Fanconi anemia (Czechowicz).
- Investigating the role of the RNA editor-exonuclease axis in RNA turnover during erythropoiesis (Han).
- Exploring the efficacy of platelet transfusion in the setting of antiplatelet therapy (Lee).
- Discovering whether plasma membrane signaling pathways underpin hematopoietic stem cell (HSC) function and developing HSC expansion methods to generate blood products in vitro (Luchsinger).
- Improving patient blood management in pediatrics through automated medical error detection and clinical decision support design (Orenstein).
- Exploring the contribution of red blood cells to coagulopathy and cerebral oxygenation after intracerebral hemorrhage (Roh).
- Validating the efficacy of novel therapeutic gene editing strategies across a diverse sickle cell disease (SCD) patient population using a patient-specific induced pluripotent stem cell (iPSC) platform as a preclinical screening tool (Vanuytsel).

Making a gift to the NBF supports early-career researchers seeking future medical breakthroughs across pediatrics, oncology, cardiology and transplantation. AABB urges members to continue to invest in emerging research by making a tax-deductible gift to the NBF today.

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**08/07/20 AABB Completes First Fully Virtual Assessment**

AABB is pleased to announce the successful completion of the Association’s first entirely virtual assessment. AABB conducted the remote cellular therapy assessment of a facility in Hong Kong, China, using APEX, AABB’s accreditation portal; a set of forms developed specifically for virtual assessments; and a combination of email, Zoom calls and cellphone video. AABB has previously conducted in-person assessments of the facility.

AABB introduced virtual assessments to ensure that AABB assessors are able to perform required assessments safely and effectively during the COVID-19 pandemic. The Association intends to conduct future virtual international assessments in instances where travel is restricted or impractical.

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**08/07/20 ACBTSA to Discuss Public Health Emergency Response at Aug. 26-27 Meeting**

ACBTSA to Discuss Public Health Emergency Response at Aug. 26-27 Meeting
The Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will discuss recommendations to improve the blood community’s response to future public health emergencies at its [next public meeting](#). The meeting will take place virtually Aug. 26-27 and will include key stakeholders from throughout the United States, including AABB CEO Debra BenAvram, FASAE, CAE, to discuss lessons learned during the latest pandemic. The Committee will also analyze strengths and weaknesses of the blood community’s COVID-19 response.

The public will have an opportunity to present their views to the ACBTSA during the meeting’s public comment session or by submitting written comments. Those who wish to provide spoken or written comments should review instructions and respond by 11:59 p.m. ET on Aug. 17. Those providing oral comments will be limited to 3 minutes each to accommodate as many speakers as possible.

Additional information, including a meeting agenda and registration, is available [online](#).

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**REGULATORY UPDATE: CDC Revises COVID-19 Travel Health Notices**

The Centers for Disease Control and Prevention (CDC) revised information on its [Travel Health Notices web page](#) this week. The revisions included a move to “Watch Level 1” for COVID-19 in Thailand, New Zealand and Fiji, as well as Bonaire, Sint Eustatius and Saba in the Dutch Caribbean and Saint Barthélemy. “Watch Level 1” recommends that travelers “practice usual precautions for this destination.” The remaining COVID-19 Travel Health Notices continue as “Warning Level 3, Avoid Nonessential Travel.”

Also included on the updated page is a link to the [COVID-19 Travel Recommendations by Country web page](#), where CDC has posted a list of 13 countries in which COVID-19 risk is very low and for which the agency is currently not issuing travel health notices.

AABB reminds members of FDA’s [current thinking](#) that “respiratory viruses, in general, are not known to be transmitted by blood transfusion. There have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide.”

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**AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services**

AABB released a [graphic summary](#) of the week 20 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 152 respondents from 40 states completed survey, conducted Aug. 3-5.

The percentage of hospitals reporting delay of more than 24 hours in obtaining CCP units declined to
22.1% this week; several hospitals in states with the highest number of COVID-19 cases in last 7 days are reporting delays. The percentage of hospitals transfusing CCP (78.7%) was slightly higher than week 19. Most hospitals are prioritizing CCP to severely ill patients (46.1%). In addition, 67.2% hospitals reported that CCP use would not be affected if the hospitals had to absorb the cost of CCP units, a slight increase compared to week 19.

This week, 10% of respondents reported an increase in product outdating due to pandemic-related changes, an increase compared to week 19. Of these hospitals, 66.7% reported that the outdating increased compared week 19.

With regard to the blood utilization, 2.6% of responding hospitals that previously resumed elective surgeries have put these procedures on hold, a decline from weeks 18 and 19. In addition, 23% (n=35) of hospitals received notice from their blood supplier that they will not be able to meet typical inventory needs. Platelets were the most affected component this week. Of all respondents, 47.4% have implemented inventory management strategies to address these shortages.

In terms of in-patient census, 34.2% of responding hospitals are operating at 75-90% of pre-pandemic levels. Among hospitals that resumed elective surgeries, 34.1% are operating at 75-90% of pre-pandemic levels. Among the trigger points for canceling surgeries/procedures, the top 3 remain ICU bed availability, blood availability and COVID-19 caseload. The percentage of hospitals that considered availability of PPE increased slightly this week.

Past results are available on the AABB Survey and Reports web page.

08/07/20 NIAID to Study mAbs in Patients With Mild and Moderate COVID-19, Hospitalized Patients

**NIAID to Study mAbs in Patients With Mild and Moderate COVID-19, Hospitalized Patients**

Investigators from the National Institute of Allergy and Infectious Diseases (NIAID) will evaluate the safety and efficacy of LY-CoV555, an investigational monoclonal antibody (mAb), in two new clinical trials. These trials may lead to later investigations of other experimental therapeutics under the same trial protocol.

The phase 2 [ACTIV-2 trial](#) will enroll 220 volunteers who report recently experiencing symptoms of COVID-19 and who test positive for the virus but are not hospitalized. If there are no serious safety concerns during phase 2, and if the investigational therapeutic appears to meet other specific criteria, the trial will transition to phase 3.

In the phase 3 [ACTIV-3 trial](#), investigators aim to enroll approximately 300 volunteers who have been hospitalized with mild to moderate COVID-19 with fewer than 13 days of symptoms. Investigators will assess symptoms after 5 days to determine whether the investigational therapeutic will be
administered to a larger group of volunteers. If LY-CoV555 appears to be safe and effective, the trial will enroll an additional 700 participants. Investigators will also enroll more severely ill participants.

Researchers from NIAID’s Vaccine Research Center discovered LY-CoV555 in partnership with AbCellera Biologics of Vancouver, B.C., Canada, after isolating it from a blood sample from a patient who recovered from COVID-19. LY-CoV555 is made by Eli Lilly.

08/07/20 FDA Authorizes First Tests That Estimate a Patient’s Antibodies from Past SARS-CoV-2 Infection

**FDA Authorizes First Tests That Estimate a Patient’s Antibodies from Past SARS-CoV-2 Infection**

FDA recently authorized the first two COVID-19 serology tests that display an estimated quantity of antibodies present in the individual’s blood. The tests – the ADVIA Centaur COV2G and Atellica IM COV2G (Siemens) – are “semi-quantitative” tests, meaning they do not display a precise measurement, but estimate the number of antibodies produced against infection with the SARS-CoV-2 virus. In the announcement, FDA reminded patients that serology tests should not be used to diagnose an active infection, since they only detect antibodies that the immune system develops in response to the virus.

08/07/20 REGULATORY UPDATE: Investigational Vaccines and Deferral for Donors of Blood and Convalescent Plasma

**REGULATORY UPDATE: Investigational Vaccines and Deferral for Donors of Blood and Convalescent Plasma**

Investigational vaccines will soon be distributed in response to the SARS-CoV-2 pandemic, with a vaccine from Moderna expected this month. Because there are currently no applicable regulations and recommendations to address eligibility of the many blood donors that will be vaccinated in the coming months, AABB sought to clarify the impact of these investigational vaccines on donor eligibility for collections of blood and blood components, including donors of COVID-19 convalescent plasma (CCP). The [Donor History Questionnaire v2.1](https://www.aabb.org/AABB-Resources/Donor-Resources/DHQ/v2.1) (DHQ v2.1) will assess donors to identify risk for these vaccines. AABB’s 32nd edition of Standards for Blood Banks and Transfusion Services (BB/TS) apply as well.

AABB learned in prior communications with the FDA that receipt of vaccines does not automatically require a lengthy deferral, as seen when considering the infectious risk with live attenuated vaccines and non-replicating, inactivated or RNA-based vaccines. With this in mind, AABB requested the agency’s advice on investigational vaccines for SARS-CoV-2 on behalf of the Donor History Task Force. The request included information specific to the upcoming release of the [investigational mRNA-1273 vaccine](https://www.aabb.org/AABB-Resources/Donor-Resources/DHQ/v2.1) from Moderna. mRNA is a type of vaccine that does not include infectious elements in the development process and, as such, was not expected to trigger a donor deferral.

AABB received the following expedited response from FDA:
“FDA recognizes AABB’s DHQ which includes unlicensed (experimental) vaccines on the medication deferral list as a 12-month deferral or as indicated by the responsible physician.

“For routine blood donation, the responsible physician may wish to consider the potential infectious risk associated with the vaccines, and the use of short deferral periods (e.g., 14 days) for live attenuated vaccines and no deferral for non-replicating, inactivated or RNA-based vaccines.

“We agree that no deferral is necessary for routine blood donors who might have received the mRNA-1273 Moderna vaccine.

“At this time, we suggest that individuals who have received a COVID-19 investigational vaccine should not donate COVID-19 convalescent plasma until further information is available about their antibody profile.”

AABB notes that FDA’s advice for blood donors is consistent with medical director discretion provided in current BB/TS Reference Standard 5.4.1A #14 and DHQ v2.1 Question #8 flowchart.

AABB will continue to share new information in support of the policy decisions by medical directors, recognizing that some blood collectors will defer based on the specific vaccine, while others will prefer to simplify operations with a general deferral that does not require eliciting specific information for the vaccine type. AABB Reference Standard 5.4.1 #14 and DHQ v2.1 Question #8 flowchart support either approach.

Members with questions may contact AABB Regulatory Affairs.

08/07/20 AABB Releases 2020 Virtual Annual Meeting Program Guide

AABB Releases 2020 Virtual Annual Meeting Program Guide

AABB is pleased to release a detailed program guide for the 2020 Virtual Annual Meeting, to be held Oct. 3-5. AABB’s 2020 Virtual Annual Meeting will feature myriad scientific sessions, dozens of oral abstracts and more than 300 scientific posters. Although the meeting will take place virtually, AABB has ensured that this year’s program includes practice-changing information on the field’s most pressing topics, the latest scientific research and plenty of professional development opportunities.

This year’s sessions address some of the most important topics currently facing the field, including sickle cell disease, pediatric transfusion medicine, therapeutic apheresis, alternatives to platelet transfusion, red cell genotyping, platelet inventory management, cellular and genetic therapies, blood collection and utilization. Several perennial favorites – “Ask the FDA & CMS/CLIA,” “Wizardry School of Antigens and Antibodies,” and “Test Your Blood Bank Knowledge” – will return this year as well. In addition, AABB will add several hot topic sessions closer to the meeting, including those focusing on
COVID-19.

“[This year’s] sessions will span topics from the cutting-edge to returning favorites, and will exceed expectations,” said Gay Wehrli, MD, MBA, MSEd, chair of the AABB Annual Meeting Education Committee. “The 2020 AABB Annual Meeting curriculum addresses educational needs for the breadth of attendees’ professional backgrounds – from basic science research to biotherapies to blood collection centers and clinical-based services. Whether you are a first-time or returning attendee, we will not disappoint.”

AABB designed the program guide with a user-friendly interface allowing users to browse by date, topic, presenter, type of session or keyword. Registration information is available on the 2020 Virtual Annual Meeting website.

07/31/20 Late-Breaking Annual Meeting Abstracts Due Today

Late-Breaking Annual Meeting Abstracts Due Today

Today is the deadline to submit late-breaking abstracts for the virtual 2020 AABB Annual Meeting. While the Association expects that many late-breaking abstracts will reflect research related to COVID-19, AABB encourages submissions on all topics. AABB is allowing COVID-19-related abstracts that were submitted during the general abstract submission period to be resubmitted as late-breaking abstracts if the data and research have been expanded since the original submission. Additional information is available in AABB’s late-breaking abstract guidelines. Interested individuals may submit their abstracts online. The 2020 AABB Annual Meeting will be held virtually Oct. 3-5.

07/31/20 REGULATORY UPDATE: FDA Updates List of Variance Approvals

REGULATORY UPDATE: FDA Updates List of Variance Approvals

CBER recently updated the list of exceptions and alternative procedures approved under 21 CFR 640.120. This week, the agency approved an exception to the distribution and 60-day quarantine hold requirements of section 640.69(e)&(f) for use with COVID-19 convalescent source plasma units collected by blood establishments licensed to collect source plasma for the commercial manufacture of COVID-19 hyperimmune globulin (Anti-COVID-19 H-IG).

In a second approval, FDA granted an exception to section 600.15(a) to release for transfusion 27 red blood cell units collected from whole blood that were exposed to a storage temperature of 12.4 degrees Celsius for approximately 5 hours upon receipt.

Under Title 21 of Federal Regulations section 640.120(a), the director of CBER may approve an exception or alternative to any requirement in subchapter F of chapter 1 of Title 21 of the Code of Federal Regulations regarding blood, blood components or blood products. FDA noted that “requests for exceptions or alternate procedures include specific circumstances and may require submission of
supporting data unique to the circumstance. Publication of these approvals for a specific exception or alternative procedure does not necessarily mean that they can be generally applied to other manufacturers.”

07/31/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 19 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 163 respondents from 44 states completed survey conducted July 27-29.

The percentage of hospitals reporting delays greater than 24 hours in obtaining CCP units increased this week (28.4%). Several hospitals reporting delays are in states with the highest number of COVID-19 cases in the last 7 days (including California, Florida and Texas). The percentage of hospitals transfusing CCP (77.8%) was comparable to week 18. Most hospitals (50%) are prioritizing CCP to severely ill patients. In addition, 64.7% of hospitals reported that CCP use would not be affected if the hospitals had to absorb the cost of CCP units.

This week, 7.5% of respondents reported an increase in product outdating due to the pandemic, an increase compared to week 18. Of these hospitals, 50% reported the outdating increased compared to last week.

With regard to elective surgeries, 3.7% of responding hospitals that previously resumed elective surgeries reported delaying these procedures, a decline from week 18. In addition, 22.8% of respondents received notice from their blood supplier that they will not be able to meet typical inventory needs, a continued decline since the week of June 29. O-positive RBCs were the most affected component this week. A total of 48.5% of these hospitals have implemented inventory management strategies to address these shortages.

In terms of inpatient census, 36.4% of the responding hospitals are operating at 90-99% of pre-pandemic levels. Of the hospitals that resumed elective surgeries, 33.3% are operating elective surgeries at 90-99% of pre-pandemic levels. Among the trigger points for canceling surgeries/procedures, the top 3 remain availability of ICU beds, availability of blood and COVID-19 caseload. The percentage of hospitals that considered availability of ICU beds and COVID-19 caseload increased slightly this week.

Past results are available on the AABB Survey and Reports web page.

07/31/20 UK’s NHS Launches COVID-19 Vaccine Registry

UK’s NHS Launches COVID-19 Vaccine Registry
The United Kingdom’s National Health Service (NHS) launched a service last week to enable people across the U.K. to sign up for information on COVID-19 vaccine trials. The NHS COVID-19 vaccine research registry aims to recruit large numbers of people into trials over the coming months. The system will allow researchers to quickly identify and match volunteers with appropriate vaccine trials. Additional information about ongoing vaccine research in the U.K. is available online.

07/31/20 DOD Awards Johns Hopkins $35 Million to Study CCP

**DOD Awards Johns Hopkins $35 Million to Study CCP**

The Department of Defense (DOD) Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) recently awarded researchers at Johns Hopkins University $35 million to conduct two nationwide clinical trials to test the effectiveness of CCP outpatient treatment. Investigators will conduct the randomized double-blind trials totaling 1,100 people at more than 20 ambulatory clinics across the U.S. The trial will help researchers determine whether CCP therapy can effectively be used to treat people in the early stage of COVID-19 illness or prevent the infection in higher-risk populations.

07/31/20 Federal Agencies Announce COVID-19 Data Partnership

**Federal Agencies Announce COVID-19 Data Partnership**

The Department of Energy (DOE), Department of Health and Human Services (HHS) and Department of Veterans Affairs (VA) announced Tuesday the formation of the COVID-19 Insights Partnership to coordinate and share health data, research and expertise to aid in the fight against COVID-19. Research and analysis conducted by the COVID-19 Insights Partnership will focus on vaccine and therapeutic development and outcomes, virology and other critical scientific topics to better understand COVID-19. HHS and VA will provide additional updates and information on research projects as they become available.

07/31/20 Phase 3 Clinical Trial of Investigational COVID-19 Vaccine Begins

**Phase 3 Clinical Trial of Investigational COVID-19 Vaccine Begins**

A phase 3 clinical trial of mRNA-1273, an investigational vaccine to prevent symptomatic COVID-19, has begun, the National Institutes of Health announced on Monday. Investigators expect the trial to enroll approximately 30,000 adult volunteers who do not have COVID-19.

Trial volunteers will receive two intramuscular injections approximately 28 days apart. Participants will be randomly assigned to receive either two 100 microgram injections of mRNA-1273 or two shots of a saline placebo. The trial is blinded, so the investigators and the participants will not know who is assigned to which group.
The vaccine is designed to induce neutralizing antibodies directed at a portion of the coronavirus “spike” protein, which the virus uses to bind to and enter human cells. A phase 1 clinical trial found the candidate vaccine to be safe, generally well-tolerated and able to induce antibodies with high levels of virus-neutralizing activity. Moderna, which developed the vaccine in partnership with the National Institute of Allergy and Infectious Diseases, initiated phase 2 testing of the vaccine in May.

07/31/20 CMS Introduces New Hospital Procedure Codes for CCP in Response to the COVID-19 Public Health Emergency

CMS Introduces New Hospital Procedure Codes for CCP in Response to the COVID-19 Public Health Emergency


These new codes will enable CMS to conduct real-time surveillance and obtain real-world evidence in how these drugs are working and provide critical information on their effectiveness. These codes can be reported to Medicare, and other insurers may also use the codes to identify the use of COVID-19 therapies and help facilitate monitoring and data collection on their use.

07/31/20 FDA Authorizes First Diagnostic Test for Screening People Without Known or Suspected COVID-19 Infection

FDA Authorizes First Diagnostic Test for Screening People Without Known or Suspected COVID-19 Infection

FDA reissued the LabCorp COVID-19 RT-PCR diagnostic test emergency use authorization (EUA) July 24 for people who do not have COVID-19 symptoms or who have no reason to suspect COVID-19 infection. FDA also granted authorization for LabCorp to conduct pooled sample testing containing up to five individual swab specimens collected under observation.

FDA’s March 16 EUA authorized the LabCorp test for use only in people suspected of being ill with COVID-19 by their health care provider and for testing of individual specimens without sample pooling. The July 24 authorization eliminates the need for a provider to consider risk factors such as exposure or community spread when prescribing this test. The LabCorp test remains available by prescription only. Only health care provider-collected samples may be pooled at this time.
REGULATORY UPDATE: AABB Requests FDA Feedback Regarding Eligibility Requirements for Donors Receiving COVID-19 Vaccine

As investigational vaccines for SARS-CoV-2 are distributed, AABB anticipates that many blood donors will be vaccinated in the near future. AABB has expedited its process to determine if receipt of these investigational vaccines will affect blood donor eligibility.

In the absence of regulations or recommendations to specifically address eligibility for donors who receive an investigational vaccine, AABB requested advice from FDA. The Center for Biologics Evaluation and Research has provided assistance with past AABB inquiries, including FDA’s 2019 decision that no deferral was required for Jynneos (an attenuated, live, non-replicating smallpox and monkeypox vaccine manufactured by Bavarian Nordic), provided the donor is otherwise healthy as required under 21 CFR 630.10 and section 630.15.

AABB will provide updates as new information is received from the agency. Members with questions may contact Regulatory Affairs.

REGULATORY UPDATE: AABB Asks for FDA Input on Return of Blood from a COVID-19 Patient Room

AABB has received multiple questions regarding the return of blood components issued to a patient with COVID-19. Early in the pandemic, AABB confirmed its understanding regarding the return to inventory of a blood component which otherwise meets all criteria as defined in a facility’s policies and procedures, but had entered the room of a patient with COVID-19.

The Food and Drug Administration does not have additional recommendations, guidance, procedures or protocols related to infection control specific to COVID-19 or to managing blood products that have been issued for use and are later returned to the blood bank after possible exposure to the SARS-CoV-2 virus.

AABB agrees with FDA’s advice:

“We suggest you communicate your concerns to your facility’s infectious disease management department with a focus on specific infection control policies/procedures in place to help avoid exposure and cross-contamination of blood products and patients with pathogens within the hospital environment, especially in the midst of the COVID-19 pandemic.

“We recognize that the option to discard units would not be prudent considering possible blood
shortages.

“While the COVID-19 virus is not well understood at this time and may respond differently to standard viral decontamination routines, we suggest that you follow the protocols that should already be in place in your facility.

“If you decide to use a decontamination method, you should determine that it does not interact with the product in such a manner as to have an adverse effect on the product or obscure the label.”

AABB will continue to work closely with FDA and other public health authorities to address member interests and concerns. AABB encourages members to contact Regulatory Affairs with questions.

07/31/20 Trump Issues ‘National Call to Action’ for CCP Donation

Trump Issues ‘National Call to Action’ for CCP Donation

President Donald Trump joined health officials and blood and plasma community leaders to issue a “national call to action” to combat COVID-19 at a Thursday roundtable. A key part of this initiative includes encouraging convalescent plasma (CCP) donations from individuals who have recovered from COVID-19.

The event, hosted by the American Red Cross (ARC), included an explanation on how CCP can be used in the treatment of patients with COVID-19, updates on the status of CCP donor recruitment initiatives, discussion of the plasma-derived therapeutics in development, and the latest developments on clinical trials. Speakers from the blood and plasma community included Gail J. McGovern, CEO of ARC; Kate Fry, CEO of America’s Blood Centers; Paul Perreault, CEO of CSL Limited; and Adam Schechter, CEO of LabCorp. At the roundtable, the Trump Administration announced that it will invest $48 million in manufacturing CCP through the Mayo Clinic Expanded Access Program and will provide up to $270 million to ARC and America’s Blood Centers (ABC) to collect a goal of 360,000 CCP units.

Following the roundtable, AABB issued a statement in support of efforts to recruit CCP donations and research to further evaluate CCP as a potential therapy for patients with COVID-19.

The Trump Administration also released a series of public service announcements and announced an $8 million ad campaign to encourage Americans to donate plasma. The PSAs feature the nation’s top health officials and seek to dramatically increase donations of CCP by the end of August.

07/24/20 July Issue of AABB News Highlights Fluctuating Blood Supply, Relationship Testing Applications in Diverse Fields

July Issue of AABB News Highlights Fluctuating Blood Supply, Relationship Testing Applications in Diverse Fields
The COVID-19 pandemic has had an outsize impact on the blood supply, leading to cancelled blood drives and large variations in both the need for and supply of blood and blood components. The July issue of AABB News explores how blood banks and transfusion services have managed these large fluctuations while protecting donor and patient safety. Another feature describes the areas beyond paternity testing in which relationship testing labs are changing people’s lives, including in criminal investigations and immigration cases. Other articles address AABB’s plans for an all-virtual 2020 Annual Meeting and the newly released 20th edition of the Technical Manual.

A new column from AABB Chief Medical Officer Claudia Cohn, MD, debuts this month, as well. Through the column, “Conversation With the CMO,” Cohn seeks to inspire conversation in the blood community on pressing issues in transfusion medicine. The inaugural column focuses on the need for real-time data on blood collection and use. Associated posts will appear on Facebook, LinkedIn and Twitter.

07/24/20 AABB Members Receive Complimentary Access to On-Demand CCP Session

AABB Members Receive Complimentary Access to On-Demand CCP Session

AABB is pleased to provide Association members with complimentary on-demand access to “Hot Topic: Convalescent Plasma - International Perspectives,” a session from the Annual Meeting Highlights Conference in the Middle East, held virtually last month.

In this session, four experts – Miquel Lozano, MD, PhD, from Hospital Clínic de Barcelona in Barcelona, Spain; Jose Mauro Kutner, MD, PhD, from Hospital Israelita Albert Einstein in São Paulo, Brazil; Beth Shaz, MD, from the Marcus Center for Cellular Cures at Duke University; and Cheuk-Kwong Lee, MD, from Hong Kong Red Cross Blood Transfusion Service in Hong Kong, China – discussed their experience with collecting CCP. This broad conversation, moderated by Jed Gorlin, MD, MBA, of Innovative Blood Resources, addressed donor qualification, collection, dosing, and patient selection criteria and included an extended panel discussion to answer audience questions. In addition, Lee drew comparisons to work with convalescent plasma during the H1N1 and SARS pandemics.

Members may access the session at no cost in the AABB Marketplace or on the AABB Education Platform. Non-members may purchase access in the AABB Marketplace, as well. Continuing medical education (CME) and continuing education (CE) credit are available.

07/24/20 Late-Breaking Annual Meeting Abstracts Due July 31

Late-Breaking Annual Meeting Abstracts Due July 31

The deadline to submit late-breaking abstracts for the virtual 2020 Annual Meeting is July 31. While the Association expects that many late-breaking abstracts will reflect research related to COVID-19, AABB encourages submissions on all topics. Due to the unique circumstances resulting from the pandemic, AABB is allowing COVID-19-related abstracts that were submitted during the general abstract submission period to be resubmitted as late-breaking abstracts if the data and research have been
expanded since the original submission. Abstracts that have been published, presented or accepted for publication or presentation prior to July 31 will not be considered. AABB will publish accepted late-breaking abstracts in the online edition of *Transfusion*. Additional information is available in AABB’s late-breaking abstract guidelines. Interested individuals may submit their abstracts online.

**07/24/20 AABB, ASCP Partner to Launch National Blood Donation Awareness Campaign**

**AABB, ASCP Partner to Launch National Blood Donation Awareness Campaign**

AABB is **partnering** with the American Society for Clinical Pathology (ASCP) to launch a national campaign urging people to donate blood. The initiative is designed to educate the public about the need for blood donation during the COVID-19 pandemic, how to **connect with their local blood centers** to understand the needs within their communities, and why blood donation is always important. By combining their efforts, AABB and ASCP hope to broaden their reach by amplifying the message across their respective constituencies. The Associations will encourage members share this information on their social media channels and with family, friends and colleagues. The campaign will also include a patient-facing initiative, as well.

**07/24/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services**

**AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services**

AABB released a **graphic summary** of the week 18 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 175 respondents from 41 states completed the survey, conducted July 20-22.

The percentage of hospitals reporting delays greater than 24 hours in obtaining COVID-19 convalescent plasma (CCP) units showed an increase this week (19.1%); several hospitals reporting delays are in states with the highest number of COVID-19 cases (including California, Florida and Texas). The percentage of hospitals transfusing CCP showed an increase (77.9%) compared to week 17. A plurality of hospitals is prioritizing CCP to severely ill patients (46.4%). The percentage of hospitals that reported not being billed for CCP units by their blood supplier was 70.1%, an increase compared to previous weeks. Of these hospitals, 63.6% reported that CCP use would not be affected if the hospitals had to absorb the cost of CCP units, an increase compared to past weeks.

This week, 4.6% of respondents reported an increase in product outdating due to pandemic-related changes, a decrease compared to week 17. Of these hospitals, 62.5% reported outdating at the same level as week 17. In addition, 4.6% of the responding hospitals that previously resumed elective surgeries have put these procedures on hold, an increase from week 17. A total of 26.6% (n=46) of the hospitals received notice from their blood provider that they will not be able to meet typical inventory needs, a continued decline since the week of June 29. O-negative RBCs was the most
affected component this week. A total of 51.4% of respondents have implemented inventory management strategies to address these shortages.

Regarding inpatient census, 31% of the responding hospitals are operating at 75-90% of pre-pandemic levels. Of the hospitals that have resumed elective surgeries, 31.9% are operating their elective surgeries at 75-90%, of pre-pandemic levels. Among the trigger points for canceling surgeries/procedures, the top three reasons remain availability of ICU beds, availability of blood, and COVID-19 caseload. The percentage of hospitals considering the availability of personal protective equipment, availability of blood, and testing capacity increased this week, as well.

Past results are available on the AABB Survey and Reports web page.

07/24/20 OCR Issues Guidance on Title VI Civil Rights Protections During COVID-19

OCR Issues Guidance on Title VI Civil Rights Protections During COVID-19

The Office for Civil Rights (OCR) within HHS issued additional guidance July 20 to ensure that federal financial assistance recipients understand that they must comply with applicable federal civil rights laws and regulations that prohibit discrimination in HHS-funded programs during the COVID-19 pandemic. The bulletin focuses on recipients' compliance with Title VI of the Civil Rights Act of 1964, which addresses discrimination on the basis of race, color and national origin.

07/24/20 HHS Launches COVID-19 Data System

HHS Launches COVID-19 Data System

The U.S. Department of Health and Human Services (HHS) launched HHS Protect, a new data ecosystem, July 20 to aggregate COVID-19 information from the agency’s various operating divisions. HHS Protect aims to provide near-real-time information to help federal, state and local leaders make strategic decisions and maximize resources. It includes more than 200 datasets, including hospital-specific information such as inpatient bed utilization, ICU bed utilization, percentage of inpatient beds occupied by patients with and the number of COVID-19 cases. Additional information is available on the HHS Protect frequently asked questions web page.

07/24/20 FDA Approves First EUA for SARS-CoV-2 Test With Pooled Samples

FDA Approves First EUA for SARS-CoV-2 Test With Pooled Samples

FDA reissued an Emergency Use Authorization (EUA) to Quest Diagnostics July 18 for its Quest SARS-CoV-2 rRT-PCR test, which is now approved for use with pooled samples containing up to four individual upper-respiratory swab specimens collected under observation. The Quest test is the first COVID-19 diagnostic test to be authorized for use with pooled samples.
FDA Resumes Domestic Inspections Using Risk Assessment System

The Food and Drug Administration planned to resume domestic inspections of regulated facilities this week using a rating system to help the agency determine when and where it is safest to conduct prioritized domestic inspections, according to an announcement from FDA Commissioner Stephen Hahn, MD. FDA paused on-site surveillance inspections in the United States in March, instead conducting mission-critical inspections using remote assessments and other compliance strategies.

The COVID-19 Advisory Rating system (COVID-19 Advisory Level) uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national information. FDA bases the advisory level on the outcome of three metrics: Phase of the State (as defined by the White House guidelines) and statistics measured at the county level to gauge the current trend and intensity of infection. FDA will use these metrics to assign each county a COVID-19 Advisory Level, which determines what regulatory activities can safely occur within that geographic region. The three main categories of regulatory activity at the county level will be: mission-critical inspections only; all inspections, with caveats to help protect staff who have self-identified as being in a vulnerable population; and resumption of all regulatory activities.

Hahn emphasized that resuming prioritized domestic inspections will depend on the data about the virus’s trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The agency also determined that prioritized domestic inspections will be pre-announced to FDA-regulated businesses to help protect the investigator and the firm’s employees, provide the safest possible environment to accomplish regulatory activities, and ensure that appropriate staff are on-site to assist FDA staff with inspection activities.

REGULATORY UPDATE: FDA Confirms That Registered Blood Establishments May Ship CCP Between States

In response to a growing number of questions, AABB Regulatory Affairs is clarifying that registered (but not licensed) blood establishments are permitted to ship CCP across state lines for investigational use under an approved IND, as confirmed by FDA in March 2020.

AABB verified that the agency’s thinking on this issue has not changed as blood establishments begin planning to support the surge storage inventory. The following is the most current information from FDA:

“CCP is an investigational product, and registered-only blood establishments can ship CCP across state lines to stockpile locations for future investigational use. Blood centers that collect and distribute COVID-19 convalescent plasma for investigational use must label the units with the following
statement, ‘Caution: New Drug--Limited by Federal (or United States) law to investigational use,’ and should follow the recommendations in FDA’s guidance document, ‘Recommendations for Investigational COVID-19 Convalescent Plasma.’ A registered-only establishment cannot ship standard FFP or PF24 units across state lines.”

FDA is available to address facility specific questions as they arise.

07/17/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 17 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 169 respondents from 41 states completed survey, conducted July 13-15.

A total of 8.3% of responding hospitals reported an increase in product outdating due to changes related to the pandemic, an increase compared to week 16. Of these hospitals, 71.4% reported outdating at the same level compared to week 16.

Regarding blood utilization, 3% of the responding hospitals that resumed elective surgeries previously have put these procedures on hold, a decline from week 16. In addition, 32.1% (n=54) of the hospitals were alerted that their blood supplier will not be able to meet typical inventory needs, a decline compared to week 16. O-negative was the most affected component this week. A total of 53.8% of respondents have implemented inventory management strategies to address these shortages.

In terms of inpatient census, 34.3% of the responding hospitals are operating at 75-90% of pre-pandemic levels. Of the hospitals that resumed elective surgeries, 34.5% are operating their elective surgeries at 75-90% of pre-pandemic levels. Among the trigger points for canceling surgeries/procedures, the most common reasons remain availability of ICU beds, availability of blood and COVID-19 caseload. The percentage of hospitals that considered ICU bed and PPE availability increased slightly this week.

The percentage of hospitals reporting a delay greater than 24 hours in obtaining COVID-19 convalescent plasma (CCP) units was comparable to week 16 (14.5%); several hospitals reporting a delay are in states with the largest increases in COVID-19 cases in the last 7 days. The percentage of hospitals transfusing CCP increased slightly (74.7%) compared to week 16.

A majority of the responding hospitals transfused 1-unit dose (71.7%). Most hospitals are prioritizing CCP to severely ill patients (47%). The percentage of hospitals that reported not being billed for CCP units by their blood supplier showed an increase (62.9%), compared to previous weeks. Of these
hospitals, 56.3% reported that CCP use would not be affected if the hospitals had to absorb the cost of CCP units, which was comparable to week 16.

Past results are available on the AABB Survey and Reports web page.

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07/17/20 FDA Closes COVID-19 Industry Hotline

FDA Closes COVID-19 Industry Hotline

The Food and Drug Administration announced yesterday that it will close the COVID-19 industry hotline at 8 p.m. ET today. FDA set up the hotline to address questions related to COVID-19 diagnostic tests and device shortages, including personal protective equipment (PPE). To meet ongoing needs, FDA is answering industry and laboratory questions about COVID-19 and medical devices through an online contact directory.

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07/17/20 Experimental COVID-19 Vaccine Safe, Generates Immune Response

Experimental COVID-19 Vaccine Safe, Generates Immune Response

An experimental vaccine designed to protect against SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), was generally well tolerated and prompted neutralizing antibody activity in healthy adults, according to preliminary findings published this week in The New England Journal of Medicine. The experimental vaccine, called mRNA-1273, is designed to induce neutralizing antibodies directed at a portion of the coronavirus “spike” protein, which the virus uses to bind to and enter human cells.

The report includes data from 45 healthy adults, 18 to 55 years of age. Patients received two vaccinations 28 days apart in a dose of 25, 100 or 250 micrograms. There were 15 participants in each dose group. Every participant received one injection, while 42 received both scheduled injections. In April, investigators expanded the trial to enroll adults older than age 55.

Two doses of vaccine prompted high levels of neutralizing antibody activity that were above the average values seen in convalescent sera obtained from persons with confirmed COVID-19 disease. More than half of the participants reported fatigue, headache, chills, myalgia or pain at the injection site, but no serious adverse events were reported. Adverse events were more common following the second vaccination and in those who received the highest vaccine dose.

The National Institute of Allergy and Infectious Diseases is developing the vaccine in partnership with Moderna, Inc. of Cambridge, Mass. Moderna began enrollment of a phase 2 clinical trial of mRNA-1273 in late May. Plans are underway to launch a Phase 3 efficacy trial this month.
Synthesis Examines Effect of COVID-19 on Transfusion Chain

The COVID-19 pandemic has had significant implications for the transfusion chain, the authors of a synthesis of published literature related to COVID-19 and transfusion medicine wrote recently in *The Lancet*. They believe that sharing experiences and developing expert consensus on the basis of evolving publications will help transfusion services and hospitals in countries at different stages in the pandemic.

The synthesis highlighted five key themes related to the effect of COVID-19 on the transfusion chain:

- Features of SARS-CoV-2 that affect patients’ needs for transfusion.
- Donor and donation factors that need to be considered to maintain an adequate supply of blood during the COVID-19 pandemic.
- Modifications to production, specification and storage of blood components to help prevent blood shortage.
- Prioritization of blood use for patients in hospitals in the event of predicted shortage.
- Use of convalescent plasma and immunoglobulins.

For each theme, the authors discussed key considerations and best practice suggestions to help inform planning for critical imbalances in the blood supply chain. The authors proposed early planning to review mitigation options. In particular, they suggested stock building and the extension of shelf life when stocks are good. In addition, they recommended that policy documents should include a hospital-based emergency management plan, ideally based on a national plan, integrated with monitoring across the blood component supply chain and rigorous application of PBM principles.

The authors wrote that recommendations for transfusion should conform to general messages of restrictive use of blood. “In collaboration with public health agencies, blood services are well placed to contribute to epidemiological studies and biobanks evaluating the serology, features, and course of the COVID-19 pandemic,” they wrote.

NBF Grant Recipients Contribute to COVID-19 Research

Several previous recipients of National Blood Foundation (NBF) early-career Scientific Research Grants have recently published research related to COVID-19.

Seven NBF grant recipients contributed to pre-print research suggesting that the low oxygen levels seen in many patients with COVID-19 may be the result of damage to the membranes of red blood cells caused by the virus. The investigative team included Tiffany Thomas, PhD, (2019); Angelo D’Alessandro, PhD, (2016); Richard O. Francis, MD, PhD, (2014); Krystalyn Hudson, PhD, (2014); Eldad A. Hod, MD, (2011); James C. Zimring, MD, PhD, (2004); and Steven L. Spitalnik, MD, (2003). Spitalnik is also a member of the AABB Board of Directors. The team published the findings on pre
print server medRxiv ahead of peer review. Several national publications highlighted the findings following coverage by Reuters.

Three other NBF grant recipients – Larry L. Luchsinger, PhD, (2020); Karina Yazdanbakhsh, PhD, (2000); and Christopher D. Hillyer, MD, (1991) – recently published findings from a serological analysis of New York City’s CCP donors. The findings indicated that CCP donors have a wide range of neutralizing antibody concentrations against SARS-CoV-2, which suggests varying levels of immunity in preventing future infections. Investigators published the findings on medRxiv ahead of peer review. National publications, including the Los Angeles Times and Time, covered the findings.

Additional research on antibody responses to SARS-CoV-2 included contributions from grant recipients Sean Stowell, MD, PhD, (2013), and John Donald Roback, MD, PhD, (1998). In this study, investigators determined that a robust humoral immune response occurs early during severe or moderate COVID-19 infections. Cell Reports Medicine published the findings.

A review published recently in the Journal of Clinical Investigation also included contributions from two previous grant recipients. AABB President, Beth Shaz, MD, (2008), and Spitalnik contributed to a review of the use of convalescent plasma, including evidence of benefit, regulatory considerations, logistical workflow and proposed clinical trials.

The early-career Scientific Research Grants Program helps NBF achieve its mission of “fueling innovation in transfusion medicine and cellular therapies for the benefit of patients and donors.” Scientific contributions like these are possible thanks to the generous donations of NBF supporters. AABB encourages members to donate today to have an impact on the health and safety of patients and donors both in their community and worldwide.

07/10/20 AABB Accepting Late-Breaking Abstracts for 2020 Annual Meeting

AABB Accepting Late-Breaking Abstracts for 2020 Annual Meeting

AABB is accepting late-breaking abstract submissions for the 2020 AABB Annual Meeting until July 31. In doing so, the Association seeks to provide a platform for investigators to present research for which results may not have been available during the general submission period that ended May 15.

While the Association expects that many late-breaking abstracts will reflect research related to COVID-19, AABB encourages submissions on all topics. Due to these unique circumstances, AABB is allowing COVID-19-related abstracts that were submitted during the general abstract submission period to be resubmitted as late-breaking abstracts if the data and research have been expanded since the original submission. AABB asks investigators who submit late-breaking abstracts to explain why their abstract was not submitted by the general submission deadline. Abstracts that have been published, presented or accepted for publication or presentation prior to July 31 will not be considered. Additional
information is available in AABB’s late-breaking abstract guidelines. Interested individuals may submit their abstracts online.

07/10/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 16 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 174 respondents from 40 states completed the survey, conducted July 6-8.

Fewer hospitals (6.9%) reported an increase in product outdating due to changes related to the pandemic. This continues a downward trend that began the week of May 11 (survey week 8). Of these hospitals, 58.3% reported product outdating at the same level compared to week 15.

This week, 4% of responding hospitals that previously resumed elective surgeries put these procedures on hold, an increase from week 15. In addition, 39.9% (n=69) of all hospitals were alerted by their blood supplier that the supplier will not be able to meet typical inventory needs, a decrease from week 15. O-negative was the most affected component this week. In response to ongoing shortages, 50% of responding hospitals have implemented inventory management strategies.

In terms of inpatient census, 31.6% of responding hospitals are operating at 75–90% of pre-pandemic levels. Among hospitals that resumed elective surgeries, 26.7% are operating their elective surgeries at 50–75% of pre-pandemic levels. An additional 26.7% are operating at 75–90% of pre-pandemic levels.

This week, 47.9% of hospitals reported developing a formal plan for a second wave, compared with 50% in week 15. Among the trigger points for canceling surgeries/procedures, the top three most cited reasons remain the availability of ICU beds, availability of blood, and COVID-19 caseload. The percentage of hospitals that considered COVID-19 caseload (23.3%) showed a slight increase this week, compared to 21.9% in week 15.

The percentage of hospitals reporting a delay greater than 24 hours in obtaining CCP units (14.7%) decreased this week, as did the percentage of hospitals transfusing CCP (73.3%). There were slight increases in the percentage of hospitals prioritizing CCP to severely ill patients (47.8%). A majority of hospitals reported not being billed for CCP units by their blood supplier (57.9%), but the percentage of hospitals reporting so showed a decline compared to weeks 14 and 15. Among these hospitals, 56.9% reported that CCP use would not be affected if the hospitals had to absorb the cost of CCP units, a decline compared to week 14 and 15.
European Health Organizations Announce Project to Study CCP as Potential COVID-19 Treatment

The European Commission (EC) approved a new project to support high-quality clinical evaluation of COVID-19 convalescent plasma (CCP) and to seek a consensus on the appropriate use of CCP in the treatment of patients with COVID-19 throughout European Union member states. Several clinical trials are underway in Europe to demonstrate the safety and efficacy of CCP, but there has been no coordinated approach to support and harmonize protocols, produce guidelines, standardize tests to characterize CCP and validate the overall outcome of the therapy.

The SUPPORT-E (SUPPORTing high quality evaluation of COVID-19 convalescent plasma throughout Europe) project is a partnership among a consortium of EU member states, the European Blood Alliance, the European Centre for Disease Prevention and Control, and other health professionals. The project includes an open-access database that will gather and publicize data on CCP donations and patient outcomes following transfusions. It includes data from blood establishments regarding CCP donors, plasma collection and plasma components, as well as from clinical trials and from wider monitored use. It will consolidate EU evidence on safety and effectiveness, as well.

According to the EC, the project will serve as a basis for further research and allow the consortium to make evidence-based recommendations for both the current and future epidemiological outbreaks.

FDA Updates Q&A Appendix in Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency

FDA recently updated the question-and-answer (Q&A) appendix in its guidance titled “Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency.” The updated guidance clarifies two previously suggested methods for obtaining informed consent from a hospitalized patient in isolation. The guidance includes a Q&A regarding how to obtain informed consent from a prospective trial participant in certain circumstances where the enrollment time frame is limited and the patient can receive a copy of an informed consent document electronically but cannot sign it electronically or print it out for signature. In addition, the guidance clarifies recommendations on documenting details when using video conferencing for trial visits.
FDA Releases Updated Information for HCT/P Establishments Regarding the COVID-19 Pandemic

The Food and Drug Administration recently released updated considerations for facilities involved in the transplantation, infusion or transfer of human cells, tissues, or cellular or tissue-based products (HCT/Ps) related to donor screening. FDA is aware that some HCT/P establishments are considering additional donor screening and testing measures in response to the coronavirus disease 2019 (COVID-19) pandemic, but the agency does not recommend using laboratory tests to screen asymptomatic HCT/P donors.

FDA reiterated that HCT/P establishments must determine and document the eligibility of a cell or tissue donor. Important considerations include whether, in the 28 days prior to HCT/P recovery, the donor has cared for, lived with or had close contact with someone diagnosed with or suspected of having COVID-19 infection; has been diagnosed with or suspected of having COVID-19 infection; or has had a positive diagnostic test for SARS-CoV-2 but never developed symptoms.

The agency will continue to monitor the situation and issue updates as information becomes available.

Pre-Print Data Suggest CCP Donors Have a Wide Range of Antibody Concentrations

An analysis of donated CCP samples indicates that CCP donors have a wide range of neutralizing antibody concentrations, which suggests varying levels of immunity to prevent future infections. Investigators from the Lindsley F. Kimball Research Institute of the New York Blood Center and Rockefeller University published their findings on medRxiv, a pre-print server for studies undergoing peer review. The study is the first in the U.S. to look at antibody levels using commercially available clinical antibody testing platforms and antiviral activity in COVID-19 convalescent plasma donors.

Investigators analyzed 370 plasma samples from people who recovered from COVID-19 using seven different commercially available SARS-CoV-2 detection tests and in-house ELISA assays. They correlated those measurements with neutralization activity measured using pseudotyped virus particles, which offer the most informative assessment of antiviral activity of patient sera against viral infection.

The results indicated that a large proportion of CCP samples have modest antibody levels and that commercially available tests have varying degrees of accuracy in predicting neutralizing activity. Investigators found that some commercially available tests are able to accurately measure levels of antibodies that correlate with the neutralization assays.
According to the investigators, it is unclear how antibody acquisition, particularly for low-titer individuals, might afford future immunity to SARS-CoV-2. They stated that further research is necessary to determine the minimum threshold of antibody and neutralization activity necessary to accurately predict immunity. “Correlation of clinical antibody tests with neutralization activity in this study could serve as a valuable roadmap to guide the choice and interpretation of serological tests for SARS-CoV-2,” they wrote.

06/26/20 Large Safety Study Confirms CCP Safe in Patients With COVID-19

Transfusion of convalescent plasma from individuals who have recovered from COVID-19 is safe in hospitalized patients, according to a follow-up safety study of a diverse group of 20,000 patients treated with CCP under FDA’s COVID-19 Expanded Access Program (EAP). The findings—reported recently in Mayo Clinic Proceedings—also support the notion that earlier administration of plasma within the clinical course of COVID-19 is more likely to reduce mortality.

The safety report assessed the seven days following transfusion for hospitalized patients between April 3 and June 11 who were deemed at risk of progressing to a severe or life-threatening condition. Nearly 40% of the patients in the study were women; 20% were African Americans; nearly 35% of patients were Hispanic and 5% were Asian. Patients received approximately 200 – 500 mL of CCP, administered intravenously according to institutional transfusion guidelines.

The incidence of all serious adverse events was low, including transfusion reactions (less than 1%), thromboembolic or thrombotic events (less than 1%) and cardiac events (approximately 3%). The investigators noted that the vast majority of the thromboembolic or thrombotic events and cardiac events were judged to be unrelated to the plasma transfusion per se.

The 7-day mortality rate declined to 8.6% compared to 12% in the initial 5,000 patients. Seven-day mortality was higher among more critically-ill patients relative to less ill counterparts, including patients admitted to the intensive care unit versus not admitted (10.5% and 6%, respectively), mechanically ventilated versus non-ventilated patients (12.1% and 6.2%), and in patients with septic shock or multiple organ dysfunction/failure versus those without dysfunction/failure (14% and 7.6%).

Investigators noted that while the mortality rate has decreased, the clinical characteristics of the transfused patients in the EAP have shifted toward less critically-ill patients and lower proportions of apparent “rescue therapy.” They suggest this improvement may be a result of improved management of hospitalized patients with COVID-19 and the increased availability of CCP. According to investigators, the lower mortality in more recently treated patients would be consistent with greater efficacy from earlier use, as well.
While the authors believe the data provide continued optimism for the safety of CCP, they emphasized that the report does not establish efficacy of CCP. “Given the accelerating deployment of this therapy, these emerging data provide early safety indicators of convalescent plasma for COVID-19 treatment and suggest research should shift focus from safety toward determining the efficacy of convalescent plasma,” they wrote.

06/26/20 2018 NBF Grantee Publishes Research on Dose-Escalated Hydroxyurea in Blood

2018 NBF Grantee Publishes Research on Dose-Escalated Hydroxyurea in Blood

Robert S. Nickel, MD, MSc, a 2018 recipient of an NBF early-career Scientific Research Grant, recently published research in Blood, a peer-reviewed medical journal published by ASH. Nickel and his colleagues designed a single-arm clinical trial combining hydroxyurea and transfusion therapy in 15 patients with sickle cell anemia (SCA) to evaluate its feasibility and investigate its potential benefit in decreasing transfusion requirements. All patients had been receiving chronic transfusion therapy to prevent stroke.

Patients with hemoglobin (Hb) sickle cell anemia or sickle beta zero thalassemia receiving simple chronic transfusions for stroke prevention were started on hydroxyurea at a dose of 20 milligrams per kilogram per day. Nickel and his colleagues increased the dose by 5 mg/kg per day after more than 7 weeks to achieve a hydroxyurea and transfusion target dose (HAT-TD) defined by the absolute neutrophil count (ANC) or the pretransfusion Hb and Hb S percentage.

Among the study’s active population, combination hydroxyurea (median dose of 25 mg/kg per day) and chronic transfusion has generally been well tolerated. All of these patients are on concurrent chelation therapy, but investigators have not observed overlapping toxicities. No patient receiving combination therapy has developed a pretransfusion Hb level greater than 11.0 g/dL and Hb S greater than 45%.

Two patients have completed the study (defined as 1 year of combination treatment with hydroxyurea after reaching HAT-TD). One patient achieved HAT-TD after 19 weeks at a hydroxyurea dose of 30 mg/kg per day, while a second patient achieved HAT-TD after 17 weeks at a dose of 25 mg/kg per day. Notably, both patients received decreased weight-based volumes of RBCs at each transfusion, although neither patient experienced decreased transfusion frequency.

Nickel and his colleagues stated that clinical research on this topic is needed to better inform optimal chronic transfusion management and outcomes for SCA. However, they wrote that the findings could help inform clinicians considering the use of hydroxyurea for patients with SCA on chronic transfusion during the current pandemic as part of a blood-conservation strategy.
**Remind**er: **#TeamBlood Initiative Supports Community Engagement During Pandemic**

AABB and the National Blood Foundation (NBF) launched the #TeamBlood: In This Together initiative in May and it continues to provide new ways for members of the blood and biotherapies communities to connect during this time of physical distancing. The [Share a Story program](https://www.aabb.org/teamblood/shareastory) gives members a platform to describe their experiences during the COVID-19 pandemic, and a sponsored membership program allows members to help someone who has experienced economic hardship during the pandemic. Individuals interested in sponsoring an AABB membership for a friend or colleague may contact the AABB Membership Department for additional information at +1.301.215.6489 or [membership@aabb.org](mailto:membership@aabb.org).

In addition, #TeamBlood provides a means to [dedicate a donation](https://www.aabb.org/teamblood/donate) to recognize a colleague or honor their memory. Donations to the NBF support innovative research that could help launch the career of one of [tomorrow’s leading researchers](https://www.aabb.org/teamblood/donate). The NBF will send a notification letter of donation dedications that can include the donor’s personal sentiments.

**AABB’s Virtual Annual Meeting Highlights Conference Begins Sunday; Registration Open Throughout Meeting**

AABB’s virtual Annual Meeting Highlights Conference and Exhibition in the Middle East begins this Sunday. Individuals who have not yet registered may do so at any time during the conference.

This year’s program features [high-profile speakers](https://www.aabb.org/teamblood/donate) from throughout the world who will present on emerging topics in transfusion medicine and biotherapies. The conference will also address the COVID-19 pandemic in a special session, “Convalescent Plasma: International Perspectives.” This session will convene experts from Brazil, Spain and the U.S. to discuss their use of convalescent plasma during the COVID-19 pandemic, as well as related experience in Hong Kong with the SARS and H1N1 viruses.

Participants can earn up to nine [CME credits](https://www.aabb.org/teamblood/donate) during the conference. Discounted rates are available for students and non-physician clinicians. Additional information about the conference is available [online](https://www.aabb.org/teamblood/donate).

**AABB Urges Congress to Establish a National Data System to Track Blood Availability and Safety**

AABB urged Congress to establish, implement and support a sustainable, public-private system that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes.
and hemovigilance. In a letter to leaders of the Senate Committee on Health, Education, Labor and Pensions, AABB emphasized that the blood supply is a critical part of the public health infrastructure.

The letter discusses the ways in which a comprehensive data system will reinforce and organize the blood supply chain and will address issues highlighted in a Senate white paper on pandemic response. Furthermore, AABB explained how a national data system will help ensure the adequacy of the blood supply in the case of public health emergencies; identify challenges and opportunities to strengthen the donor pool; promote safety and innovation and strengthen the public health infrastructure.

AABB closed the letter by reiterating how the COVID-19 pandemic has exacerbated the fragility of the blood supply and reinforced the need for the nation to invest in the security of the blood supply chain. AABB believes that a comprehensive data system is an important step in ensuring the endurance of this critical public health resource.

06/26/20 REGULATORY UPDATE: FDA Issues Updated 2020 Guidance Agenda

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FDA’s Center for Biologics Evaluation and Research (CBER) issued its mid-year update to the 2020 Guidance Agenda. In the category of blood and blood components, CBER included the April 2020 malaria, HIV, alternative procedures and convalescent plasma guidance documents related to the COVID-19 public health emergency that were made available for immediate implementation without prior public comment. FDA also added guidance documents accepting the revised Donor History Questionnaires for use in screening donors of blood and blood components and donors of source plasma.

In a footnote to the April 2020 Creutzfeldt-Jakob Disease guidance, FDA stated that the agency intends to issue a Level 2 guidance with “minor changes intended to clarify FDA’s permanent donor deferral recommendation for individuals who have received cadaveric pituitary human growth hormone.” AABB is pleased that FDA plans to revise the 2014 syphilis guidance, which is consistent with AABB’s comments to FDA identifying donor deferral discrepancies. The Level 2 guidance intends to make the syphilis recommendations consistent with the April 2020 HIV guidance.

Guidance documents that remain on the blood and blood components list that have not been issued include the following:

- Manufacture of Blood Components Using a Pathogen Reduction Device in Blood; Guidance for Industry.
- Establishments: Questions and Answers; Guidance for Industry.
- Testing for Biotin Interference in In Vitro Diagnostic Devices; 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 Industry. This guidance will revise existing recommendations to address statistical sampling plans for process validation.

FDA added no additional guidance documents in the category of tissues and advanced therapies. Guidance documents that remain on this list that have not been issued include draft guidance on human gene therapy for neurodegenerative diseases, draft guidance on human gene therapy products incorporating genome editing, and draft guidance on chimeric antigen receptor (CAR) T-cell therapies.

In the vaccines category, FDA intends to release a guidance on the development and licensure of vaccines to prevent COVID-19.

**06/26/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services**

AABB released a graphic summary of the week 14 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 173 respondents from 40 states completed survey, conducted June 22-24.

Fewer hospitals (12.3%) reported an increase in product outdating due to pandemic-related changes. This continues a downward trend that began the week of May 11 (survey week 8). Of these hospitals, 50% reported product outdating at the same level as week 13. A total of 48.5% (n=84) of the hospitals were alerted by their blood supplier that the supplier will not be able to meet typical inventory needs, a decline compared to past weeks. O-positive RBCs were the most affected component this week, in contrast to O-negative in previous weeks. Furthermore, 52% have implemented inventory management strategies to deal with the shortages, a decline compared to week 13.

In terms of inpatient census, 37.4% of the responding hospitals are operating at 75-90% of pre-COVID levels. Of the hospitals that resumed elective surgeries, 37.2% are operating their elective surgeries at 75-90% of pre-pandemic levels. Additionally, 43.8% of the hospitals reported having developed a formal plan for a second wave, although this is a decline compared to past weeks. Among the trigger points for canceling surgeries/procedures, the availability of ICU beds and blood showed upward trend, while PPE availability, COVID caseload and testing capacity showed downward trends.

The number of respondents reporting a delay greater than 24 hours in obtaining CCP units continued on a downward trend. This week, there was a slight increase in the number of hospitals prioritizing CCP to patients as the final option. A majority (63.3%) of hospitals reported not being billed for CCP units by their blood supplier. This continues an upward trend that began during survey week 12 (June
8). Of these hospitals, 61.6% reported that CCP use would not be affected if the hospitals had to absorb the cost of CCP units, compared with 55.6% of respondents during week 13.

06/26/20 **HHS Webinar to Address Strengthening Care for Patients With SCD During COVID-19 Pandemic**

**HHS Webinar to Address Strengthening Care for Patients With SCD During COVID-19 Pandemic**

The United States Department of Health and Human Services (HHS) recently announced an upcoming webinar on strengthening sickle cell disease (SCD) treatment efforts during and beyond the COVID-19 pandemic. This 90-minute webinar, to be held at 9 a.m. ET on June 29, will highlight current knowledge about the impact of COVID-19 on health care systems and access to care for individuals living with SCD. The webinar will also include a discussion on the next steps of the Global Coalition on Sickle Cell Disease, an initiative that seeks to foster collaborations to develop, organize and implement a global multi-sectoral approach to combatting SCD.

HHS developed the webinar in partnership with the American Society of Hematology (ASH), SickleinAfrica and the World Health Organization. Registration is complimentary and available online.

06/26/20 **FDA Updates Recommendations for Serology and Antibody Tests That Should Not Be Used**

**FDA Updates Recommendations for Serology and Antibody Tests That Should Not Be Used**

The Food and Drug Administration recently updated recommendations related to the use of COVID-19 antibody tests that are listed on FDA’s “removed” test list, found on the FDA’s FAQs on Testing for SARS-CoV-2 web page. The “removed” list includes tests for which the commercial manufacturer has not adequately addressed significant clinical performance problems in a timely manner, tests for which a manufacturer has not submitted an Emergency Use Authorization request within a reasonable period of time as outlined in FDA guidance, and tests voluntarily withdrawn by the respective commercial manufacturers.

The FDA issued the following recommendations for laboratories and health care providers:

- Stop using the antibody tests listed on FDA’s “removed” test list.
- Evaluate, in the context of the patient’s clinical presentation and medical history, whether prior test results generated using these tests may have been incorrect, and whether the patient should be retested using an FDA-authorized test.
- Remove from stock any remaining tests that are listed on FDA’s “removed” test list.
- Report any issues with using COVID-19 antibody tests to the FDA.

FDA will continue to keep health care providers and the public informed if new or additional information becomes available.
BARDA Launches COVID-19 Support Service Partnerships Web Page

The Biomedical Advanced Research and Development Authority (BARDA) recently introduced a new web page that details the agency’s partnerships to develop medical countermeasures to diagnose, treat and protect against coronavirus disease 2019 (COVID-19). The searchable web page outlines the agency’s ongoing collaborations to develop vaccines, diagnostics, therapeutics and other rapidly deployable capabilities.

Partners within the blood community include America’s Blood Centers and the American Red Cross, which are collaborating with BARDA on the collection and distribution of COVID-19 convalescent plasma (CCP) for therapeutic use in treating hospitalized patients with COVID-19. BARDA will update the page as new partnerships develop.

No Measurable Risk for SARS-CoV-2 Transmission Through Blood Components From Asymptomatic Donors

There is no measurable risk for transmission of SARS-CoV-2, the virus that causes COVID-19, through blood components donated by asymptomatic SARS-CoV-2-infected individuals, according to findings published recently in Transfusion. Investigators reported on molecular detection of SARS-CoV-2 in 18 German patients with COVID-19. Of these, 15 patients developed symptoms of different severity. Investigators performed SARS-CoV-2 testing targeting the E and RNA-dependent RNA polymerase gene.

Of the 18 patients, three fulfilled the requirements for blood donation in Germany. Oral swabs or sputum from the lower respiratory tract from all 18 patients tested RT-PCR positive, but investigators detected SARS-CoV-2 genomes in 1 of 77 blood samples. This sample was one of eight serum/plasma samples taken from a patient with acute respiratory distress syndrome.

According to investigators, the findings are in line with published data and confirm that SARS-CoV-2 infection may go without noticeable manifestation of clinical symptoms. They noted that RNAemia is not equivalent to infectiousness and that there have been no documented hematogenous transmissions for SARS-CoV-2. Furthermore, symptomatic donors would not be eligible for blood donation in Germany. Therefore, the risk for transfusion transmission of SARS-CoV-2 is considered negligible.

Readers who successfully complete a short activity about this article can earn continuing medical education (CME) credit. Those who correctly answer at least 70% of the post-test items can also earn Self-Assessment Module (SAM) credit toward Maintenance of Certification (MOC).
**AABB News Examines Optimal Hemorrhage Treatments, How the Blood Community Mobilized to Manufacture CCP**

Blood-based resuscitation is becoming the treatment of choice for hemorrhage and hemorrhagic shock, according to experts. The June issue of *AABB News* features an article on how trauma resuscitation transitioned away from blood to crystalloid or colloid fluids and is now coming back full circle to blood products again. Another article highlights how some facilities responded to calls to develop policies and procedures for collecting and transfusing CCP in a matter of weeks. The issue also announces the AABB Nominating Committee’s slate of nominees for the 2020-21 Board of Directors, the opening of registration for the 2020 AABB Annual Meeting and two new inductees into the National Blood Foundation’s Hall of Fame.

**1 Week Left to Register for AABB’s Virtual Annual Meeting Highlights Conference**

Registration for AABB’s virtual Annual Meeting Highlights Conference and Exhibition in the Middle East, to be held June 28-30, ends on June 27. The virtual conference includes high-profile speakers from throughout the world who will present on emerging topics in transfusion medicine and biotherapies. The conference will also address the COVID-19 pandemic in a session titled, “Convalescent Plasma: International Perspectives.” This session will convene experts from Brazil, Spain and the U.S. to discuss their use of convalescent plasma during the COVID-19 pandemic, as well as related experience in Hong with the SARS and H1N1 viruses. Participants can earn up to nine CME credits during the conference. Discounted rates are available for students and non-physician clinicians. Additional information about the conference is available online.

**AABB, Facebook Encourage Blood Donations in Recent Op-Ed**

On World Blood Donor Day (June 14), AABB CEO Debra BenAvram, FASAE, CAE; and Sheryl Sandberg, MBA, chief operating officer at Facebook, published an op-ed in *Modern Healthcare*, encouraging healthy, eligible Americans to make a blood donation. The two stressed the importance of blood donations to maintain the adequacy of the blood supply, particularly during the COVID-19 pandemic. "Blood has a limited shelf life and the supply must continually be replenished to prevent shortages," BenAvram and Sandberg wrote, adding that as states reopen and hospitals resume elective surgeries, "We may face an even greater threat to the nation's blood supply."

The op-ed also highlighted the new partnership between AABB and Facebook that is designed to help increase the blood supply. As part of the partnership, AABB will help connect donors to blood collection
facilities throughout the country and educate its hospital members about Facebook's blood donation tool, which is now available to them. Since 2017, this tool has helped people find places to donate blood in their communities and to be notified when a nearby blood donation center is facing a critical shortage. Facebook recently expanded use of this feature to five additional counties and will offer it to additional countries that request it.

06/19/20 FDA Issues Warning Letter to Nevada Company for Marketing Unapproved HCT/Ps

FDA Issues Warning Letter to Nevada Company for Marketing Unapproved HCT/Ps

FDA recently issued a warning letter to Nevada-based Eucyt Laboratories for marketing several unapproved human cells, tissues, or cellular or tissue-based products (HCT/Ps), including one exosome product marketed to prevent or treat COVID-19.

In the June 4 letter, FDA stated that the company’s umbilical cord, umbilical cord blood, exosome and amniotic fluid derived products appear to be HCT/Ps and are subject to additional regulation, including appropriate premarket review. FDA reiterated that in order to lawfully market HCT/Ps, a company needs a valid biologics license application or investigational new drug (IND) application.

In addition, during the November 2019 inspection, FDA investigators documented evidence of significant deviations from current good manufacturing practice (cGMP) and current good tissue practice (cGTP). These deviations include deficient donor eligibility practices, unvalidated manufacturing processes, deficient environmental monitoring and inadequate aseptic practices.

FDA urged Eucyt to take prompt action to correct these violations and requested the company respond in writing within 15 working days of receipt of the letter, outlining the specific steps it has taken or plans to take to correct the noted violations and prevent their recurrence.

06/19/20 REGULATORY UPDATE: FDA Publishes FRNs for April 2020 CJD, HIV and Malaria Guidance Documents

REGULATORY UPDATE: FDA Publishes FRNs for April 2020 CJD, HIV and Malaria Guidance Documents

The Food and Drug Administration published Federal Register notices (FRNs) on Tuesday for the April 2020 Creutzfeldt-Jakob Disease (CJD), HIV and malaria guidance documents. In April, FDA released a statement outlining its process for making guidance documents available for immediate implementation to address the urgent need for blood during the COVID-19 pandemic. The process, which follows FDA’s established good guidance practices regulations, allowed the agency to issue the HIV and malaria documents without prior public comment. Rather than publishing a separate Notice of Availability (NOA) for each COVID-19-related guidance, FDA stated that it would periodically publish a consolidated NOA.
Although issued without prior public comment, FDA is soliciting comments, will review all comments received and revise the documents as appropriate. Each guidance document and FRN specifies the docket number to which comments can be submitted. On June 5, AABB submitted comments on the April 2020 HIV guidance. Members with questions may contact regulatory@aabb.org.

06/19/20 AABB Urges Establishment of National Data System to Track Blood Availability and Safety

AABB Urges Establishment of National Data System to Track Blood Availability and Safety

AABB urged HHS officials to include a request for policymakers to use a legislative vehicle to establish, implement and support a sustainable, public-private system that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes and hemovigilance.

In a June 17 letter, AABB asked HHS to include the request in the agency’s upcoming report to Congress on recommendations to maintain the blood supply, which is stipulated by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAI).

AABB stated that a comprehensive data system is needed to reinforce and organize the blood supply chain and address the challenges highlighted by Congress, including ensuring the adequacy of the blood supply in the case of public health emergencies, identifying challenges and opportunities to strengthen the donor pool, promoting safety and innovation, and building upon the implementation and intent of the Transfusion-Transmissible Infections Monitoring System (TTIMS).

AABB continued by examining the four subject areas in which a national data system would play a critical role in maintaining the safety and availability of the blood supply:

- A national data system that monitors the blood supply chain from vein to vein is critical to the nation’s preparedness infrastructure and is essential to ensuring the adequacy of the blood supply in the case of public health emergencies.
- A comprehensive data system that makes available data on the blood supply and changes in utilization would enable policymakers and organizations throughout the blood community identify challenges and opportunities to strengthen the blood donor pool.
- A holistic data system that captures data on hemovigilance and patient outcomes would promote blood safety and innovation.
- A comprehensive data system would be a critical part of the public health infrastructure, should be supported by federal funds through a public-private partnership, and should leverage and build upon existing platforms, including TTIMS.

AABB closed the letter by reiterating how the COVID-19 pandemic has exacerbated the fragility of the blood supply and reinforced the need for the nation to invest in the security of the blood supply chain.
AABB believes that a comprehensive data system is an important step in ensuring the endurance of this critical public health resource.

06/19/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 13 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 202 respondents from 43 states completed the survey, conducted June 15-17.

Fewer hospitals (15.3%) reported an increase in product outdating due to changes related to the pandemic. This continues a downward trend that began the week of May 11 (survey week 8). Of these hospitals, 54.8% reported outdating at the same level as last week. In addition, 56.2% (n=113) of the hospitals were alerted by their blood supplier that they will not be able to meet typical inventory needs. O-positive and O-negative RBCs were the most affected components; 59% of hospitals have implemented inventory management strategies to address shortages.

In terms of inpatient census, 37.5% of hospitals are operating at 75-90% of pre-COVID levels. Of the hospitals that resumed elective surgeries, a plurality (32.6%) are operating their elective surgeries at 75-90% of pre-COVID levels.

In addition, 46.8% of the hospitals reported having developed a formal plan for a second wave, an increase compared to past weeks. For 26.3% of hospitals, ICU bed availability was a major trigger point for cancelling surgeries/procedures; 19.3% of hospitals also considered blood availability as one of the trigger points for cancelling surgeries/procedures, a slight increase compared to week 12.

The percentage of hospitals reporting delays of more than 24 hours in obtaining CCP units was comparable to week 12. Compared to previous weeks, there was a slight increase in the percentage of hospitals prioritizing CCP to moderately and severely ill patients. A majority of the hospitals reported not being billed for CCP units by their blood supplier (57.3%). Of these hospitals, 55.6% reported that CCP would not be affected if the hospitals had to absorb the cost of CCP units, a decline compared to week 12.

06/19/20 NIH Launches Initiatives to Collect COVID-19 Data to Advance Treatments, Track Disease Spread

NIH Launches Initiatives to Collect COVID-19 Data to Advance Treatments, Track Disease Spread

The National Institutes of Health (NIH) introduced new efforts this week to expand data collection in order to advance COVID-19 therapies and track disease spread. On Monday, NIH announced the launch of a centralized, secure enclave to store and study vast amounts of medical record data from
people diagnosed with COVID-19. The program is part of an effort called the National COVID Cohort Collaborative (N3C), which seeks to help scientists analyze data to better understand COVID-19 and develop treatments.

The N3C will include an analytics platform to systematically collect clinical, laboratory and diagnostic data from health care organizations nationwide. It will then harmonize the aggregated information into a standard format and make it available for researchers and health care providers. A demonstration of the platform is available online.

In addition, NIH’s All of Us research program will leverage its participant base to seek new insights into COVID-19 through antibody testing, a survey on the pandemic’s impacts and the collection of electronic health record information. Investigators will give approved researchers access to the data gathered through these activities. Analyses may help reveal the origins of entry, as well as the spread and impact of COVID-19 in the U.S. Additional information about the All of Us program is available online.

06/19/20 OCR Guidance Details How Health Care Providers Can Contact Former COVID-19 Patients About Blood and Plasma Donation

OCR Guidance Details How Health Care Providers Can Contact Former COVID-19 Patients About Blood and Plasma Donation

The Office of Civil Rights (OCR) within the United States Department of Health and Human Services (HHS) issued guidance last week clarifying that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) allows for health care providers to contact individuals who have recovered from coronavirus disease 2019 (COVID-19) about blood and COVID-19 convalescent plasma (CCP) donation. The guidance explains that HIPAA permits covered health care providers to identify and contact patients who have recovered from COVID-19 for population-based activities relating to improving health, case management or care coordination. It also states that the providers cannot receive any payment from or on behalf of a blood and plasma donation center in exchange for communications with recovered patients without the patient’s authorization.

06/12/20 Protein Features Could Differentiate SARS-CoV-2 From Less Severe Coronaviruses

Protein Features Could Differentiate SARS-CoV-2 From Less Severe Coronaviruses

Investigators from the National Library of Medicine (NLM), part of the National Institutes of Health, used genome analysis to identify features of SARS-CoV-2, the virus that causes COVID-19, and other high-fatality coronaviruses that distinguish them from less severe members of the coronavirus family. The findings, published this week in the Proceedings of the National Academy of Sciences, may help scientists develop approaches to predict the severity of future coronavirus disease outbreaks and detect animal coronaviruses that have the potential to infect humans.
Investigators used integrated comparative genomics and machine learning techniques to compare the genome of the SARS-CoV-2 virus against the genomes of other members of the coronavirus family. They identified protein features – including insertions of specific stretches of amino acids into two virus proteins, the nucleocapsid and the spike – that are unique to SARS-CoV-2 and two other coronavirus strains with high fatality rates, SARS-CoV and MERS-CoV. These features correspond with the high fatality rate of these coronaviruses, as well as their ability to move from animal to human hosts.

Investigators identified the protein features in all three high-fatality coronaviruses and their closest relatives that infect animals, but not in four other human coronaviruses that cause non-fatal disease. Insertions in the spike protein may facilitate the recognition of the coronavirus receptors on human cells and the subsequent penetration of the virus into those cells. According to investigators, identifying these features in animal coronavirus isolates could predict the jump to humans and the severity of disease.

“This innovative research is critical to improve researchers’ understanding of SARS-CoV-2 and aid in the response to COVID-19,” NLM Director Patricia Flatley Brennan, RN, PhD, said in an NIH statement. “Predictions made through this analysis can inform possible targets for diagnostics and interventions.”

06/12/20 House Democrats Introduce Resolution in Support of Individual Risk Assessment

House Democrats Introduce Resolution in Support of Individual Risk Assessment

A coalition of Democratic members of the House of Representatives recently introduced a resolution that calls for the elimination of deferral periods for men who have sex with men (MSM) who wish to donate blood. The resolution emphasized the urgent need for blood resulting from the COVID-19 pandemic and called for policies governing blood and blood product donation to be grounded in science and based on individual risk factors that do not unfairly restrict or single out any group of individuals.

06/12/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 12 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 236 respondents from 44 states completed the survey, conducted June 8-11. AABB invited additional contacts from hospitals that did not respond to any of the past survey invitations to participate.

Fewer hospitals (18.6%) reported an increase in wastage due to changes related to the pandemic. This continues a downward trend that began the week of May 11 (survey week 8). Of these hospitals,
44.2% reported product outdating at the same level as last week. In addition, 56.4% (n=133) of hospitals received notification from their blood provider that they will not be able to meet typical inventory needs. O-negative RBC was the most affected component.

In terms of inpatient census, a plurality of the responding hospitals (39.9%) are operating at 50-75% of pre-COVID levels. Of the hospitals that resumed elective surgeries, a plurality (37%) are operating at 50-75% of pre-pandemic levels.

A total of 45.4% of the hospitals reported having developed a formal plan for a second wave of COVID-19, an increase compared to previous weeks. While ICU bed availability was the major trigger point for cancelled surgeries or procedures (26.5%), 18.2% of hospitals also considered blood availability as one of the trigger points for cancelling surgeries/procedures.

There is a continued downward trend in reported delay (greater than 24 hours) in obtaining COVID-19 convalescent plasma (CCP) units. There is a slight increase in the proportion of hospitals prioritizing CCP based on the timing of diagnosis/admission compared to previous weeks. There was an increase in the proportion of hospitals transfusing CCP within 4 to 6 days of COVID diagnosis/admission.

A majority (54.2%) of hospitals were not billed for CCP units by their blood supplier. Of these hospitals, 58.5% reported that CCP use would not be affected if the hospitals had to absorb the cost of CCP units, a decline compared to week 11.

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**06/12/20 Health Canada Announces Changes to Increase Flexibility of COVID-19 Clinical Trials**

**Health Canada Announces Changes to Increase Flexibility of COVID-19 Clinical Trials**

Canadian Minister of Health Patty Hajdu recently announced a series of policy changes to allow for a more flexible process for clinical trials related to COVID-19 therapies. The changes are designed to allow a wider range of health professionals and investigators to be involved in running clinical trials and medical device clinical trials, respectively; reduce certain labeling and record-keeping requirements; enable multiple-stream clinical trials to continue when one stream has been stopped; and allow for clinical trials to continue without in-person interaction. To date, Health Canada has approved 37 clinical trials for potential COVID-19 therapies and vaccines.

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**06/12/20 HHS Releases New Laboratory Data Reporting Guidance for COVID-19 Testing**

**HHS Releases New Laboratory Data Reporting Guidance for COVID-19 Testing**

The Department of Health and Human Services (HHS) released a new guidance last week that specifies what additional data laboratories must report to the agency along with coronavirus disease 2019 (COVID-19) test results. The updated requirements include demographic data such as race, ethnicity,
age and sex, which will help officials track the burden of infection on vulnerable populations. Additionally, the new reporting requirements will provide information needed to better monitor disease incidence and trends by initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources and anticipating potential supply chain issues.

06/12/20 General Registration Now Open for 2020 AABB Annual Meeting

**General Registration Now Open for 2020 AABB Annual Meeting**

Registration for the [2020 AABB Annual Meeting](https://www.aabb.org/annualmeeting) — to be held Oct. 3-6 in Baltimore — is now open to AABB members and non-members. The meeting allows attendees to discover the next wave of scientific and clinical research in the fields of transfusion medicine and biotherapies. Expert-led sessions will address some of today’s most pressing issues, including adherence to standards and regulatory guidances during the coronavirus disease 2019 (COVID-19) pandemic, trends in blood collection and utilization, and innovative cord blood-derived therapies.

The safety and well-being of attendees and staff remain AABB’s top priority. As the COVID-19 pandemic continues, AABB is working closely with members, meeting vendors and local health authorities to ensure that protocols are in place to adhere to federal, state and local health and safety guidelines. AABB is also evaluating contingency plans for a virtual event in case an in-person meeting is not practical, possible or safe.

As part of this contingency plan, AABB is offering a "worry-free" cancellation and refund policy for the 2020 Annual Meeting through Sept. 23. Registrations can also be transferred between colleagues at any point prior to the meeting.

AABB will communicate updates on the status of the Annual Meeting as they develop. Additional information on how AABB is adapting the 2020 Annual Meeting to the COVID-19 pandemic is available on the [Frequently Asked Questions page](https://www.aabb.org/annualmeeting/frequently-asked-questions).

06/05/20 CCP Transfusion May Not Improve Outcomes in Critically Ill Patients With COVID-19

**CCP Transfusion May Not Improve Outcomes in Critically Ill Patients With COVID-19**

Adding CCP therapy to standard treatment had no statistically significant benefit in clinical improvement at 28 days or mortality among patients with critical or severe COVID-19, according to findings published this week in *JAMA*. However, the data suggest a possible benefit for certain subgroups of severely ill patients.

The trial, conducted at seven medical centers in Wuhan, China, enrolled 103 participants with laboratory-confirmed COVID-19 that was severe (respiratory distress and/or hypoxemia) or life-threatening (shock, organ failure or requiring mechanical ventilation). Notably, the investigators stated
that the trial was terminated early, which may have been underpowered to detect a clinically important difference.

Of these, 51 patients received standard treatment and 52 patients received CCP in addition to standard treatment standard treatment. Investigators stratified patients by disease severity. The primary outcome was time to clinical improvement within 28 days.

In the primary analysis, clinical improvement occurred within 28 days in 27 patients (51.9%) in the CCP group, compared with 22 patients (43.1%) in the control group. Among patients with severe disease, 21 patients (91.3%) in the CCP group met the primary outcome, compared with 15 patients (68.2%) in the control group. There were no significant differences among those with life-threatening disease, with 6 patients (20.7%) in the CCP group and 7 patients (24.1%) in the control group met the primary outcome.

In an accompanying editorial, Arturo Casadevall, MD, PhD; Michael J. Joyner, MD; Liise-Anne Pirofski, MD, wrote that trial’s secondary end points appeared to signal a more favorable outcome for patients who received CCP, which may influence future randomized controlled trials. “Although the observed differences in mortality rates and hospital discharge rates between the convalescent plasma group and the control group did not reach statistical significance, these data provide valuable information for the magnitude of effects that may be expected in convalescent plasma studies,” they wrote.

06/05/20 Group Exploring MSM Deferral in the U.K. Expects to Report Findings in 2020

A group exploring whether some men who have sex with men (MSM) might be able to donate blood in the United Kingdom without a deferral period is still hoping to report its findings before the end of the year. The work of the For the Assessment of Individualized Risk (FAIR) steering group had been delayed by the COVID-19 pandemic, but it is progressing, according to NHS Blood and Transplant.

The U.K.’s current 3-month deferral is based on population-based risk, but findings from FAIR could inform the potential use of individualized risk assessment. This might enable some MSM who are deferred under the current policy to give blood.

A central part of FAIR’s work is considering which new questions could successfully be added to identify donors, including MSM, at lower risk of acquiring certain transfusion-transmissible infections. As part of this effort, FAIR is conducting focus groups with gay and bisexual men and examining existing public health data and research to determine how best to identify individuals at high and low risk of infections. FAIR is also surveying thousands of current and potential blood donors to examine how people would respond to possible new and more detailed questions about their sexual behaviors.
The British Department of Health and Social Care established FAIR at the beginning of 2019. The steering group includes representatives from the U.K.’s four blood services, LGBT groups, medical and scientific experts, and patient and donor representatives.

06/05/20 REGULATORY UPDATE: FDA Updates List of Variance Approvals under 21 CFR 640.120

REGULATORY UPDATE: FDA Updates List of Variance Approvals under 21 CFR 640.120

FDA’s Center for Biologics Evaluation and Research (CBER) recently updated the list of exceptions and alternative procedures approved under 21 CFR 640.120. In May, the agency approved an exception to sections 630.30(a)(2) and 630.30(b)(1) to distribute seven apheresis red blood cell units that, when collected, resulted in the donor exceeding their annual accumulated blood loss.

This specific exception (exceed annual blood loss) was not included in the April 2020 Alternative Procedures guidance for use during the COVID-19 public health emergency. This guidance, which is in effect only for the duration of the public health emergency, provided exceptions to sections 630.30(a)(2) and 630.30(b)(1) “to release donations for transfusion or further manufacturing when the review of records, required after donation under 21 CFR 630.30(a)(2), identifies the donation as unsuitable because of failure to follow procedures to ensure that the donation would not adversely affect the health of the donor (i.e., for blood pressure; pulse; weight; and donation frequency), and the donation is otherwise suitable under 21 CFR 630.30(a).”

AABB encourages members to review the list of exceptions and alternative procedures issued by CBER to identify new options that might be useful to their facility’s policies and operations.

06/05/20 ASTCT, CIBMTR Release New Guidelines to Combat Spread of COVID-19 Among HCT Recipients


The American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood and Marrow Transplant Research (CIBMTR) recently announced updated guidelines and measures to combat the spread of COVID-19 among hematopoietic cell transplant (HCT) recipients. The guidelines include the introduction of the CIBMTR Respiratory Virus Post-Infusion Data Form (2149), which collects detailed data regarding the diagnosis, treatment and outcome of COVID-19 infections.

06/05/20 Blood Community, CDC, NIH Collaborate on Large-Scale SARS-CoV-2 Antibody Survey

Blood Community, CDC, NIH Collaborate on Large-Scale SARS-CoV-2 Antibody Survey
Vitalant Research Institute (VRI), Creative Testing Solutions and several blood organizations will launch a nationwide SARS-CoV-2 seroprevalence survey in 25 American metropolitan areas this month. The 18-month study, funded by the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), will measure the percentage of people who have antibodies in their blood against SARS-CoV-2, indicating that a person was previously infected with COVID-19.

Blood centers, including the American Red Cross (ARC), Bloodworks Northwest, New York Blood Center, OneBlood, Vitalant and other regional blood collection organizations, along with affiliated donor screening laboratories will provide residual blood donation specimens to be tested for the presence of SARS-CoV-2 antibodies using validated assays and confirmation algorithms.

VRI and its partner organizations will collect and test approximately 1,000 leftover de-identified samples from blood donations from each city every month for 12 months and again at 18 months. This will allow investigators to take “snapshots” of the percentage of people who have antibodies against SARS-CoV-2 at different time points to assess differences in infection rates around the country and over time, as well as among subgroups of blood donors based on demographic data.

“Public health officials need access to ongoing infection rate data in order to make the best decisions for their communities,” said Michael Busch, MD, PhD, director of VRI. “By collaborating with government institutions and leveraging the diverse donor populations and testing systems in place to support our national blood supply, the blood banking community can provide these data relatively quickly. This allows us to monitor and respond to ongoing outbreaks and help evaluate the effectiveness of evolving policies to prevent future widespread transmissions.”

This seroprevalence survey is an expansion of the ongoing REDS (Recipient Epidemiology and Donor Evaluation Study) SARS-CoV-2 “RESPONSE” Program. CDC will publish regularly updated reports on the results and, along with partner organizations, ensure that results are accessible to government partners, researchers and the public.
were alerted by their blood supplier that they will not be able to meet typical inventory needs. O-negative RBC was the most affected component.

In terms of inpatient census, the majority of the responding hospitals (41.3%) are operating at 50-75% of pre-COVID levels. Of the hospitals that resumed elective surgeries, the majority (43%) are operating their elective surgeries at 50-75% of pre-pandemic levels.

In total, 41.3% of hospitals reported having developed a formal plan for a second pandemic wave, an increase from week 10. While intensive care unit bed availability was the major trigger point for cancelling surgeries/procedures, 18.6% of hospitals also considered blood availability a trigger point.

There is a continued downward trend in reported delays (greater than 24 hours) in obtaining COVID-19 convalescent plasma units. Compared to week 10, there was a slight increase in the proportion of hospitals prioritizing CCP to severely ill patients or as a final option. The proportion of hospitals transfusing CCP within 1-3 days of COVID diagnosis/admission showed a continued upward trend.

The majority of hospitals reported not being billed for CCP units by their blood supplier (57.0%). Of these hospitals, 62.5% hospitals reported that CCP use would not be affected if the hospital had to absorb the cost of CCP units.

For results from past weeks, please visit the AABB Surveys and Reports web page.

06/05/20 FDA Guidance Revises IRB Review Procedure in Response to COVID-19

FDA Guidance Revises IRB Review Procedure in Response to COVID-19

FDA issued a new guidance on Tuesday that establishes procedures for single institutional review board (IRB) member review of individual patient expanded access requests for investigational drugs and biologic products to treat COVID-19. The guidance also addresses considerations when assessing benefits and risks for a particular patient being treated under expanded access. The guidance applies only to expanded access requests on behalf of individual patients.

06/05/20 Mobile App Available to Obtain Informed Consent Electronically During the COVID-19 Pandemic

Mobile App Available to Obtain Informed Consent Electronically During the COVID-19 Pandemic

The Food and Drug Administration made the previously released MyStudies app available to investigators as a free platform to obtain informed consent securely from patients for eligible clinical trials when face-to-face contact is not possible due to the COVID-19 pandemic.

The app – released as “COVID MyStudies” – allows investigators to electronically send informed consent documents to patients or legally authorized representatives. Once a patient or representative
has signed the form, they will receive an electronic copy. The investigator can then access the signed consent in a secure manner and print it or transfer the file electronically.

The app is available in the Google Play and Apple App stores. Investigators interested in using the app should contact the CDER Real-World Evidence Program and reference their pre-IND or IND numbers if applicable.

06/05/20 Member Registration Now Open for 2020 AABB Annual Meeting; AABB Offers Worry-Free Cancellation Policy

Member Registration Now Open for 2020 AABB Annual Meeting; AABB Offers Worry-Free Cancellation Policy

Registration for the 2020 AABB Annual Meeting — to be held Oct. 3-6 in Baltimore — is now open to AABB members. Members who register early will save more than $450 on the cost of registration.

AABB’s Annual Meeting allows attendees to discover the next wave of scientific and clinical research in the fields of transfusion medicine and biotherapies. Expert-led sessions will address some of today’s most pressing issues, including adherence to standards and regulatory guidances during the coronavirus disease 2019 (COVID-19) pandemic, trends in blood collection and utilization, and innovative cord blood-derived therapies.

The safety and well-being of attendees and staff remains AABB’s top priority. As the COVID-19 pandemic continues, AABB is working closely with members, meeting vendors and local health authorities to ensure that protocols are in place to adhere to federal, state and local health and safety guidelines. AABB is also evaluating contingency plans for a virtual event in case an in-person meeting is not practical, possible or safe.

As part of this contingency plan, AABB is offering a "worry-free" cancellation and refund policy for the 2020 Annual Meeting through Sept. 23. Registrations can also be transferred between colleagues at any point prior to the meeting.

AABB will communicate updates on the status of the Annual Meeting as they develop. Additional information on how AABB is adapting the 2020 Annual Meeting to the COVID-19 pandemic is available on the Frequently Asked Questions page.

05/29/20 Pre-Print Data Suggest CCP Transfusion Improves Supplemental Oxygen Requirements, Survival in Patients With Severe COVID-19

Pre-Print Data Suggest CCP Transfusion Improves Supplemental Oxygen Requirements, Survival in Patients With Severe COVID-19
Patients with COVID-19 who received a CCP transfusion were more likely than control patients to remain the same or have improvements in their supplemental oxygen requirements 14 days after transfusion, according to pre-print findings from a small matched control study made available on medRxiv. Plasma recipients also demonstrated improved survival when compared to control patients.

Investigators compared the supplemental oxygen requirements and survival of 39 hospitalized patients with severe to life-threatening COVID-19 who received convalescent plasma transfusion (anti-spike antibody titer of greater than or equal to 1:320 dilution) against a cohort of retrospectively matched controls.

Notably, investigators found that in a covariates-adjusted Cox model, CCP transfusion improved survival for non-intubated patients (hazard ratio 0.19 (95% CI: 0.05 ~0.72); p=0.015), but not for intubated patients (1.24 (0.33~4.67); p=0.752). According to investigators, the results indicate that CCP transfusion is a potentially efficacious treatment option for patients hospitalized with COVID-19, but non-intubated patients may benefit more than those requiring mechanical ventilation.

05/29/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the week 10 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 96 respondents from 35 states completed the survey, conducted May 25-28.

As more hospitals resumed elective surgeries this week (81.3% of the responding hospitals), fewer (41.7%) reported an increase in product outdating due to changes related to the pandemic. This continues a downward trend that began the week of May 11 (survey week 8). While 5.2% of responding hospitals are resuming elective surgeries before mid-June, 4.2% are doing so after mid-June.

In terms of inpatient census, 39.4% of hospitals are operating between 50-75% of pre-COVID levels. Of the hospitals that resumed elective surgeries, 39.5% are operating their elective surgeries at less than 50% level, compared to pre-COVID levels. In addition, 39.6% of hospitals reported having developed a formal plan for a second wave. Availability of beds in the ICU was the major trigger point for surgeries/procedures.

There is a downward trend in reported delay (greater than 24 hours) in obtaining CCP units. There was a slight increase in proportion of the hospitals prioritizing CCP to moderately ill patients and a slight decline in those prioritizing CCP to severely ill patients, compared to past weeks. The proportion of hospitals reporting CCP transfusion within 1-3 days of COVID diagnosis/admission is showing an
upward trend. The majority of hospitals reported not being billed for CCP units by their blood supplier (56.3%). Of these hospitals, 52.3% hospitals reported that CCP use would not be affected if hospital had to absorb the cost of CCP units.

For results from past weeks, please visit the AABB Surveys and Reports web page.

**05/29/20 FDA's COVID-19 FAQs Updated to Include Tests That Should No Longer Be Distributed**

**FDA's COVID-19 FAQs Updated to Include Tests That Should No Longer Be Distributed**

The Food and Drug Administration added a list of serological COVID-19 tests that should no longer be distributed to its FAQs on Testing for SARS-CoV-2 web page this week. The update reflects FDA’s revised May 2020 guidance, which states that manufacturers of serological tests must submit an emergency use authorization (EUA) request within a reasonable period of time. FDA removed the manufacturers and tests from the notification list for which it did not receive a timely EUA request or it identified significant test problems that could not or have not been addressed in a timely manner. FDA expects that the tests on the list will not be distributed without an EUA and the agency may take additional actions as appropriate.

**05/29/20 Blood Community Organizations Join Nationwide Coalition to Promote CCP Donation**

**Blood Community Organizations Join Nationwide Coalition to Promote CCP Donation**

AABB, ABC and Blood Centers of America (BCA) joined a nationwide coalition that aims to unite the blood and plasma community around joint efforts related to coronavirus disease 2019 (COVID-19) convalescent plasma (CCP). The coalition, initiated and led by Microsoft and the Gates Foundation, also includes Mayo Clinic, Washington University and the CoVIg-19 Plasma Alliance.

The first initiative to launch under the coalition is a nationwide multimedia campaign, “The Fight Is In Us,” that encourages those who have recovered COVID-19 to donate CCP at a blood or plasma center. The campaign will highlight an online tool that provides donation locations for those who have been diagnosed with COVID-19 (with a clinical diagnosis or laboratory test).

Although the donation locator algorithm is currently based on geography and provides the five closest CCP donor sites, it may mature to respond to specific supply needs in the future. Member centers that prefer not to include their CCP collection site should inform AABB by emailing amckinnon@aabb.org. AABB will update members of new initiatives within this project and encourages member feedback on the Association’s participation in this effort.
AABB, ABC, ARC Urge Americans to Donate Blood

AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) are urging eligible individuals to make an appointment to donate blood. In a joint statement released this week, the organizations noted that blood centers are reporting inventories at their lowest levels since the early stages of the pandemic as hospitals resume elective surgeries. In addition, blood drives continue to be canceled, and social distancing measures have limited blood centers’ ability to collect blood at pre-pandemic levels. The organizations emphasized that the availability of an adequate blood supply is a key aspect of ensuring optimal treatment for all patients and that blood must be replenished to help prevent shortages during the coming weeks and months.

Pre-Print Data Suggest CCP Safe in Patients With COVID-19

An analysis of key safety metrics following transfusion of ABO-compatible CCP in hospitalized adults with severe or life-threatening COVID-19 suggests that the treatment is safe for hospitalized patients. The analysis includes data from the first 5,000 patients with COVID-19 with symptoms defined as “severe or life-threatening” or who were reportedly “at high risk of progression to severe or life-threatening” symptoms who enrolled in an FDA-led Expanded Access Program (EAP) in collaboration with the Mayo Clinic. Investigators posted the pre-print results on a public server, MedRxiv, so their peers could quickly review the data.

Within 4 hours of completing a CCP transfusion (inclusive of the plasma transfusion), 36 serious adverse events (SAEs) were reported (less than 1% of the patient population), including mortality (0.3%). Of the 36 reported SAEs, there were 25 reported incidences of related SAEs, including mortality (4), transfusion-associated circulatory overload (7), transfusion-related acute lung injury (11) and severe allergic transfusion reactions (3). Treating physicians judged two of these SAEs as definitely related to CCP transfusion. The 7-day mortality rate was 14.9%.

According to investigators, the experience from these patients provides no signal of toxicity beyond what is expected from typical plasma use in severely ill patients. In addition, they believe that the mortality rate does not appear excessive given the deadly nature of COVID-19 and the large population of critically ill patients with multiple comorbidities included in these analyses.

The authors noted that the efficacy of convalescent plasma for treating COVID-19 has not yet been determined and emphasized that this report should not be misconstrued as evidence of effectiveness.

“Future analyses of EAP data will include exposure control cohorts of patients who did not receive COVID-19 convalescent plasma,” the authors wrote. “However, randomized controlled trials — some of which are currently in progress — will ultimately be necessary to evaluate the potential efficacy of convalescent plasma treatment along the continuum of disease-severity.”
05/22/20 **Reminder: New Educational Sponsorship Opportunities Available**

**Reminder: New Educational Sponsorship Opportunities Available**

AABB developed two new educational sponsorship opportunities for industry partners seeking to connect virtually with the blood community during the COVID-19 pandemic. The first, an educational sponsored eCast, consists of a one-hour educational webinar with continuing education credit options for participants. The second, a virtual innovation theater, is a virtual version of the session of the same name typically held in the exhibit hall during the AABB Annual Meeting. In these programs, industry partners present a product during a live 60-minute webinar, which includes a question-and-answer period. AABB invites individuals and industry representatives interested in learning more about these opportunities to contact Margie Boraz, director, Business Development.

05/22/20 **Be The Match BioTherapies, NantKwest Announce Partnership to Accelerate Cell Therapy to Treat ARDS in COVID-19 Patients**

**Be The Match BioTherapies, NantKwest Announce Partnership to Accelerate Cell Therapy to Treat ARDS in COVID-19 Patients**

Be The Match BioTherapies announced that it will provide donor materials from the Be The Match BioBank to NantKwest, a cellular therapies developer, for use in an investigational off-the-shelf cell therapy for acute respiratory distress syndrome (ARDS). ARDS is a leading cause of death in COVID-19 patients.

The allogeneic cell therapy, called BM-Allo.MSC, is derived from human bone marrow and uses mesenchymal stem cells (MSCs) to reduce lung inflammation associated with ARDS. Similar work in Europe with allogeneic MSC products in patients with COVID-19 and ARDS has demonstrated safety and efficacy in reducing inflammatory processes. NantKwest recently received FDA authorization of its IND application for BM-Allo.MSC and is working to initiate a phase 1b trial in patients with severe COVID-19.

05/22/20 **AABB Consulting Services Begins Virtual Operations**

**AABB Consulting Services Begins Virtual Operations**

AABB Consulting Services will begin offering consultations, interviews and gap analyses via Zoom in response to the COVID-19 pandemic. These virtual services will help blood, plasma and tissue collection and/or management facilities; transfusion services; clinical laboratories; and cellular and related biological therapy facilities improve their quality management and process improvement systems without risk to employee health and safety. AABB Consulting Services is also developing plans for virtual site visits. Those interested in scheduling virtual services may contact Margie Boraz, director,
Business Development, or Christine Bales, BS, MT, I(ASCP), CQA (ASQ), vice president, Consulting and Global Services. Additional information on AABB’s portfolio of services is available online.

**05/22/20 #TeamBlood Initiative Aims to Foster Community Engagement During Pandemic**

#TeamBlood Initiative Aims to Foster Community Engagement During Pandemic

AABB and the National Blood Foundation (NBF) recently launched the #TeamBlood: In This Together initiative to provide new ways for members of the blood and biotherapies communities to connect during this time of physical distancing. The Share a Story program allows members to describe their experiences during the COVID-19 pandemic. Readers can add their stories of funny, sad, challenging or generous happenings online. The first #TeamBlood story, from AABB President Beth Shaz, MD, appeared in the May issue of AABB News. AABB also began sharing stories this week on its social media pages.

The initiative also includes a sponsored membership program to help someone who has experienced economic hardship during the pandemic. Individuals interested in sponsoring an AABB membership for a friend or colleague may contact the AABB Membership Department for additional information at +1.301.215.6489 or membership@aabb.org.

In addition, this initiative provides a means to dedicate a donation to the NBF in honor of an associate or in memory of a friend or colleague. Donations to the NBF support innovative research that could help launch the career of one of tomorrow’s leading researchers. The NBF will send a notification letter of donation dedications that can include the donor’s personal sentiments.

**05/22/20 AABB Seeks Member Feedback on In-Person Annual Meeting, Virtual Alternatives**

AABB Seeks Member Feedback on In-Person Annual Meeting, Virtual Alternatives

AABB is seeking feedback to help guide the Association’s decision-making process in determining the best approach to the 2020 AABB Annual Meeting, planned for Oct. 3-6 in Baltimore. The Association is working closely with vendors and local health authorities to determine if the meeting can be held as scheduled. AABB is also evaluating alternative options.

The health and safety of AABB members and meeting attendees remains AABB’s top priority, and attendee feedback will help the Association provide the best possible experience for the blood banking and biotherapies community. AABB requests responses by Monday, May 25. The Association will immediately communicate any changes to the status of the meeting.
**05/22/20 REGULATORY UPDATE: AABB Developing DHQ v2.1 Q&A Resource**

**REGULATORY UPDATE: AABB Developing DHQ v2.1 Q&A Resource**

AABB Regulatory Affairs staff is developing an easy to use question-and-answer (Q&A) reference to assist members with implementation of the Donor History Questionnaire (DHQ) v2.1 and Related Materials that were formally recognized by FDA in its May 5 guidance. DHQ v2.1 incorporated the recommendations outlined in FDA’s April 2020 guidance to address the urgent need for blood during the pandemic. AABB is currently pursuing clarification from FDA on a few key topics. AABB will update the document regularly and encourages members to submit their questions on this or any other issue to regulatory@aabb.org.

**05/22/20 AHRQ Grantee Releases Surge Capacity Tool for Hospitals**

**AHRQ Grantee Releases Surge Capacity Tool for Hospitals**

A new surge capacity tool developed by Agency for Healthcare Research and Quality (ARHQ) grantee James Benneyan, PhD, may help hospitals determine their operational needs during a pandemic, including requirements for beds, ventilators, personal protective equipment, medications and staff. This complimentary tool automatically generates results for 1- to 30-day projections, based on individual hospital and patient data, and is available to hospitals worldwide. The surge capacity tool is among AHRQ-supported resources, toolkits and research findings available to help fight the COVID-19 pandemic.

**05/22/20 NIH Officials Outline Ongoing Efforts to Advance COVID-19 Therapeutics**

**NIH Officials Outline Ongoing Efforts to Advance COVID-19 Therapeutics**

Officials from the National Institutes of Health (NIH) outlined the efforts of Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) in a Viewpoint published recently in JAMA. ACTIV, a public-private initiative organized by NIH and the Foundation for the NIH, is developing an international strategy for an integrated research response to COVID-19 in collaboration with pharmaceutical companies, federal agencies and the European Medicines Agency (EMA).

In the commentary, officials described how ACTIV has established a collaborative framework to prioritize therapeutic and vaccine candidates; to streamline human clinical trials and tap into existing trial networks; and to coordinate regulatory processes and leverage assets among all partners. The authors also discussed the steps ACTIV’s partners have taken to prioritize therapeutic and vaccine candidates and have indicated willingness to contribute their respective clinical trial capacities, irrespective of the agent to be studied. Additional information about ACTIV is available online.
Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'

The Trump Administration announced the appointment of Moncef Slaoui, PhD, as chief advisor and General Gustave F. Perna as chief operating officer of Operation Warp Speed (OWS) on Friday. OWS is a public-private partnership to facilitate the development, manufacturing and distribution of COVID-19 countermeasures between agencies within the Department of Health and Human Services (HHS), private firms and other federal agencies.

Slaoui is a venture capitalist and former chairman of Global Research and Development and chairman of Global Vaccines at GlaxoSmithKline, where he led the development of five major novel vaccines. As the four-star general in charge of the U.S. Army Materiel Command, Perna oversees the global supply chain and installation and materiel readiness for the U.S. Army, including more than 190,000 military, civilian and contract employees.

AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services; Previous Findings Now Available Online

AABB released a graphic summary of the week 9 results of a weekly survey of AABB member hospital transfusion services and their actions in response to the COVID-19 pandemic. This week, 106 respondents from 39 states completed the survey, conducted May 18-21.

As more hospitals resumed elective surgeries, fewer hospitals (51%) reported an increase in product outdated due to changes related to the pandemic. This week, 75.2% of the responding hospitals already resumed “some” elective surgeries, while 11.4% plan to resume elective surgeries before mid-June. In addition, 36.5% of the hospitals that resumed elective surgeries reported 0-5% increase in RBC usage compared to week 8.

Compared to week 8, there was a slight increase in the proportion of hospitals prioritizing CCP to moderately ill patients; 42.3% of the hospitals that considered timing of diagnosis/admission as an important factor transfused CCP within 1-3 days of COVID diagnosis/admission, showing an upward trend. Fewer hospitals reported delays (greater than 24 hours) in obtaining CCP units (35.4%) and a slightly higher percentage of hospitals reported obtaining CCP units from their own hospital-based donor center (22.4%). There was an increase in hospitals using eIND to obtain CCP for critically ill patients this week (32.9% in week 9 and 22.8%: week 8).

AABB will continue to report the results to participating hospitals on a weekly basis.
In addition, AABB members may now access findings from each of AABB’s weekly survey snapshots on the AABB Surveys and Reports [web page](#). These findings, available exclusively to AABB members, may assist hospital-based transfusion services in understanding the trends and practices affected by the COVID-19 pandemic.

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05/22/20 **AABB Announces Slate of Nominees for 2020-21 Board of Directors**

**AABB Announces Slate of Nominees for 2020-21 Board of Directors**

AABB’s 2020 Nominating Committee is pleased to present the slate of candidates for the 2020-21 Board of Directors. The slate includes the Committee’s recommendations to fill the officer positions for 2020-21: Dana Devine, PhD, for president-elect; Brian Gannon, MBA, for vice president; and Aaron Tobian, MD, for secretary.

The slate also includes the Committee’s recommendations for this year’s open at-large director positions. The Committee recommends Delisa English, MBA, for position #2; Magali Fontaine, MD, PhD, for position #4; Phil Accooe, MLS(ASCP)SBB, CLS, for position #6; Celina Montemayor-Garcia, MD, PhD, for position #8; and Meghan Delaney, DO, MPH, for position #10.

After careful consideration and deliberation, the Committee opted to recommend that this year’s candidates run unopposed. This decision was made to ensure consistency and fairness among each of the at-large director positions. In addition, noting that this is a critical and transitional time for the AABB community as it navigates the ongoing COVID-19 pandemic, the Committee sought to put forth the most favorable candidates for each position. The Committee believes this slate of candidates represents the strong and diverse range of skills needed to ensure AABB’s success as it addresses the current long- and short-term challenges and opportunities facing the organization.

On July 24, electronic ballots will be distributed to all members in good standing. Voting will end on Aug. 28, and the results will be published shortly thereafter.

Per AABB’s bylaws, additional nominees for the open at-large director positions may be submitted using the petition process. Instructions for submitting a nomination by petition and related submission requirements are available on [AABB’s website](#). The deadline to submit nominations by petition is July 10 at 11:59 pm ET.

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05/15/20 **AABB News Highlights CCP, Other Blood Components Being Investigated as Treatments for Several Conditions**

**AABB News Highlights CCP, Other Blood Components Being Investigated as Treatments for Several Conditions**

Updated by AABB Regulatory Affairs 10/16/20
As the COVID-19 infection rate continues to rise in many parts of the United States, CCP is becoming a more common experimental treatment for those suffering the most severe symptoms. The May issue of AABB News explores the history of convalescent plasma, from variolation in 10th century China to Edward Jenner’s research with cowpox in 1794 and today’s CCP research protocols. Another feature examines controversial uses of blood components, such as attempts to reverse the effects of aging with “young blood” and efforts to heal wounds with platelet-rich plasma.

The issue also includes columns that detail government actions in response to the pandemic; highlights the National Blood Foundation’s new #TeamBlood initiative, which offers members ways to stay connected while physically apart; and summarizes the recent Twitter chat on CCP led by AABB President Beth Shaz, MD, and Claudia Cohn, MD, PhD, AABB’s chief medical officer.

05/15/20 2020 AABB Annual Meeting Abstracts Due Today

Abstracts for the 2020 AABB Annual Meeting are due today. Abstract categories include various scientific and administrative categories in transfusion medicine and cellular therapies, and submissions from both members and nonmembers are welcome. Abstract preparation and submission guidelines are available online.

As the COVID-19 pandemic unfolds, AABB is working closely with members, meeting vendors and local health authorities to determine if the 2020 AABB Annual Meeting can be held live as scheduled for Oct. 3-6 in Baltimore. The Association is currently evaluating potential alternative options, including a virtual Annual Meeting that would allow attendees to continue to benefit from the superior education content the meeting offers. The health and safety of AABB members and Annual Meeting attendees is the Association’s top priority. Any changes to the status of the 2020 Annual Meeting will be communicated immediately.

05/15/20 State Attorneys General Ask HHS to Reconsider MSM Deferral for Blood, CCP Donation

Attorneys general from 20 states asked the Department of Health and Human Services (HHS) to end time-based restrictions on blood donation from men who have sex with men (MSM) and to “immediately clarify” that the deferral period does not bar MSM from donating CCP. In the April 22 letter, officials stated that FDA’s recently revised guidance is an important first step for protecting the nation’s blood supply during the COVID-19 pandemic, but they noted that the 3-month deferral “still precludes many LGBTQ Americans from fully contributing to the blood shortages while still requiring a waiting period for healthy individuals.”
The attorneys general believe that additional precautions regarding who can donate blood should be narrowly tailored to achieve safety goals while maximizing the blood supply. Furthermore, they believe that a risk-based model will protect both the blood supply and donor dignity. They cited a \textit{2014 analysis} by the Williams Institute, which indicated that lifting the blood donation ban for MSM completely would produce more than 2 million additional eligible blood donors, including nearly 175,000 likely blood donors, and would lead to nearly 300,000 pints of additional donated blood annually.

In addition, the attorneys general noted that FDA requires that convalescent plasma “must only be collected from recovered individuals if they are eligible to donate blood,” which appears to bar MSM from donating CCP, even within a monogamous relationship. “The FDA should immediately clarify that the new three-month MSM deferral period announced does not bar MSM from donating convalescent plasma to their loved ones,” they wrote. “This helps expand the pool of individuals eligible to donate convalescent plasma and potentially helps treat COVID-19.”

In a separate letter, Democrats on the House Committee on Oversight and Reform urged FDA Commissioner Stephen Hahn, MD, to lift restrictions on MSM who have recovered from COVID-19 from donating CCP for research. The representatives stated that the current policy stigmatizes gay and bisexual men and undermines critical research into potential coronavirus treatments. They asked FDA to “immediately modify its deferral recommendations so that all gay and bisexual men who have recovered from coronavirus and can safely donate plasma to support treatment research efforts are able to do so.”

\textbf{05/15/20 FDA Issues Untitled Letters Regarding Unapproved Umbilical Cord Blood Product, Adipose Tissue-Derived Products}


FDA recently issued untitled letters to two companies regarding unapproved products that appear to be human cells, tissues, or cellular or tissue-based products (HCT/Ps). The agency issued the \textit{first letter} to Texas-based Houston Stem Cell on April 27 regarding an umbilical cord blood-derived cellular product marketed as a treatment for Parkinson’s disease, Alzheimer’s disease, fibromyalgia and lupus.

FDA sent a \textit{second untitled letter} to Sparrow Health and Performance, LLC, of Hoover, Ala., on May 11. Sparrow Health and Performance offers cellular products derived from adipose tissue as a “stem cell therapy” to treat numerous diseases and conditions, including COVID-19. The company also lists exosomes as one of its provided services.

FDA believes that these products appear to be human cell, tissue, or cellular or tissue-based products (HCT/P) and should be regulated as both drug and biological products. In order to lawfully market these products, a valid biologics license application or IND application must be in effect, as specified by
FDA regulations. In addition, FDA noted in the May 11 letter that exosomes for clinical use in humans are also regulated as drugs and biological products and subject to the same premarket review and approval requirements.

The agency directed both companies to FDA’s comprehensive regenerative medicine policy framework for HCT/Ps and requested written responses from both within 30 days of receipt of their respective letters.

05/15/20 Reminder: AABB Temporarily Suspends Assessments Due to COVID-19 Risk

Reminder: AABB Temporarily Suspends Assessments Due to COVID-19 Risk

AABB has temporarily suspended all assessments in response to the ongoing COVID-19 pandemic. This action will ensure that member facilities can focus on their own internal needs and challenges during the current outbreak, and it will also help protect the health and safety of AABB employees and volunteers. The Association’s other programs and services remain fully operational, and scheduled educational programs will continue as planned.

05/15/20 AABB, ABC, ARC Urge CMS to Update Reopening Guidelines to Promote Communication Between Blood Suppliers, Hospitals to Protect Blood Inventory

AABB, ABC, ARC Urge CMS to Update Reopening Guidelines to Promote Communication Between Blood Suppliers, Hospitals to Protect Blood Inventory

AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) urged CMS Administrator Seema Verma to update the agency’s recommendations and encourage hospitals to work with their blood supplier to ensure blood inventory is sufficient when deciding when and how to resume non-emergent health care.

In a May 13 letter, the organizations explained that the blood supply remains fragile as a result of necessary social distancing efforts, decreased utilization and blood’s short shelf life. They acknowledged that the agency’s current recommendations are part of a planned, phased approach to prevent overwhelming health care systems, but reiterated the critical nature of close collaboration between blood centers and health care providers.

“We strongly believe that coordination between hospitals and blood centers is critical to this effort,” the organizations’ letter said. “CMS should encourage hospitals to work with their blood suppliers, blood banks and transfusion services to continually assess their blood inventory to ensure that it supports their changing utilization needs.”
AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services

AABB released a graphic summary of the results from week 8 of a weekly survey of AABB member hospital transfusion services. This week, 100 respondents from 37 states completed survey, conducted May 11-14. As more hospitals are planning to resume elective surgeries, fewer hospitals (52%) reported an increase in product outdating due to the pandemic. In total, 59% of the responding hospitals are resuming “some” elective surgeries before mid-May, and 28% are doing so after mid-May, an upward trend compared to previous weeks. There was a slight increase in the number of hospitals prioritizing CCP to severely ill patients, as well as to patients within 1 to 3 days of COVID diagnosis or admission.

While the expanded access protocol remains the major route to obtain CCP, there was a slight increase in number of units obtained through the eIND. In addition, there was an increase in hospitals using the eIND to obtain CCP for pediatric patients (26.3% in week 8 and 17.1%: week 7). Hospitals offering options for antibody titer tests showed an upward trend (59.2% during week 8, 47% during week 7, 37.6% during week 6, and 24 % during week 5). Fewer hospitals reported a delay (longer than 24 hours) in obtaining CCP units compared to previous weeks (43.3% in week 8, 46.4% in week 7 and 51.2% in week 6). AABB will continue to report the results to participating hospitals on a weekly basis. Members interested in viewing results from previous surveys may contact Srijana Rajbhandary.

ARHQ to Award $5 Million for Health Services Research Related to COVID-19

The Agency for Healthcare Research and Quality (AHRQ) announced a new funding opportunity announcement on Thursday that will award $5 million to support novel, high-impact studies that evaluate the responsiveness of health care delivery systems, health care professionals and the overall U.S. health care system to the COVID-19 pandemic. AHRQ expects to fund research focused the effects on quality, safety and value of the health system response to COVID-19; the role of primary care practices and professionals during the COVID-19 epidemic; understanding how the response to COVID-19 affected socially vulnerable populations and people with multiple chronic conditions; and the integration of digital health in the response to COVID-19, including innovations and challenges encountered in the expansion of telehealth.

This funding opportunity is applicable for relevant research in all health care settings, including hospitals, primary care and other ambulatory care settings, pre-hospital care, long-term and nursing home care, home health care, mental health and substance use care, pharmacy, and transitions of care between settings. The application deadline is June 15.
05/15/20 **FDA Updates Guidance on Conducting Clinical Trials During COVID-19**

**FDA Updates Guidance on Conducting Clinical Trials During COVID-19**

FDA released an updated question-and-answer appendix in its March 2020 guidance on conducting clinical trials of medical products during the COVID-19 pandemic. The updated guidance includes new content with considerations for using alternate laboratories or imaging centers, holding trial participant visits via video conference and conducting required postmarketing clinical trials. The guidance also includes updated information on managing protocol deviations, amendments to ongoing trials and consulting with the FDA regarding administering investigational product infusions at home.

05/15/20 **FDA Releases New Guidances to Advance Investigational COVID-19 Therapies**

**FDA Releases New Guidances to Advance Investigational COVID-19 Therapies**

FDA released two guidance documents this week to accelerate the development of prevention and treatment options for COVID-19. The first guidance, “COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products,” outlines a more efficient process for researchers to receive feedback from FDA on their supporting data with the goal of starting clinical trials as soon as possible. The guidance also provides clarity on the types of data and information that sponsors should provide to address clinical, nonclinical and quality considerations before submitting an application to initiate studies.

The second guidance, “COVID-19: Developing Drugs and Biological Products for Treatment or Prevention,” provides FDA’s current recommendations on later-stage clinical trials intended to establish safety and effectiveness for COVID-19 treatments. The guidance outlines critical sponsor considerations, such as appropriate patient selection, including the evaluation of therapies in patients at high risk of complications from COVID-19. The guidance also helps sponsors understand how to design optimal trials during the pandemic, including considerations of study duration, assessment of efficacy and monitoring for safety. FDA anticipates this guidance will help sponsors to efficiently design studies that may lead to the review and potential approval of safe and effective pharmacotherapies and biological products to treat patients with COVID-19.

05/15/20 **REGULATORY UPDATE: FDA Updates Information for Blood Establishments Regarding COVID-19**

**REGULATORY UPDATE: FDA Updates Information for Blood Establishments Regarding COVID-19**

The Food and Drug Administration issued updated considerations for blood establishments in response to the ongoing coronavirus disease 2019 (COVID-19) pandemic. The May 11 update replaces the agency’s March 2020 communication. In its update, the agency said that “there have been no reported cases of transfusion-transmitted coronavirus, including SARS-CoV-2, worldwide” and continues to confirm that “routine measures used to determine blood donor eligibility prevent individuals with
clinical respiratory infections from donating blood.”

The May 11 communication supports the use of blood donor educational materials that instruct individuals to refrain from donation for 14 days based a short list of risk criteria. Self-deferral is encouraged for those with symptoms who have been diagnosed with or suspected of having COVID-19 and individuals with a positive diagnostic test for SARS-CoV-2, even if they never developed symptoms.

FDA clarified that individuals who have tested positive for SARS-CoV-2 antibodies but never developed symptoms and never had diagnostic testing can donate without a waiting period and without performing a diagnostic test.

AABB has updated the COVID-19 Toolkit to identify and incorporate all of the changes in the May 11 communication. Individuals with questions or concerns may contact regulatory@aabb.org.

05/08/20 AABB Announces New Sponsorship Opportunities

AABB Announces New Sponsorship Opportunities

AABB has developed a new sponsorship program for industry partners seeking opportunities to connect with the blood community during the COVID-19 pandemic.

Two of the new sponsorship opportunities focus on professional development, which is consistently rated by AABB members as one of the most valuable resources provided by the Association. The first of these is an Educational Sponsored eCast, which will consist of a one-hour educational webinar with continuing education credit options for participants. The second is a Virtual Innovation Theater, designed as a virtual version of sessions by the same name typically held in the exhibit hall during the AABB Annual Meeting. As part of such programs, industry partners present a product during a live 60-minute webinar, which includes a question-and-answer period.

AABB staff are available to work with industry partners to customize a program that matches their needs and would benefit the blood community. AABB invites individuals and industry representatives interested in learning more about sponsorship to contact Margie Boraz, AABB’s director of business development.

05/08/20 AABB and NBF Launch New Initiative to Foster Community Engagement During Pandemic

AABB and NBF Launch New Initiative to Foster Community Engagement During Pandemic

AABB and the National Blood Foundation (NBF) are pleased to launch an exciting program, #TeamBlood In This Together, to provide new ways for members of the blood and biotherapies communities to connect during this time of forced distancing. One offering, Share a Story,
allows members to tell their story about working during the COVID-19 pandemic. Readers can add their stories of funny, sad, challenging or generous happenings online. These stories may appear in future issues of AABB News.

The pandemic has created financial hardships for many in the community, especially those just starting their careers. To help someone who has experienced economic hardship during the pandemic, the NBF introduced a means to sponsor AABB membership for a colleague or friend. Contact the AABB Membership Department for additional information at +1.301.215.6489 or membership@aabb.org.

In addition, this initiative provides a means to dedicate a donation to the NBF in honor of an associate or in memory of a friend or colleague. As always, a donation to the NBF supports innovative research that could help launch the career of one of tomorrow's leading researchers. The NBF will send a notification letter of donation dedications that can include the donor's personal sentiments.

05/08/20 2020 AABB Annual Meeting Abstracts Due Next Friday

2020 AABB Annual Meeting Abstracts Due Next Friday

The deadline to submit abstracts for the 2020 AABB Annual Meeting is May 15. Submissions from both members and nonmembers are welcome. Abstract categories include various scientific and administrative categories in transfusion medicine and cellular therapies. Abstract preparation and submission guidelines are available online.

As the COVID-19 pandemic unfolds, AABB is working closely with members, meeting vendors and local health authorities to determine if the 2020 AABB Annual Meeting can be held live as scheduled for Oct. 3-6 in Baltimore. The Association is currently evaluating potential alternative options, including a virtual Annual Meeting that would allow attendees to continue to benefit from the superior education content the meeting offers. The health and safety of AABB members and Annual Meeting attendees is the Association’s top priority. As new information becomes available, AABB will provide updates in Weekly Report.

05/08/20 AABB, Accumen and TJC Partner for Webinar Series on PBM During COVID-19

AABB, Accumen and TJC Partner for Webinar Series on PBM During COVID-19

AABB’s partnered webinar series, “COVID-19 Lessons Learned in Patient Blood Management,” continues at 1 p.m. ET on Wednesday, June 3, with a program on the impact of COVID-19 on blood availability and utilization. The next and final webinar in the series will explore the critical role of anemia management programs as hospitals recover from the COVID-19 crisis. This webinar will take place at 1 p.m. ET on Wednesday, July 8. Registration information is available online.
BCA to Administer CCP Resource-Sharing Network

Blood Centers of America (BCA) will administer a resource-sharing network to help meet the need for CCP at hospitals without a regular blood supplier. Hospitals that require assistance in locating CCP may contact the network via phone at +1.844.633.3226 or email at covidplasma@bca.coop. BCA will staff the number between 8 a.m. and 7 p.m. ET, Monday-Friday. After 7 p.m., an automated attendant will answer and generate an email, which resource-sharing staff will address the next day. On-call staff will respond to requests received on the weekend.

AABB Releases Latest Findings From Member Hospital Snapshot Survey

AABB released a graphic summary of the results from week 7 of a weekly survey of AABB member hospital transfusion services. A total of 100 respondents from 37 states completed the survey, conducted May 4-7. This week, 54% of respondents reported an increase in product outdating due to changes related to the pandemic, a continued upward trend. In addition, 56% of the responding hospitals are resuming “some” elective surgeries before mid-May, and 19% plan to do so after mid-May, an upward trend compared to weeks 5 and 6.

The majority of hospitals (56%) are prioritizing CCP for severely ill patients; 25% reported using CCP as a final option if no other treatment is effective. Among hospitals that considered timing of diagnosis/admission as an important factor in CCP administration, the majority administered CCP within 4-6 days of COVID-19 diagnosis.

Week 7 showed an increase in hospitals using the eIND route to obtain CCP for critically ill patients (35.7%), compared to week 6 (29.6%). Hospitals offering options for antibody titer tests showed an upward trend (47% during week 7, 37.6% during week 6 and 24% during week 5).

AABB will continue to report the results to participating hospitals on a weekly basis. Members interested in viewing results from previous surveys may contact Srijana Rajbhandary.

House Members Push for Blood Center Relief in COVID-19 Response

A bipartisan group of legislators urged leaders of the U.S. House of Representatives to include assistance for blood centers in the next COVID relief legislative package in a letter released last Thursday. In the letter, Reps. Jerry McNerney (D-Calif.), Eliot L. Engel (D-N.Y.), Rodney Davis (R-Ill.) and Brian Fitzpatrick (R-Pa.), joined by 42 of their colleagues, highlighted how blood centers are actively engaged in supporting the needs of patients during the COVID-19 pandemic but emphasized that this has resulted in many financial stressors. They discussed several of these challenges –
expenditures related to necessary social distancing, decreased blood utilization due to the postponement of elective surgery, and the cancellation of thousands of blood drives during the pandemic – and their added cost to blood center operations, both directly and through decreased efficiency. The representatives concluded by reiterating the importance of the blood supply and highlighting its essential role in the health care system. “We urge you to include blood center-specific relief sufficient to address the impact of the entirety of this pandemic in the next legislative package,” they wrote. "Blood centers need assistance now in order to survive."

**05/08/20** ECDC Updates Document on Managing COVID-19 Risk in Substances of Human Origin

**ECDC Updates Document on Managing COVID-19 Risk in Substances of Human Origin**

The European Centre for Disease Prevention and Control (ECDC) updated the agency’s document on risk assessment and management options for the safe and sustainable supply of substances of human origin in the European Union and European Economic Area during the COVID-19 pandemic. The risk assessment document now includes reproductive and some non-reproductive tissues and cells, along with blood and blood components; cells and tissues; and organs. ECDC will update the document as and when new relevant information becomes available, or as required by the epidemiological situation.

**05/08/20** COVID-19 Patients in the U.K. Begin Receiving CCP Transfusions

**COVID-19 Patients in the U.K. Begin Receiving CCP Transfusions**

The United Kingdom’s NHS Blood and Transplant (NHSBT) has supplied the first units of CCP to hospitals and the first transfusions have taken place, the agency announced this week. NHSBT is conducting initial transfusions through the ongoing international REMAP-CAP trial, which was created to evaluate a number of treatment options simultaneously. The NHSBT Clinical Trials Unit is collaborating with the main REMAP-CAP team to deliver the convalescent plasma domain of REMAP-CAP in the U.K.

Concurrently, NHSBT is building capacity to collect plasma so that it can deliver at a large scale if transfusions are shown to help patients. NHSBT is contacting potential CCP donors directly, using recovered patient data supplied through the NHS. Individuals in the U.K. may also register their interest online in donating CCP. Individuals may donate no sooner than 28 days after resolution of COVID-19 symptoms.

In the U.S., individuals are eligible to donate CCP as recently as 14 after the resolution of COVID-19 symptoms. Those interested in making a donation may use AABB’s blood bank locator to find a participating blood center near them. Additional information about CCP is available on AABB’s COVIDPlasma.org website.
HHS Begins Distributing Payments to Hospitals With High COVID-19 Admissions

The United States Department of Health and Human Services (HHS) began processing payments from the provider relief fund to hospitals with large numbers of COVID-19 inpatient admissions. The fund will provide $12 billion to 395 hospitals that provided inpatient care for 100 or more COVID-19 patients through April 10. The agency will distribute $2 billion to these hospitals based on their Medicare and Medicaid disproportionate share and uncompensated care payments. These hospitals accounted for 71% of COVID admissions reported to HHS.

CMS Releases IFC on the Agency’s COVID-19 Response

CMS released an Interim Final Rule with Comment Period (IFC) on Thursday outlining the agency’s efforts to increase flexibility in the health care system’s response to the COVID-19 pandemic. The IFC outlines actions CMS is taking to ensure states and localities have the flexibilities they need to ramp up diagnostic testing and access to medical care. The agency also updated fact sheets that summarize changes made through regulatory actions in response to COVID-19.

CMS Guidance Clarifies COVID-19 Testing Requirements, FDA Requires Serologic Test Manufacturers to Submit Accuracy Data

The Centers for Medicare and Medicaid Services (CMS) recently issued an administrative memo to assist clinical laboratories in responding to COVID-19. The guidance clarifies the different types of COVID-19 testing available for laboratories, describes whether the tests are being offered under an FDA emergency use authorization (EUA) or as described in FDA’s COVID-19 test guidance, and provides the CLIA certificates under which testing can be performed. The agency also released an infographic that summarizes the information contained within the memo. The guidance takes effect immediately and should be communicated to survey and certification staff, their managers and state/regional office training coordinators within 30 days. Those with questions may contact LabExcellence@cms.hhs.gov.

Additionally, FDA announced in an FDA Voices article on Monday that companies selling coronavirus antibody tests must submit data proving accuracy within the next 10 days or face removal from the market. The agency has provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers.

The announcement revises the agency’s March 16 policy, which allowed for regulatory flexibility in
serologic test development. FDA announced the change in response to reports that some test
developers falsely marketed their products as FDA-approved or as diagnostic tests. Officials stated that
"when we become aware of these issues, we have and will continue to take appropriate action against
firms unlawfully marketing their tests."

In addition to the updated policy, FDA introduced a more streamlined process to support EUA
submissions and review, as well as an umbrella EUA for certain antibody tests that undergo validation
at FDA-designated government agencies.

Officials reiterated that FDA will continue to take steps to balance assurances that an antibody test is
accurate and reliable with timely access to such tests as the continually evolving circumstances and
public health needs warrant.

05/08/20 FDA Updates Recommendations for COVID-19 Convalescent Plasma Donation

**FDA Updates Recommendations for COVID-19 Convalescent Plasma Donation**

Individuals interested in making a coronavirus disease 2019 (COVID-19) convalescent plasma (CCP)
donation should have complete resolution of symptoms for at least 14 days prior to donation,
according to recommendations outlined in FDA’s [updated guidance](#) on convalescent plasma and the
associated [web page](#). Previously, the guidance recommended complete resolution of symptoms for 28
days or resolution for 14 days and a negative diagnostic test. A negative lab test for COVID-19 is not
necessary to qualify for donation.

Additional updates clarify how to submit investigational applications for CCP and specify that FDA does
not recommend storing a retention sample from the CCP donation for single-patient emergency
investigational new drug (IND) applications.

05/08/20 REGULATORY UPDATE: FDA Accepts Version 2.1 DHQ; AABB Issues Association Bulletin #20-04

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History Questionnaire (DHQ) and abbreviated DHQ (aDHQ) in a [level 2 guidance](#) on Tuesday, stating
the documents are an acceptable mechanism for collecting blood donor history information from
donors of blood and blood components. The scope of revisions in the v2.1 DHQ and related materials
were limited to those necessary for FDA’s expedited review of recommendations to [address the urgent
need for blood during the pandemic](#).

This expedited timeline captured recommendations related to HIV risk, variant Creutzfeldt-Jakob
disease and malaria; it did not permit FDA to review the full version v3.0 update planned by the AABB
Donor History Task Force (the DHTF), including new donor eligibility questions related to prophylactic use of HIV medications. Consequently, it is necessary to capture these donor eligibility questions at the end of the v2.1 DHQ, as described in Association Bulletin (AB) #20-04.

To reduce the operational complexity for implementing multiple updates, AABB concurrently released AB #20-04, The Impact on Blood Safety of Effective Antiretroviral Medications for HIV Prevention and Treatment. In the bulletin, AABB recommends blood collection facilities evaluate the use of antiretroviral medications taken as therapy (ART) by individuals with an established HIV infection or taken as pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) to prevent HIV infection.

These recommendations were developed by the Transfusion Transmitted Diseases Committee and the DHTF, which include representatives from FDA and the Centers for Disease Control and Prevention, to address concerns raised in recent publications (refer to the reference section) that the risk of HIV transmission by blood transfusion may increase due to the growing use of antiretroviral medications. Therefore, AABB recommends that AABB-accredited facilities use the DHQ v2.1 documents that include donor assessment for use of PrEP, PEP and ART.

AABB Regulatory Affairs has developed the DHQ v2.1 Implementation Toolkit with documents highlighting all revisions, to help members more easily identify changes in DHQ v2.1 and Related Materials and AB #20-04. AABB reminds collection facilities that, as expected, the draft v2.1 documents posted for planning purposes have been revised during the FDA review process. Refer to the final documents posted by AABB and the toolkit for those revisions.

Facilities may contact regulatory@aabb.org with any questions regarding the v2.1 DHQs and Related Materials and their FDA consumer safety officer with questions regarding implementation.

05/05/20 AABB News Flash, REGULATORY UPDATE: FDA Accepts Version 2.1 DHQ as AABB Issues Association Bulletin #20-04

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05/01/20 AABB Announces New COVID-19 Convalescent Plasma Town Hall eCast Series

AABB Announces New COVID-19 Convalescent Plasma Town Hall eCast Series

A new AABB town hall eCast series will bring together experts from blood centers and hospital transfusion services to examine vein-to-vein considerations for collection and administration of COVID-19 convalescent plasma (CCP). AABB is pleased to provide complimentary registration to members through the generous support of Cerus Corporation.

The first eCast, Donor Recruitment Considerations, will focus on identifying and engaging CCP donors. The program will feature presentations from two blood center medical directors — Richard Gammon, MD, medical director at OneBlood, and Erin Goodhue Meyer, DO, MPH, executive medical director of Patient Services at ARC — on challenges, lessons learned and other considerations when recruiting and qualifying CCP donors. The eCast will begin at 2 p.m. ET on Tuesday, May 5.
The second eCast, Hospital Considerations, will explore the continuum of acquiring CCP units through administration and follow-up. It will feature a presentation by Tina Ipe, MD, MPH, division director of Transfusion Medicine Services at the University of Arkansas for Medical Sciences, on the protocol being used for expanded use in Arkansas, known as the “Arkansas Initiative.” A second presentation from Jay Thomas, BS, MT(ASCP), lab manager, Blood Donor Services, and Vince Cataldo, MD, hematology and oncology, at Our Lady of the Lake Regional Medical Center in Baton Rouge, La., will discuss considerations from the perspective of a hospital that collects and utilizes CCP under the Mayo protocol. This eCast will take place at 2 p.m. ET on Thursday, May 7.

Both eCasts will be moderated by Sharon Carayiannis, MT(ASCP)HP, AABB’s senior director of Regulatory Affairs, and include a 45-minute question-and-answer session following the presentations. Registration is complimentary for AABB members. Individuals who are not members of AABB may purchase access to the town hall series in the AABB Marketplace.

05/01/20 Presentations from ACBSCT Meeting Now Available Online

Presentations from the latest virtual meeting of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) are now available online. Monday’s meeting included an overview of the Patient Access to Cellular Therapy (PACT) Act and its potential impact on blood stem cell transplantation; a presentation on deceased bone marrow for advanced cellular therapies and emergency medicine; and a discussion of challenges and opportunities in cord blood transplantation.

The meeting also focused on the effect of COVID-19 on stem cell transplantation, cord blood transplantation and related research. Steven Devine, MD, at the National Marrow Donor Program (NMDP)/Be The Match, presented on the impact of COVID-19 on unrelated blood stem cell transplantation. He reported a severe curtailment of marrow harvest capacity and said that apheresis capacity has been cut back in response to the pandemic. However, Devine noted that the COVID-19 pandemic had presented opportunities to collaborate with partner organizations to develop potential therapies such as mesenchymal stem cells, natural killer cells and CCP.

05/01/20 FDA Issues Untitled Letters Regarding Unapproved Exosome, Umbilical Cord Blood Products

FDA issued untitled letters to two companies regarding unapproved products that appear to be human cells, tissues, or cellular or tissue-based products. On April 10, FDA issued a letter to Regenerative Solutions of New Jersey regarding its marketing of unapproved exosome products as a treatment for COVID-19. According to FDA, the company also marketed the exosome products, manufactured by Florida-based Kimera Labs, Inc., to treat numerous diseases and conditions, including Parkinson’s
disease, multiple sclerosis, brain injuries, diabetes, stroke and spinal cord injuries.

In addition, the agency issued an untitled letter to California-based Infuze MD regarding an unapproved stem cell product derived from umbilical cord blood, as well as unapproved exosome products. According to the April 27 letter, the company markets the cord blood-derived product, administered intravenously, to treat several immunodeficiency disorders, autoimmune diseases and muscular diseases. FDA also noted that the high-risk product administration method could cause a range of adverse events.

FDA believes that these products would be regulated as both drugs and biological products, which require a valid biologics license application or investigational new drug application to be lawfully marketed. The agency requested written responses within 30 days of receipt of the letter from both companies.

FDA’s “Issuance of Untitled Letters” web page notes that untitled letters are used for violations that may not meet the threshold of regulatory significance for a warning letter. An untitled letter does not include a statement warning the individual or firm that failure to promptly correct the violation may result in enforcement action.

05/01/20 AABB Releases Latest Findings From Member Hospital Transfusion Services Survey

AABB Releases Latest Findings From Member Hospital Transfusion Services Survey

AABB released a graphic summary of the results from week 6 of a weekly survey of AABB member hospital transfusion services. A total of 102 respondents from 36 states completed the survey, conducted April 27-30. Among responding hospitals, 43.1% reported an increase in product outdating due to changes related to the pandemic, an upward trend. Additionally, 46.5% of the responding hospitals are resuming “some” elective surgeries prior to mid-May and 12.9% plan to resume elective surgeries after mid-May. While the majority of the hospitals are still prioritizing CCP based on patient’s severity of illness, there was a slight increase in CCP being administered to severely ill patients (ie, those in the ICU or on ventilators) as opposed to those not in the ICU, compared to week 5. A majority of the responding hospitals obtain CCP units from their regular blood supplier. In addition, 51.2% of the responding hospitals reported delay a delay of at least 24 hours in obtaining CCP. Hospitals offering options for antibody titer tests increased from 24% in week 5 to 37.6% in week 6.

AABB will continue to report the results out to participating hospitals on a weekly basis. Members interested in viewing results from previous surveys may contact Srijana Rajbhandary.
AABB Urges Congressional Leaders to Address Care for SCD Patients in COVID-19 Stimulus

AABB joined a coalition of organizations urging congressional leaders to authorize CMS to develop a program that improves access to comprehensive outpatient care for Medicare/Medicaid dual-eligible and Medicaid beneficiaries living with sickle cell disease (SCD).

In the April 24 joint letter, the organizations explained the pre-existing barriers to health care access that individuals with SCD face and emphasized that the COVID-19 pandemic has exacerbated these challenges. The letter also highlighted previous efforts to advance SCD care, such as publication of clinical practice guidelines and new treatment approvals, and reiterated the urgency of improving access to state-of-the-art care for this vulnerable population.

House Members Release Concept Paper to Improve Health Care Delivery, Pandemic Response

Reps. Diana DeGette (D-Colo.) and Fred Upton (R-Mich.) released a concept paper for their bipartisan “Cures 2.0” effort, which aims to safely and efficiently modernize the delivery of health care in the wake of the coronavirus pandemic. Cures 2.0 is the follow-up legislation to the bipartisan 21st Century Cures Act, enacted in 2016, which aimed to accelerate the discovery and development of new medicines and devices.

In the paper, DeGette and Upton address six high-level focus areas. These focus areas contain several topics of interest to the AABB member community, including the following:

- Improving the nation’s surveillance and testing capabilities to support the U.S. response to the COVID-19 pandemic, as well as future pandemics.
- Supporting innovative clinical trial design.
- Improving FDA-CMS communication regarding transformative new therapies.
- Requiring the Department of Health and Human Services to establish a regulatory framework for the recognition and utilization of real-world evidence.
- Modernizing coverage and reimbursement approaches for new medical products.
- Addressing barriers to coverage and patient access to new cell and gene therapy products.

AABB will continue to monitor the development of this bill for opportunities to advance AABB’s mission to improve lives by making transfusion medicine and biotherapies safe, available, and effective. The Association will update members as new information becomes available.

FDA, EC Issue Updated Guidances on Conducting Clinical Trials During COVID-19 Pandemic

FDA, EC Issue Updated Guidances on Conducting Clinical Trials During COVID-19 Pandemic
FDA recently added additional questions and answers to the appendix of its March 2020 guidance on conducting clinical trials during the COVID-19 pandemic. The guidance provides recommendations on obtaining informed consent during the pandemic, considerations for remote clinical outcome assessments, remote site monitoring and electronic common technical document waivers.

The European Commission (EC) also updated its guidance on managing clinical trials during the pandemic to include advice on distributing medicine to patients participating in clinical trials, remote source data verification and communicating actions to protect trial patient safety with authorities.

05/01/20 CBER Issues Updated Letter to Sponsors, Applicants and Regulated Entities on COVID-19

CBER Issues Updated Letter to Sponsors, Applicants and Regulated Entities on COVID-19

The Center for Biologics Evaluation and Research (CBER) updated a March 27 letter to sponsors, applicants and regulated entities that outlines the agency’s efforts to advance the national response to the COVID-19 pandemic. CBER converted in-person meetings with industry representatives to teleconferences through May 29. The agency will continue to assess whether in-person meetings scheduled later than May 29 should be converted to teleconferences and will provide periodic updates. In addition, CBER’s document control center ceased processing paper submissions received after Wednesday, April 29, until further notice. CBER strongly encourages sending submissions through FDA’s preferred secure method of transmission, the Electronic Submissions Gateway.

05/01/20 CMS Announces Expanded COVID-19 Testing, Changes to Medicare Payment Programs

CMS Announces Expanded COVID-19 Testing, Changes to Medicare Payment Programs

The Centers for Medicare and Medicaid Services (CMS) announced several regulatory waivers and rule changes on Thursday to deliver expanded care to Medicare and Medicaid beneficiaries and provide flexibility to the health care system in response to the COVID-19 pandemic. The agency announced the actions to help ensure that states and localities have the flexibilities they need to ramp up diagnostic testing and access to medical care, key precursors to ensuring a phased, safe and gradual reopening of the country.

These changes include new rules to support and expand COVID-19 diagnostic testing for Medicare and Medicaid beneficiaries. Medicare will now cover COVID-19 testing when ordered by any health care professional authorized to do so under state law. A written practitioner’s order is no longer required for the COVID-19 test for Medicare payment purposes, as well.

Medicare and Medicaid will also cover certain serology tests, which may aid in determining whether a person has developed an immune response and may not be at immediate risk for COVID-19.
reinfection. Medicare and Medicaid will cover laboratory processing of certain tests authorized by the Food and Drug Administration that beneficiaries self-collect at home.

Additional actions aim to increase hospital capacity, expand the health care workforce and reduce administrative burden. These changes take effect immediately and will last throughout the duration of the public health emergency declaration.

In addition, CMS **announced** on Sunday that it is suspending an advanced payment program to Medicare Part B suppliers effective immediately. CMS will also reevaluate the amounts paid to health systems under an accelerated payment program. Through these programs, CMS has paid more than $100 billion to health care providers and suppliers since March 28. CMS expanded these temporary loan programs to ensure providers and suppliers had the resources needed to combat the beginning stages of the COVID-19 pandemic. Funding continues to be available to hospitals and other health care providers on the front lines of the coronavirus response through the **provider relief fund**.

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**05/01/20**  **BARDA Announces Partnerships to Develop Investigational COVID-19 Therapies**

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The Biomedical Advanced Research and Development Authority (BARDA), part of the United States Department of Health and Human Services’ office of the Assistant Secretary for Preparedness and Response, **announced a collaboration** with multiple non-government organizations to develop investigational treatments for coronavirus disease 2019 (COVID-19). The products in development include COVID-19 convalescent plasma (CCP) and hyperimmune globulin, both developed from the plasma of people who have recovered from COVID-19.

BARDA is **collaborating** with the American Red Cross and America's Blood Centers to ensure the collection and distribution of convalescent plasma across the country. BARDA will also partner with Emergent BioSolutions to collect donated plasma and manufacture COVID-19 hyperimmune globulin and with both the Department of Defense’s Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and Grifols to collect plasma and manufacture CCP and hyperimmune globulin.

Additionally, BARDA announced a partnership with JPEO-CBRND and SAb Biotherapeutics to develop a new immunotherapy called SAB-185. SAB-185 is produced from human antibodies without plasma donated from recovered patients. This approach produces greater quantities of the product than traditional methods that rely on donated blood. BARDA could support a phase 1 clinical trial for initial testing in humans.

AABB's [COVIDPlasma.org](https://www.COVIDPlasma.org) website contains information about convalescent plasma for patients, health
care providers and the public. The website also links to AABB’s blood bank locator to assist recovered patients in scheduling a CCP donation.

**04/24/20 Tomorrow is World Malaria Day**

**Tomorrow is World Malaria Day**

AABB joins a global coalition of organizations led by the RBM Partnership to End Malaria in marking the 12th Annual World Malaria Day on April 25. This year’s theme, “Zero Malaria Starts with Me,” emphasizes everyone’s power and responsibility – no matter where they live – to ensure no one dies from a mosquito bite. Additionally, World Malaria Day 2020 will urge greater investment in building and supporting resilient health systems to protect and advance progress against existing infectious diseases like malaria and preparation to effectively address new outbreaks like COVID-19. The World Malaria Day website includes a toolkit that organizations can use to promote the day, share advice for malaria prevention, raise awareness of the global challenges in beating malaria and teach the importance of ending malaria for good.

AABB is proud to support research to improve health outcomes for patients with malaria through the National Blood Foundation (NBF). In 2018, AABB members helped fund an NBF grant awarded to Antonella Nai, PhD. Nai’s NBF-funded research sought to establish the role of TFR2 on erythroid precursors in a murine model of malaria to provide a new potential therapeutic intervention. AABB encourages members to invest in emerging research by making a tax-deductible gift to the NBF today.

**04/24/20 AABB News Highlights COVID-19, Bleeding Disorders**

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COVID-19 is having a significant impact on the blood community, and the April issue of AABB News contains several articles addressing the pandemic. The “High Priority” column summarizes actions by AABB and federal agencies in response to the coronavirus, including the $2 trillion Coronavirus Aid, Relief and Economic Security (CARES) Act; FDA’s revised donor criteria; and updates to AABB’s CCP protocol. In addition, the “Significant Findings” column describes new research on CCP from Shenzhen, China, and results from AABB’s COVID-19 impact survey. The “Of Note” column contains items related to the pandemic, including summaries of Town Hall eCast lectures, which are complimentary and available on demand.

Other articles include a feature on how existing technologies are being adapted for new at-risk populations; a feature on how CAR T-cell treatments offer patients with blood cancers an improved quality of life; and an interview with Stella Chou, MD, an associate professor of pediatrics at the University of Pennsylvania’s Perelman School of Medicine and a pediatric hematologist and transfusion medicine specialist at the Children’s Hospital of Philadelphia.
FDA Sends Untitled Letter to Florida Company Regarding Unapproved Exosome Products

FDA sent an untitled letter to Florida-based Kimera Labs, Inc. regarding the company’s unapproved exosome products. According to the April 10 letter, the company markets exosome products to treat numerous diseases or conditions, including Parkinson’s disease, multiple sclerosis, brain injuries, diabetes, stroke and spinal cord injuries. Kimera Labs also supplies products to other companies, one of which has marketed products to prevent or treat COVID-19. (Kimera Labs is not an AABB-accredited facility).

FDA believes that the company’s exosome products would be regulated as both a drug and biological product. In order to lawfully market these products, a valid biologics license application or investigational new drug application must be in effect, as specified by FDA regulations. The agency requested a written response from the company within 30 days of receipt of the letter.

FDA’s “Issuance of Untitled Letters” web page notes that untitled letters are used for violations that may not meet the threshold of regulatory significance for a warning letter. An untitled letter does not include a statement that warns the individual or firm that failure to promptly correct the violation may result in enforcement action.

AABB Releases Week 5 Member Hospital Transfusion Service Survey Data

AABB released the week 5 results from its survey of member hospital transfusion services. A total of 100 respondents from 37 states completed the survey, conducted April 20-22. Data indicated an upward trend in increase in outdated product. In addition, 50% of the responding hospitals do not have a date selected to resume elective surgery. A total of 42% of responding hospitals are transfusing CCP. A majority of the hospitals are prioritizing CCP based on patient’s severity of illness. The expanded access protocol is the most common route to obtain CCP units.

Clinical Trials Underway for 72 Potential COVID-19 Therapies

Clinical trials for 72 potential treatments for COVID-19 are underway with FDA oversight, agency officials reported in an FDA Voices article published Monday. Through its Coronavirus Treatment Acceleration Program, FDA has streamlined approval of clinical trials to evaluate direct-acting antivirals, anti-inflammatory medications, COVID-19 convalescent plasma (CCP) and other investigational therapies.

According to the agency, more than 1,600 sites and 2,100 physician investigators nationwide have
signed on to participate in the Mayo Clinic-led expanded access protocol to evaluate CCP. Officials also emphasized the importance of plasma donations from patients who have recovered from COVID-19 in this process.

AABB’s COVIDPlasma.org website includes a blood bank locator to assist those who have recovered from COVID-19 in finding a participating blood center near them. The site also contains CCP information for patients, health care providers and the public.

04/24/20 FDA Updates Q&A Appendix in Guidance on Conducting Clinical Trials of Medical Products During the COVID-19 Pandemic

**FDA Updates Q&A Appendix in Guidance on Conducting Clinical Trials of Medical Products During the COVID-19 Pandemic**

The Food and Drug Administration updated the question-and-answer appendix in its March 2020 guidance, "Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency." The updated guidance includes new content on conducting remote clinician-reported outcome or performance outcome assessments; remote site monitoring; electronic common technical document requirements; investigational product administration by a local health care provider who is not a sub-investigator; and information for sponsors on contacting FDA regarding certain changes to ongoing trials. There is also updated information about obtaining informed consent from a patient who is unable to travel to the clinical trial site due to COVID-19 illness or travel restrictions in situations where electronic informed consent is not an option.

04/24/20 CMS, ASPR Launch COVID-19 Virtual Workforce Toolkit

**CMS, ASPR Launch COVID-19 Virtual Workforce Toolkit**

CMS, in partnership with the Assistant Secretary for Preparedness and Response (ASPR), recently launched a curated set of resources and tools for managing health care workforce challenges in response to the COVID-19 pandemic. The COVID-19 Health Care Workforce Toolkit is a searchable online hub that includes information on funding flexibilities, liability protections and workforce training sorted by medical specialty.

04/24/20 CMS Encourages Reporting of COVID-19 Clinical Trial Data Through QPP

**CMS Encourages Reporting of COVID-19 Clinical Trial Data Through QPP**

Clinicians who participate in the Quality Payment Program (QPP) may now earn credit in the Merit-based Incentive Payment System (MIPS) for participation in a clinical trial and reporting clinical information by attesting to the new COVID-19 Clinical Trials improvement activity, CMS announced on Monday. MIPS is a performance-based track of QPP that rewards quality and value. CMS believes this will provide data to help improve patient care and develop best practices to manage the spread of COVID-19.
COVID-19 within communities. This action is part of ongoing White House Task Force efforts to respond to COVID-19. Additional information about Task Force initiatives is available online.

04/24/20 CMS Issues Recommendations on Reopening Facilities to Provide Non-Emergent, Non-COVID-19 Health Care; Health Care Groups Release Roadmap to Resume Elective Surgeries

CMS Issues Recommendations on Reopening Facilities to Provide Non-Emergent, Non-COVID-19 Health Care; Health Care Groups Release Roadmap to Resume Elective Surgeries

The Centers for Medicare and Medicaid Services (CMS) issued recommendations on Sunday to begin a phased approach to reopening non-emergent health care services in areas with low or stable incidence COVID-19. The recommendations update the March 16 guidance that limited non-essential surgeries and medical procedures. States or regions that meet the COVID-19 gating criteria outlined in the Opening Up America Again guidelines may proceed to the Phase 1 approach.

The recommendations reference general considerations, the availability of personal protective equipment (PPE) and other supplies, sanitation protocols, workforce availability, testing capacity and facility considerations to assist facilities in low-incidence regions in determining whether to resume or increase in-person care. The agency stipulated that facilities should continually monitor their area’s risk level and be prepared to cease non-essential procedures if there is a surge in incidence. Furthermore, CMS stated that decisions should be consistent with public health information and in collaboration with state public health authorities.

In addition, leaders from the American College of Surgeons, American Society of Anesthesiologists, Association of periOperative Registered Nurses and the American Hospital Association issued a joint statement this weekend outlining a roadmap to resuming elective surgeries after the COVID-19 pandemic. The roadmap includes guiding principles and considerations for physicians, nurses and local facilities in their resumption of care in operating rooms and procedural areas. The considerations address timing for reopening of elective surgery, COVID-19 testing in the facility, PPE, case prioritization and scheduling, data collection and management, and post-COVID-19 issues for the five phases of surgical care. The roadmap also includes suggestions for safety and risk mitigation during a potential second wave of infections.

04/24/20 Expert Panel Develops NIH Treatment Guidelines for COVID-19

Expert Panel Develops NIH Treatment Guidelines for COVID-19

A panel of U.S. physicians, statisticians and other experts has developed treatment guidelines for coronavirus disease 2019 (COVID-19), the National Institutes of Health (NIH) announced on Tuesday. The panel based the guidelines, intended for health care providers, on published and preliminary data and the clinical expertise of the panelists. The guidelines consider two broad categories of therapies currently in use by health care providers for COVID-19: antivirals, which may target the coronavirus
directly, and host modifiers and immune-based therapies, which may influence the immune response to the virus or target the virus.

The guideline document provides background information about each agent that forms the basis for the recommendation. It also describes the evaluation and stratification of patients based on their risk of infection and severity of illness. In addition, a comprehensive section of the guidelines addresses a range of considerations for clinicians caring for the most critically ill hospitalized patients. Finally, the guidelines include recommendations concerning the use of concomitant medications.

The panel will update the guidelines as new data are published in peer-reviewed scientific literature and other authoritative information emerges.

04/17/20 SunCoast Blood Centers Open New Donor Location

SunCoast Blood Centers Open New Donor Location

SunCoast Blood Centers opened its new donor center and administrative headquarters in Lakewood Ranch, Fla., on March 30. SunCoast fast-tracked the facility’s opening in response to the ongoing COVID-19 pandemic. “The original opening date was scheduled for April 7,” said Jayne Giroux, director of community development for SunCoast Blood Centers. “However, in light of the current coronavirus pandemic, we need to be prepared in the likely event we will need to appeal to the community to donate blood and platelets in the coming weeks.”

The new donor center will house all SunCoast’s operations under one roof and replaces a smaller Lakewood Ranch location. SunCoast also operates donor centers in Venice and Bradenton, along with a flagship location in Sarasota.

04/17/20 AABB to Celebrate Medical Laboratory Professionals Week With Social Media Events, Education Discounts

AABB to Celebrate Medical Laboratory Professionals Week With Social Media Events, Education Discounts

AABB will celebrate Medical Laboratory Professionals Week (MLPW), which begins Sunday, April 19, by offering several ways to thank laboratory professionals within the transfusion medicine and biotherapies community.

As part of its celebration, AABB will give away a copy of the 20th edition of the Technical Manual (expected to publish this June) and other prizes to winners of the Association’s MLPW social media giveaway. Individuals may register for a chance to win by visiting AABB’s Facebook, Twitter or Instagram pages during the week and sharing why they are happy or proud to be a medical laboratory professional using the hashtag #AABBLabWeek. The giveaway’s full terms and conditions are available online.
Additionally, AABB will host an Instagram takeover on Thursday featuring Maria Roussakis, an early-career medical laboratory technologist at McMaster University in Hamilton, Ontario, Canada. Roussakis will take over AABB’s Instagram account for a day to showcase the important functions medical laboratory professionals play every day.

Closing Lab Week, AABB’s CMO Claudia S. Cohn, MD, PhD, will join Diana Berrent, the founder of Survivor Corps, a grassroots movement of survivors of COVID-19, to answer questions from the public about CCP. The 30-minute Q&A event will take place at 1 p.m. ET on Friday, April 24, via Facebook live on AABB’s Facebook page.

Throughout the week, AABB will offer a 10% discount on publications and single-viewer eCasts. Use the code LABWEEK20 in the AABB Marketplace to apply the discount.

MLPW is sponsored by 17 national clinical laboratory organizations, including AABB, the American Society for Clinical Laboratory Science, the American Society for Clinical Pathology and the College of American Pathologists. It provides hospitals and blood banks the opportunity to celebrate clinical laboratory personnel and the vital role they play in promoting public health.

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**04/17/20 AABB Extends Submission Deadline for 2020 Annual Meeting Abstracts**

AABB extended the deadline to submit abstracts for the 2020 Annual Meeting until May 15. Submissions from both members and nonmembers are welcome. Abstract categories include various scientific and administrative categories in transfusion medicine and cellular therapies. Abstract preparation and submission guidelines are available online.

As the COVID-19 pandemic unfolds, AABB is working closely with members, meeting vendors and local health authorities to determine if the 2020 AABB Annual Meeting can be held live as scheduled for Oct. 3-6 in Baltimore, Md. The Association is currently evaluating alternative options, including a virtual Annual Meeting that would allow attendees to continue to benefit from the superior education content the meeting offers.
Reminder: Spanish Language Versions of COVID-19 Resources Available

The translation volunteer team from AABB’s Cellular Therapies (CT) Spanish-Language Subsection (SLS) partnered with the Latin American Transfusion Medicine Association (GCIAMT) to develop an open resource of COVID-19 transfusion medicine documents in the Spanish language. The list of translated documents includes resources from AABB, FDA, Vitalant, GCIAMT and the Global Advisory Panel for the Voluntary Non-Remunerated Blood Donation. AABB reminds those who utilize the Spanish-language resources that the volunteer translation may not be as precise as if performed commercially. For the official text, please refer to the English-language versions. AABB thanks the translation volunteer team for their efforts in making these resources accessible to the Spanish-speaking community.

AABB Twitter Chat Explores COVID-19 Convalescent Plasma

Individuals who missed last Friday’s @AABB Twitter chat featuring AABB President Beth Shaz, MD, and AABB Chief Medical Officer (CMO) Claudia S. Cohn, MD, PhD, can read the discussion on the collection and administration of CCP using the Twitter hashtag #AABBPEPtalk. For about an hour, participants discussed CCP collection protocols, challenges in setting up a collection program and efforts to reach and recruit donors. A transcript of the Twitter chat is also available online. AABB’s new website www.COVIDplasma.org contains additional CCP resources for the public, blood centers and hospital transfusion services.

AABB Releases Summary of Weeks 1-4 Hospital Snapshot Survey Findings

AABB released a graphic summary of the results from weeks 1-4 of a weekly survey of AABB member hospital transfusion services. The infographic shows that as blood availability improved, the percentage of hospitals implementing prospective audits for RBC orders, lowering the threshold to 7 grams per deciliter of hemoglobin for most patients, lowering the threshold below 7g/dL hemoglobin for any patients, implementing prospective audits for platelet orders, lowering platelet count threshold and discontinuing prophylactic platelet threshold for transfusions for hematology/oncology patients showed a downward trend. There was an overall upward trend in hospitals responding that they have planned for splitting platelet and/or RBC units and extending expiration of platelet units beyond 5 days. There was an upward trend towards moving to split shifts to ensure staffing continuity.

While there was an upward trend in plans to assist recovered patients to donate CCP, plans to participate in a protocol to obtain CCP under IND, and plans to transfuse (or intend to transfuse) CCP, there appeared to be no change in the percentage of responding hospitals that collect or intend to
collect CCP – either for use in the donor collection area or for national use. Survey results in coming weeks will help AABB understand this trend.

AABB will continue to report the results out to participating hospitals on a weekly basis. Members interested in viewing results from previous surveys may contact Srijana Rajbhandary.

04/17/20 FDA Issues Updated Table of Novel Coronavirus Diagnostic EUAs

**FDA Issues Updated Table of Novel Coronavirus Diagnostic EUAs**

FDA updated the table of emergency use authorizations (EUAs) for in vitro diagnostics for detection and/or diagnosis of the novel coronavirus. The updated table now includes a column for the technology (molecular or serology) and the assigned complexity (high, moderate, waived) for each test. There is a key in the footnotes. Additionally, there is a footnote on the Appendix A table for the Umbrella EUA that clarifies that these are all high-complexity tests authorized only for use in the single authorized lab.

04/17/20 NIH Study Seeks to Quantify Undetected COVID-19 Cases

**NIH Study Seeks to Quantify Undetected COVID-19 Cases**

Investigators at the National Institutes of Health (NIH) announced the launch of a new study this week to help determine how many adults in the U.S. without a confirmed history of infection with SARS-CoV-2, the virus that causes COVID-19, have antibodies to the virus.

Investigators will collect and analyze blood samples from as many as 10,000 volunteers to help illuminate the extent to which the novel coronavirus has spread in the U.S. and provide insights into which communities and populations are most affected.

Healthy adults from anywhere in the U.S. can participate. Individuals with a confirmed history of COVID-19 or current symptoms consistent with COVID-19 are not eligible to participate. Individuals interested in joining this study may contact clinicalstudiesunit@nih.gov.

04/17/20 FDA Encourages Recovered COVID-19 Patients to Donate Plasma

**FDA Encourages Recovered COVID-19 Patients to Donate Plasma**

The Food and Drug Administration encouraged individuals who have recovered from coronavirus disease 2019 (COVID-19) to contact their local blood collection center to discuss COVID-19 convalescent plasma (CCP) donation. Preliminary findings indicate that CCP has the potential to lessen the severity or shorten the length of illness caused by COVID-19.

The agency emphasized that those individuals who have recovered from COVID-19 could have an
immediate impact in helping others who are severely ill, noting that one donation has the potential to help up to four patients. In addition, CCP can be used to manufacture hyperimmune globulin, which can similarly be used to treat patients with COVID-19. Individuals who have fully recovered from COVID-19 for at least two weeks can contact their local blood center today to schedule an appointment.

FDA launched a web page with information for patients interested in donating CCP. The page includes information for those interested in participating in the expanded access protocol, conducting clinical trials or submitting emergency investigational new drug (eIND) applications. FDA previously announced a partnership under which the Mayo Clinic is serving as the lead institute for the expanded access program and the American Red Cross has been charged with serving as the national coordinator for CCP. Nearly all blood collectors in the United States are collecting CCP or in the process of standing up collection capabilities. AABB’s COVIDplasma.org web page features additional resources and a blood bank locator for potential CCP donors, as well as information for blood centers and hospital transfusion services.

Following the release of FDA new recommendations addressing the unprecedented challenges to the blood supply, FDA’s review of the new version 2.1 donor history questionnaire is moving forward on an expedited timeline. AABB encourages members to check for updates on the Blood Donor History Questionnaires web page frequently. AABB will announce the new version once formally recognized in FDA guidance.

04/10/20 AABB Members Will Receive Print Edition of April Transfusion Issue

AABB Members Will Receive Print Edition of April Transfusion Issue

Wiley, publishers of AABB’s peer-reviewed journal Transfusion, notified AABB this week that the April issue was printed prior to the company’s move to digital-only operations. AABB members and Transfusion subscribers should receive a print copy within two weeks. Wiley announced the action in response to the COVID-19 pandemic last week. Beginning with the May issue, all journal issues will be delivered solely via Wiley Online Library, a platform that includes options for remote subscriber access.

04/10/20 FDA Sends Untitled Letter to Nevada Company Regarding Unapproved HCT/P Products

FDA Sends Untitled Letter to Nevada Company Regarding Unapproved HCT/P Products

FDA sent an untitled letter to Nevada-based Dynamic Stem Cell Therapy regarding the company’s unapproved cellular products derived from adipose tissue and human umbilical cord. According to the April 1 letter, the company advertised these products, administered intravenously, as treatments for cardiopulmonary conditions, degenerative eye diseases, neurological disorders, autoimmune
diseases and metabolic disorders. Dynamic Stem Cell Therapy also recently began marketing its cellular products for treatment or prevention of COVID-19. (Dynamic Stem Cell Therapy is not accredited by AABB.)

FDA believes that the company’s adipose-derived cellular product and human umbilical cord derived-cellular product are human cell, tissue and cellular and tissue-based products (HCT/Ps) that should be regulated as both drug and biological products. In order to lawfully market these products, a valid biologics license application or investigational new drug application must be in effect, as specified by FDA regulations. FDA also noted that the company’s social media advertising referenced exosomes, which are also regulated as drug and biological products for clinical use in humans and subject to the same premarket review and approval requirements.

FDA stated that the use of these unapproved products raises significant safety concerns and that the high-risk administration methods could cause a range of adverse events. The letter directs the company’s attention to FDA’s comprehensive regenerative medicine policy framework for HCT/Ps, which is intended to spur efficient access to safe and effective regenerative medicine products.

FDA’s “Issuance of Untitled Letters” web page notes that untitled letters are used for violations that may not meet the threshold of regulatory significance for a warning letter. An untitled letter does not include a statement that warns the individual or firm that failure to promptly correct the violation may result in enforcement action.

04/10/20 AABB Publishes Week 3 Hospital Snapshot Survey Findings

Findings from the third weekly survey of AABB member hospital transfusion services are now available. A total of 115 AABB institutional member hospitals from 38 states responded to the week 3 COVID-19 impact survey, conducted through April 6-8. The survey found that 45 respondents (39.1%) have implemented prospective audits for red blood cell orders this week, a decline from 41.7% in week 2. Meanwhile, 48 hospitals (41.7%) had implemented prospective audits for platelet orders this week, an increase from 39.7% in week 2.

Additionally, 65 (56.5%) responding hospitals plan to assist patients who have recovered from COVID-19 to donate convalescent plasma. While 65.2% of the responding hospitals either transfuses or intends to transfuse CCP, only 15.6% either collects or intends to collect CCP; 64.3% of responding hospitals plan on participating in a protocol to obtain CCP under IND.

AABB will continue to report the results out to participating hospitals on a weekly basis. Members interested in viewing results from previous surveys may contact Srijana Rajbhandary.
**04/10/20 CDC Launches Weekly Surveillance Summary of U.S. COVID-19 Activity**

**CDC Launches Weekly Surveillance Summary of U.S. COVID-19 Activity**

The Centers for Disease Control and Prevention launched a weekly surveillance summary of U.S. COVID-19 activity on April 3. The report, COVIDView, summarizes and interprets key indicators, including information related to COVID-19 outpatient visits, emergency department visits, hospitalizations and deaths, as well as laboratory data. CDC will update COVIDView each Friday.

**04/10/20 CMS Issues Framework to Prioritize Non-Emergent Medical Services During Pandemic**

**CMS Issues Framework to Prioritize Non-Emergent Medical Services During Pandemic**

The Centers for Medicare and Medicaid Services (CMS) provided considerations this week to limit non-emergent, elective or preventative medical services that could be deferred to reduce burdens on the existing health system during the COVID-19 pandemic. The agency recommended a tiered framework to prioritize services and care to those who require emergent or urgent attention to save a life, manage severe disease or avoid further risks from an underlying condition. The document cites examples of care separated into tiers by acuity level, along with considerations to manage patient care, conserve resources and protect provider and patient safety for each tier. CMS will refine these recommendations throughout the pandemic based on feedback from subject matter experts.

**04/10/20 FDA Authorizes Blood Purification Device to Treat COVID-19**

**FDA Authorizes Blood Purification Device to Treat COVID-19**

FDA issued an emergency use authorization for a blood purification system to treat patients adults with confirmed COVID-19 who have been admitted to an intensive care unit with confirmed or imminent respiratory failure. The system works by filtering a patient’s blood to reduce the number of cytokines and other inflammatory mediators in the bloodstream and returning the filtered blood to the patient. The proteins that are removed can be associated with a "cytokine storm" that occurs in some patients with COVID-19, leading to increased risk for severe inflammation, rapidly progressive shock, respiratory failure, organ failure and death. FDA issued this emergency use authorization to Terumo BCT Inc. and Marker Therapeutics AG for their Spectra Optia Apheresis System and Depuro D2000 Adsorption Cartridge devices.

**04/10/20 FDA Issues Recommendations for Investigational COVID-19 Convalescent Plasma**

**FDA Issues Recommendations for Investigational COVID-19 Convalescent Plasma**

FDA issued a new guidance on Wednesday to provide recommendations to health care providers and investigators on the study and administration of investigational convalescent plasma collected from
individuals who have recovered from COVID-19, COVID-19 convalescent plasma (CCP).

The guidance outlines recommendations for approved pathways for use of investigational CCP; which patients are eligible to receive CCP; collection procedures, including donor eligibility and qualifications; labeling requirements and record keeping requirements.

AABB encourages readers to visit COVIDPlasma.org for additional CCP information and resources.

**04/10/20 REGULATORY UPDATE FDA: AABB Submits New Version of the DHQ to FDA for Review**

**REGULATORY UPDATE FDA: AABB Submits New Version of the DHQ to FDA for Review**

Immediately following FDA's April 2 announcement of the updated guidance to address the urgent need for blood during the COVID-19 pandemic, AABB began preparation for submission of the updated donor history questionnaire (DHQ) to FDA. FDA’s expedited timeline for review of the updated DHQ will limit the scope of changes to those necessary to promptly implement new FDA recommendations.

This partial version change will be issued as version 2.1, similar to the process used after FDA issued updated malaria recommendations in 2014. Based on the limited scope of FDA’s review, AABB could not submit the full version change prepared by the Donor History Task Force, which included additional changes, such as new donor eligibility criteria for use of antiretroviral drugs to prevent or treat HIV. AABB will address these issues in a future update.

Once the review is completed, FDA will issue a level 2 guidance to formally recognize the DHQ and related materials, which will be announced by AABB. Consistent with AABB’s longstanding practice, the v2.1 DHQ and related materials will be posted on the DHQ web page with unlimited public access. AABB has posted the draft documents sent to FDA. These documents can be used to assist with implementation planning only and must not be considered final.

**04/03/20 AABB Announces Early-Career Education Package**

**AABB Announces Early-Career Education Package**

AABB is pleased to announce a package of highly discounted educational resources designed for early-career professionals, to enable them to further their education remotely during the COVID-19 pandemic. For a limited time, early-career professionals can access an eCast series at a significantly discounted rate. The package includes eight on-demand AABB eCasts on alloimmunization, immunohematology and management of obstetrical hemorrhage and neurotrauma. Nonmembers can take advantage of a package that also includes an early-career AABB membership, which provides access to additional complimentary education, as well as valuable members-only resources. Additional information and early-career resources are available on AABB’s website.
FDA Issues Updated Considerations for HCT/P Establishments

FDA does not recommend that establishments use laboratory tests to screen asymptomatic donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps) for evidence of COVID-19 infection, the agency stated in updated considerations issued Wednesday. According to FDA, it appears that SARS-CoV-2, the virus that causes COVID-19, has only been detected in blood samples of a small percentage of severely ill patients.

However, the HCT/P establishment’s responsible person must evaluate prospective donors and determine eligibility (21 CFR 1271.50). Based on the limited information available at this time, establishments may wish to consider whether, in the 28 days prior to HCT/P recovery, the donor cared for, lived with or had close contact with individuals diagnosed with or suspected of having COVID-19 infection; or were diagnosed with or suspected of having COVID-19 infection. The agency noted that while the potential for transmission of COVID-19 by HCT/Ps is unknown at present, there have been no reported cases of transmission of COVID-19 via these products.

FDA is continually assessing available scientific evidence to determine whether SARS-CoV-2 testing is warranted on certain types of HCT/Ps used in manufacturing biological products. The agency will continue to monitor the situation and issue updates as information becomes available.

CCP Transfusion May Improve Clinical Outcomes for COVID-19 Patients

Administration of convalescent plasma from individuals who have recovered from COVID-19 (CCP) may improve the clinical status of critically ill patients with COVID-19 and acute respiratory distress syndrome (ARDS), according to preliminary findings published in the Journal of the American Medical Association. The study took place at the infectious disease department of Shenzhen Third People’s Hospital in Shenzhen, China, between Jan. 20 and March 25. The final date of follow-up was March 25.

In this uncontrolled case series, five critically ill patients with laboratory-confirmed COVID-19 and ARDS received CCP transfusion characterized by SARS-CoV-2–specific antibody (IgG) binding titer greater than 1:1000 and neutralization titer greater than 40 between 10 and 22 days after admission. All patients had experienced severe pneumonia with rapid progression, continuously high viral load despite antiviral treatment and mechanical ventilation. CCP donors had been previously diagnosed with laboratory-confirmed COVID-19 and subsequently tested negative for SARS-CoV-2, along with other viral infections. All had been asymptomatic for at least 10 days.

Within 12 days of CCP transfusion, patient viral loads decreased and became negative, and SARS-CoV-2–specific ELISA and neutralizing antibody titers increased. Body temperature normalized within 3 days in 4 of 5 patients, and ARDS resolved in 4 patients at 12 days after transfusion. In addition, three
patients who had been receiving mechanical ventilation were weaned within 9 days of CCP transfusion; one patient was removed from extracorporeal membrane oxygenation (ECMO) support 5 days after transfusion. Three patients have been discharged, and two are in stable condition at 37 days after transfusion. All patients received antiviral agents during and following CCP transfusion, which investigators believe may have contributed to the observed viral clearance.

The authors stated that the limited sample size and study design preclude a definitive statement about the potential effectiveness of this treatment and that these observations require evaluation in clinical trials. However, investigators wrote that, “the results highlight the possibility that antibodies from convalescent plasma may have contributed to the clearance of the virus and also the improvement of symptoms.”
of the print version to start accessing publications digitally. The company will provide ongoing updates to AABB’s membership and Transfusion subscribers as it develops solutions.

04/03/20 AABB Twitter Chat Will Address COVID-19 Convalescent Plasma Collection

AABB’s next Twitter chat will explore the collection of convalescent plasma from patients who have recovered from COVID-19 as a potential treatment for critically ill patients. Beth Shaz (@BethShaz), MD, AABB president, and Claudia S. Cohn (@cohn_md), MD, PhD, AABB’s chief medical officer, will lead a discussion and answer questions on strategies and recommendations regarding the collection and transfusion of COVID-19 convalescent plasma for this purpose. The Twitter chat will take place next Friday, April 10, at 1 p.m. ET. AABB encourages members to follow @AABB and use the hashtag #AABBPEPTalk to join the conversation.

04/03/20 AABB Launches New COVID-19 Convalescent Plasma Website

AABB launched a new website today to share information with the public, blood collectors and clinicians about convalescent plasma from individuals who have recovered from COVID-19 (CCP). FDA recently announced new guidelines permitting the use of CCP as an investigational treatment for patients with moderate or severe COVID-19 infections. Many AABB-accredited blood centers are now collecting CCP. The website, COVIDPlasma.org, includes information to help identify eligible CCP donors and a tool to assist those donors in contacting their local blood center or hospital blood collector to schedule a CCP donation. In addition, the website provides CCP resources for blood collectors and the blood community.

04/03/20 AABB Publishes Week 2 Hospital Snapshot Survey Findings

Findings from the second weekly survey of AABB member hospital transfusion services are now available. The survey is intended to provide a weekly snapshot into the impact of the blood supply on patient care during the COVID-19 pandemic. AABB will continue to report the results out to participating hospitals on a weekly basis. Members interested in viewing results from previous surveys may contact Srijana Rajbhandary.

04/03/20 OCR Memo Addresses Discrimination in COVID-19 Treatment

OCR Memo Addresses Discrimination in COVID-19 Treatment
The Department of Health and Human Services (HHS) Office of Civil Rights (OCR) issued a memo March 28 reminding entities covered by civil rights authorities that they cannot deny services based on a patient’s disabilities. In the memo, OCR reiterated that “providing care quickly and efficiently must be guided by the fundamental principles of fairness, equality and compassion that animate civil rights laws” and that persons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person’s relative “worth” based on the presence or absence of disabilities.

The agency stated further that decisions as to whether an individual is a candidate for treatment should be based on an individualized assessment of the patient that follows the best available objective medical evidence. The memo also outlined several considerations to help ensure all segments of the community are served.

**04/03/20 Guidance on Conducting Clinical Trials During COVID-19 Pandemic Updated**

**Guidance on Conducting Clinical Trials During COVID-19 Pandemic Updated**

FDA updated its March 18 guidance on conducting clinical trials of medical products during the COVID-19 pandemic to include an appendix of questions and answers that further explains the considerations outlined in the guidance. The considerations may assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity during the COVID-19 pandemic. Individuals may contact FDA for additional information.

**04/03/20 New FDA Guidance Addresses Discontinuance of or Interruptions to Drug, Biological Product Manufacturing**

**New FDA Guidance Addresses Discontinuance of or Interruptions to Drug, Biological Product Manufacturing**

FDA issued a guidance last Friday to assist applicants and manufacturers of certain drugs and biological products, including blood products, in notifying FDA of production changes to help the agency prevent or mitigate product shortages. In the guidance, FDA stated that under section 506C of the Federal Food, Drug, and Cosmetic Act, persons covered by the notification requirement must notify FDA of any permanent discontinuance or interruption in the manufacture of covered drugs and biological products that is “likely to lead to a meaningful disruption (or, in the case of blood or blood components intended for transfusion, a significant disruption) in the supply of such products in the United States,” and the reasons for such discontinuance or interruption.

The products covered by the notification requirement include prescription drugs and biological products, including blood or blood components for transfusion, that are life supporting, life sustaining or intended for use in the prevention or treatment of a debilitating disease or condition. This includes
any such product used in emergency medical care or during surgery, but not radiopharmaceutical drug products or any other products designated as such FDA.

Manufacturers covered by the notification requirement include applicants with an approved biologics license application (BLA) for a covered biological product, other than blood or blood components. Applicants with an approved BLA for blood or blood components for transfusion are included if the applicant is a manufacturer of a significant percentage of the U.S. blood supply.

Notifications must be submitted to FDA at least 6 months in advance of a permanent discontinuance or interruption in manufacturing. If the discontinuance or interruption in manufacturing was not reasonably anticipated, then the notification must be submitted as soon as practical and no later than 5 business days after the discontinuance or interruption in manufacturing occurs. Detailed instructions are outlined in the guidance.

AABB members may contact AABB’s Regulatory Affairs staff for additional information.

04/03/20 FDA Announces Coronavirus Treatment Acceleration Program

**FDA Announces Coronavirus Treatment Acceleration Program**

FDA announced a new program on Tuesday to expedite the development of potentially safe and effective treatments for COVID-19. The program, known as the Coronavirus Treatment Acceleration Program (CTAP), aims to bring new therapies to sick patients as quickly as possible while supporting research to further evaluate whether these medical countermeasures are safe and effective for treating patients.

As part of the program, FDA staff is providing regulatory advice, guidance and technical assistance to developers and scientists seeking new drug and biologic therapies. The agency also redeployed medical and regulatory staff to serve on review teams dedicated to COVID-19 therapies, streamlined the inquiry request processes and operations for developers and scientists, and provided resources to health care providers and researchers to assist them in submitting emergency requests to use investigational products.

FDA plans to enhance and expand the program to accelerate COVID-19 treatments and other medical countermeasures. The agency will outline additional information on the full breadth of this work in the future.
**04/03/20 FDA to Coordinate National Effort to Develop Blood-Related COVID-19 Therapies**

**FDA to Coordinate National Effort to Develop Blood-Related COVID-19 Therapies**

FDA announced a new effort today to facilitate the development of potential COVID-19 therapies made from blood donated by people who have recovered from the virus. According to the agency, limited data suggest that CCP and hyperimmune globulin (hyper-IG) collected from those who have recovered from COVID-19 may have the potential to lessen the severity or shorten the length of illness in patients currently fighting the infection.

The agency is facilitating access to CCP and hyper-IG, a blood product made from CCP, using multiple pathways. FDA’s initial effort was focused on facilitating access to CCP through an emergency investigational new drug (IND) process. The agency provided information to help health care providers submit these applications to treat individual patients and to facilitate the implementation of well-controlled clinical trials at academic institutions to rigorously evaluate the safety and efficacy of convalescent plasma.

FDA and industry, academic and government partners developed and plan to implement a protocol to provide CCP to patients who may not have access to institutions with clinical trials in place. In this partnership, the Mayo Clinic will serve as the lead institution for the program and the American Red Cross will help collect plasma and distribute it for use across the country. FDA anticipates that this collaborative effort will be able to move thousands of units of plasma to the patients who need them in the coming weeks.

The agency is also working with industry and government partners to accelerate the development and availability of hyper-IG as a potential COVID-19 treatment. FDA is helping to coordinate a study of hyper-IG that will be conducted by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, as well as coordinating other efforts in this area.

In addition, FDA continues to provide advice, guidance and technical assistance to help expedite the development of these products. The agency intends to use regulatory flexibility in making these products and other critical medical countermeasures available to prevent and treat COVID-19.

**04/03/20 REGULATORY UPDATE: Protocol for COVID-19 Convalescent Plasma Collection Updated**

**REGULATORY UPDATE: Protocol for COVID-19 Convalescent Plasma Collection Updated**
The AABB COVID-19 Convalescent Plasma Collection protocol has been updated. The protocol, prepared by the COVID-19 Convalescent Plasma (CCP) Working Group in consultation with FDA’s Center for Biologics Evaluation and Research (CBER) serves as an FDA-reviewed protocol to help ensure CCP collections are rapidly available, well-coordinated locally and nationally, and meet FDA and AABB criteria for allogeneic blood donations with eventual administration to a patient under an FDA-approved individual new drug application (IND). AABB hosted a COVID-19 conference call April 1 with CBER director Peter Marks, MD, PhD, who shared FDA’s current thinking on CCP collections and administration under IND.

The changes to the protocol, highlighted for easy identification, reflect new information and clarification provided by Marks. AABB will continue to provide updates each time FDA releases new information.

04/03/20 REGULATORY UPDATE: FDA Announces Revised Donor Eligibility Criteria to Reduce Blood Shortages During COVID-19 Pandemic

**REGULATORY UPDATE: FDA Announces Revised Donor Eligibility Criteria to Reduce Blood Shortages During COVID-19 Pandemic**

The Food and Drug Administration released several new recommendations today to support a safe and adequate blood supply during the coronavirus disease 2019 (COVID-19) pandemic. FDA based these changes on new data from recent studies.

FDA’s updated HIV risk guidance reduces the donor deferral period to 3 months for risk associated with:

- Men who have sex with men (MSM) and their female contacts.
- Blood transfusion, recent tattoos and piercings.
- Injection of non-prescription drugs.
- Exchanging sex for money or drugs.

The agency also finalized the January 2020 draft guidance on Creutzfeldt–Jakob disease (CJD) and variant CJD that recommends the following:

- Deferral for the United Kingdom, France and Ireland.
- Eliminating deferral for time spent in numerous European countries or on military bases in Europe. FDA recommends allowing reentry of these donors.

Additionally, FDA issued updated malaria recommendations that reduce the deferral following travel to malaria-endemic regions to 3 months and remove the travel deferral for certain donors of pathogen-reduced platelets and plasma.

FDA also provided alternative procedures during the pandemic that include the following:

- Blood centers are no longer required to discard collections based on errors in blood pressure, pulse, weight and donation interval.
• Blood centers now have 72 hours to clarify a donor’s response or obtain omitted information that is required to determine donor eligibility and component suitability.

FDA put forth these guidances for immediate implementation and expects them to remain in place after the COVID-19 pandemic ends. The alternatives to certain donor eligibility requirements will apply only for the duration of the declared pandemic. Blood establishments are not required to implement the changes in the FDA recommendations or the alternative procedures.

AABB Submits Updated DHQ for FDA Review

AABB submitted the version 2.1 Blood Donor History Questionnaire (DHQ) and related documents to FDA today. The revised documents include the changes in the FDA guidance documents referenced above. FDA will issue a level 2 guidance to recognize the v2.1 DHQ as an acceptable method to screen donors, which means blood establishments will not be required to submit a changes being effected (CBE) supplement for the changes implemented in v2.1. The new v2.1 DHQ and related materials will be posted on AABB’s DHQ web page.

03/27/20 AABB Delays Effective Dates for BBTS, IRL Standards

AABB Delays Effective Dates for BBTS, IRL Standards

Due to the ongoing COVID-19 pandemic, AABB has elected to delay the effective dates of the 32nd edition of Standards for Blood Banks and Transfusion Services (BBTS) and 11th edition of Standards for Immunohematology Reference Laboratories (IRL) to July 1, 2020. AABB previously scheduled both sets of Standards to take effect on April 1, 2020. AABB reserves the right to extend the effective dates past July 1, 2020, if deemed appropriate.

At this time, AABB expects each set of Standards to remain in effect for 21 months, with the next editions of each set of Standards taking effect April 1, 2022. To prepare for the July 1, 2020, effective dates, individuals can access the Standards Committee’s responses to comments and significant changes online. Those with questions should contact AABB’s Standards department at standards@aabb.org.

03/27/20 HHS Seeks Feedback on Legislation to Maintain Adequate Blood Supply

HHS Seeks Feedback on Legislation to Maintain Adequate Blood Supply

HHS is seeking public comments on Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAI), which addresses recommendations to maintain an adequate national blood supply. Specifically, HHS welcomes feedback on the following four subject areas:

• 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-Transmissible Infections Monitoring System (TTIMS).
• 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.

The deadline to submit comments is April 22. Instructions to submit comments electronically or in writing are available in the Federal Register notice.

03/27/20 Reminder: AABB Temporarily Suspends Assessments Due to COVID-19 Risk

Reminder: AABB Temporarily Suspends Assessments Due to COVID-19 Risk

AABB has temporarily suspended all assessments in response to the ongoing COVID-19 pandemic. This action will ensure that member facilities can focus on their own internal needs and challenges during the current outbreak, and it will also help protect the health and safety of AABB employees and volunteers. The Association’s other programs and services remain fully operational, and scheduled educational programs will continue as planned.

03/27/20 AABB, ABC, ARC Highlight Importance of Blood Supply in HHS, FDA Letters

AABB, ABC, ARC Highlight Importance of Blood Supply in HHS, FDA Letters

AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) reminded officials at HHS and FDA of the importance of maintaining an adequate blood supply during the ongoing COVID-19 pandemic. In a March 20 letter to HHS Secretary Alex M. Azar II and Assistant Secretary for Health Admiral Brett P. Giroir, MD, the organizations thanked the officials for their ongoing support of the blood community and requested that HHS continue to address challenges facing the nation’s blood supply as a result of the COVID-19 pandemic.

In a March 20 letter to Stephen M. Hahn, MD, commissioner of Food and Drugs, the organizations asked Hahn to include challenges to the nation’s blood supply in his response to the House of Representatives Committee on Energy and Commerce about the potential impact that COVID-19 could have on the supply of safe drugs and other medical products. AABB, ABC and ARC reiterated that governmental support is required to encourage all healthy individuals to donate blood and to ensure that the entire blood supply chain stays intact.

03/27/20 Report Published in Transfusion Examines Response to COVID-19 in Washington State

Report Published in Transfusion Examines Response to COVID-19 in Washington State

Adequate blood supply and public messaging, testing capacity, highly skilled laboratory personnel, transportation and alterations to hospital operations should be considered to adequately support the
community during the COVID-19 outbreak, according to a brief report published this week in *Transfusion*. The report describes the response from the hospital, the regional blood center and the hospital-based transfusion service to the events that took place in the community during the first and second weeks of the COVID-19 pandemic in Washington state. The report also details a number of transformations that were required to protect the blood supply as community activities were disrupted and hospital activities switched from routine operations to pandemic-focused and urgent care-oriented operations.

**03/27/20 AABB Releases Findings From Weekly Member Survey on COVID-19 Response**

**AABB Releases Findings From Weekly Member Survey on COVID-19 Response**

Almost half of AABB member hospitals that participated in AABB’s inaugural weekly survey of member transfusion services have implemented prospective audits for red blood cell orders and platelet orders in response to the COVID-19 pandemic. AABB intends for these findings to provide a snapshot into the impact of the blood supply on patient care during the COVID-19 pandemic. A total of 132 AABB member hospitals from 39 states responded to the survey, while total responses per question varied.

Of 131 respondents, 63 (48.1%) have implemented prospective audits for red blood cell orders, while 60 (45.8%) have not; similarly, 63 out of 132 hospitals (47.7%) implemented audits for platelets orders and 59 (44.7%) have not. A total of 75 (56.8%) and 18 (13.8%) have lowered RBC transfusion thresholds to 7 grams per deciliter of hemoglobin for most patients or any patients, respectively. In addition, among 131 respondents, 12 (9.2%) had implemented splitting of platelet and/or RBC units, while 111 (85.5%) had not; 27 of 129 (20.9%) had planned for splitting platelet and/or RBC units, while 78 (60.5%) had not. AABB will refine the questionnaire in next iterations to understand if these trends are based on whether the responding hospitals are pediatric- versus adult-serving institutions. A total of 48 of 131 respondents (36.6%) have created or revised a plan in the event that no blood is available for transfusion, while 78 (59.5%) have not.

AABB will continue to survey member transfusion services and report the results out to participating hospitals on a weekly basis in the months ahead.

**03/27/20 AABB’s Spanish-Language Subsection, GCIAMT Translate COVID-19 Resources**

**AABB’s Spanish-Language Subsection, GCIAMT Translate COVID-19 Resources**

The translation volunteer team from AABB’s Cellular Therapies (CT) Spanish-Language Subsection (SLS) partnered with the Latin American Transfusion Medicine Association (GCIAMT) to develop an open resource of COVID-19 transfusion medicine documents in the Spanish language. The web page includes translated resources from AABB’s Coronavirus Resources web page, as well as
information from FDA, Vitalant, GCIAMT and the Global Advisory Panel for the Voluntary Non-Remunerated Blood Donation. AABB reminds those who utilize the Spanish-language resources that the volunteer translation may not be as precise as if performed commercially. For the official text, please refer to the English-language version.

AABB extends its gratitude to the SLS translation volunteer team and GCIAMT for making these important resources accessible to the Spanish-speaking community. Additional information about AABB’s CT Spanish-Language Subsection is available online.

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**03/27/20 AABB Announces Town Hall eCast Series on COVID-19 Considerations**

**AABB Announces Town Hall eCast Series on COVID-19 Considerations**

AABB is pleased to introduce an educational town hall eCast series to assist blood centers and hospital transfusion services in navigating the pressing challenges presented by the ongoing COVID-19 pandemic. Registration to the series is complimentary thanks to the generous support of the Commonwealth Transfusion Foundation (CTF).

This series comprises four 30-minute expert-led virtual town hall lectures on managing collections, operations and inventory during the pandemic, as well as highlighting the experience of professionals in Washington state in responding to COVID-19. A 30-minute Q&A period will follow each lecture, and registrants will receive supportive resources such as tools and fact sheets. Dates and descriptions of each town hall are available online.

Both the live and on-demand versions of each eCast in the series will be eligible for one continuing education credit/contact hour. Registration is required and includes access to all four eCasts in the series, both live and on-demand.

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**03/27/20 European Health Officials Issue Guidance on Managing Clinical Trials during the COVID-19 Pandemic**

**European Health Officials Issue Guidance on Managing Clinical Trials during the COVID-19 Pandemic**

The EMA, the EC and the Heads of Medicines Agency (HMA) released a guidance on Friday for European pharmaceutical companies whose clinical trials may be affected by the ongoing COVID-19 pandemic. The guidance outlines several considerations to protect the health and safety of participants and investigators. It also addresses the pandemic’s potential effect on the completion of trial assessments and visits and the provision of investigational medicinal products. FDA issued a guidance last Wednesday for industry, investigators and institutional review boards conducting clinical trials during the COVID-19 pandemic in the United States.
Global Regulatory Workshop Explores Development of Novel Coronavirus Vaccine

The first global regulatory workshop on COVID-19 brought together delegates representing more than 20 regulatory authorities, including experts from the World Health Organization and European Commission (EC), to discuss the development of a vaccine for SARS-CoV-2. FDA and the European Medicines Agency (EMA) co-chaired the virtual workshop, convened under the umbrella of the International Coalition of Medicines Regulatory Authorities, on March 18. Peter Marks, MD, PhD, director of CBER, provided an overview of the meeting’s discussion and outlined the next steps for FDA’s and EMA’s collaboration in an FDA Voices article.

CMS Releases COVID-19 Emergency CLIA Guidance FAQ Document

The Centers for Medicare & Medicaid Services (CMS) answered a series of frequently asked questions (FAQs) related to Clinical Laboratory Improvement Amendments (CLIA) guidance during the COVID-19 pandemic. The document addresses alternative specimen collection devices, COVID-19 testing and emergency use authorizations, among other topics. Additional resources from CMS are available on the agency’s coronavirus web page.

CDC Issues Interim COVID-19 Infection Control Guidance for Blood, Plasma Collection Personnel

CDC issued interim guidance last Saturday to protect the health of staff, volunteers and donors at blood and plasma collection centers and help them set up facilities to minimize spread of COVID-19. CDC’s interim guidance reinforces routine measures that are currently followed by blood centers, including considerations described in FDA’s March 11 communication on the COVID-19 outbreak. The guidance complements CDC’s interim infection prevention and control recommendations and AABB’s Association Bulletin #20-02, which outlines recommendations for providing a safe environment for blood donation.

CBER Pauses Some Lot Release Activities Due to Coronavirus

FDA’s Center for Biologics Evaluation and Research (CBER) paused certain lot release activities and stopped accepting biological product samples or protocols in physical form this week in response to the ongoing COVID-19 pandemic. CBER’s Office of Compliance and Biologics Quality provided manufacturers with logistical information to assist with continuation of the lot release process during
this period. In addition, the agency emphasized that the lot release process for licensed biological products will continue. CBER will notify manufacturers when the agency resumes normal operations.

03/27/20 FDA Alerts Consumers to Unauthorized Fraudulent COVID-19 Test Kits

**FDA Alerts Consumers to Unauthorized Fraudulent COVID-19 Test Kits**

FDA has not authorized any test that is available to purchase for at-home testing for COVID-19, the agency [reminded the public](https://www.fda.gov) last Friday. However, the agency sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection. FDA is actively working with test developers in this space. In addition, the agency emphasized that it continues to monitor the market for any firms selling products with fraudulent COVID-19 diagnostic, prevention and treatment claims. FDA will take appropriate action against those marketing tests that pose risks to patient health.

03/27/20 $2 Trillion COVID-19 Stimulus Legislation Includes Blood Donor Awareness Campaign, Funding for Blood Supply Chain

**$2 Trillion COVID-19 Stimulus Legislation Includes Blood Donor Awareness Campaign, Funding for Blood Supply Chain**

President Donald Trump signed the [Coronavirus Aid, Relief and Economic Security Act (CARES Act)](https://www.congress.gov), which includes AABB-supported provisions to promote blood donation and strengthen the blood supply chain during the COVID-19 pandemic. The Senate unanimously passed the $2 trillion stimulus package late Wednesday evening; the House of Representatives passed the bill by a voice vote this afternoon.

The legislation requires the Secretary of Health and Human Services (HHS) to carry out a national campaign to improve awareness of the need for blood donations during the COVID-19 pandemic. Additionally, the legislation supports outreach to the public and health care providers about the importance and safety of blood donations. The legislation also mandates that the Secretary send a report to the House within two years that includes a description of the activities carried out as part of the awareness campaign, a description of trends in blood donations, and an evaluation of the impact of the public awareness campaign, including any geographic or population variations.

Additionally, the legislation allocates $27 billion for the Public Health and Social Services Emergency Fund to prevent, prepare for and respond to coronavirus, domestically or internationally. This funding may be used to address the blood supply chain, develop several necessary countermeasures, and for other preparedness and response activities.

03/27/20 REGULATORY UPDATE: FDA Issues Considerations to Preserve Medical Gloves

**REGULATORY UPDATE: FDA Issues Considerations to Preserve Medical Gloves**
FDA issued a letter to health care providers last week outlining considerations to conserve surgeons’ gloves and patient examination gloves should the need for personal protective equipment outpace supply during the COVID-19 pandemic.

In settings where medical glove supplies are critically low and demand is high, the agency suggests health care providers consider the following strategies:

- Refer to the CDC’s Hand Hygiene in Healthcare Settings.
- Use medical gloves beyond the manufacturer-designated shelf life in a setting where there is a lower risk of transmission.
- Extend the use of medical gloves for health care providers without changing the gloves between patients with the same infectious disease diagnosis or exposure and no other infections. FDA stated, “Gloved hands can be cleaned between patients and at other times when hand hygiene would normally be performed during routine patient care. Alcohol-based hand sanitizers may degrade vinyl gloves. If a glove becomes damaged (for example, discolored, deteriorated, visible tears, holes) or contaminated (for example, body fluids, chemotherapy drugs), replace it.”
- Consider using radiographic protective gloves or radiation attenuating surgeon’s gloves that are clean and offer fluid barrier protection.
- Consider using non-medical gloves, such as those used for food service, embalming, cleaning or other industrial-grade gloves.

FDA categorized the conservation strategies for a range of needs and supply levels, which are available in full online. Importantly, the agency noted that these strategies are not limited to use in the care of patients with COVID-19.

FDA also stated that it intends the conservation strategies described in the letter to augment, not replace, specific controls and procedures developed by health care organizations, the CDC or the CDC’s Healthcare Infection Control Practices Advisory Committee to aid in infection prevention and control.

FDA is collaborating with manufacturers of medical gloves to better understand the current supply chain issues related to the COVID-19 pandemic and to help mitigate any widespread shortages of these products. The agency will continue to keep health care providers, manufacturers and the public informed if new or additional information becomes available.

AABB’s Association Bulletin #20-02 and AABB’s Coronavirus Resources web page provide additional information and strategies designed to promote a safe environment for blood donation.

AABB encourages members to review FDA’s recent communication, FDA’s Process for Making Available Guidance Documents Related to Coronavirus Disease 2019, which announces procedures to allow the agency to rapidly disseminate recommendations and policies related to COVID-19 to industry, FDA staff and other stakeholders. As provided in the communication, “FDA is committed to providing timely recommendations, regulatory advice, guidance, and technical assistance ... including to clarify our expectations regarding regulatory requirements to support response efforts to this emergency.”

The new procedure allows for the following changes in FDA’s processes:

- COVID-19-related guidance documents will be released for immediate implementation without prior public participation or comment.
- FDA will solicit and review comments received [after implementation], and revise the guidance documents as appropriate.

COVID-19 guidance documents will be posted on FDA’s Coronavirus Disease 2019 (COVID-19) webpage and announced in a consolidated Federal Register notice using one docket for each center or office.

03/27/20 REGULATORY UPDATE: FDA to Expedite Emergency Access to COVID-19 Convalescent Plasma

REGULATORY UPDATE: FDA to Expedite Emergency Access to COVID-19 Convalescent Plasma

The Food and Drug Administration is facilitating emergency access to convalescent plasma from individuals who have recovered from coronavirus disease 2019 (COVID-19) for investigational use in patients with serious or immediately life-threatening COVID-19 infections. According to FDA, it is possible that COVID-19 convalescent plasma (CCP) containing antibodies to the 2019 novel coronavirus (SARS-CoV-2) might be effective against the infection.

FDA’s emergency Investigational New Drug Application (eIND) process allows for the use of CCP for the investigational treatment of an individual patient by a licensed physician upon FDA authorization. This does not include the use of CCP for the prevention of SARS-CoV-2 infection. FDA outlines requirements for collection of CCP, patient eligibility criteria and eIND authorization instructions on its Emergency INDs web page.

FDA continues to work with the National Institutes of Health and the Centers for Disease Control and Prevention to develop master protocols for use by multiple investigators in order to coordinate the collection and use of CCP.

03/20/20 AABB, Mayo Clinic Laboratories Cancel Transfuse 2020

AABB, Mayo Clinic Laboratories Cancel Transfuse 2020
AABB and Mayo Clinic Laboratories announced the cancellation of Transfuse 2020 this week in response to the ongoing COVID-19 pandemic. Transfuse 2020 was scheduled for May 12-13 in Rochester, Minn. Registrants who have already paid will receive a refund. AABB thanks participants for their understanding during this challenging time.

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**03/20/20 REGULATORY UPDATE: AABB, ABC, ARC, ASBP Submit Joint Comments on CJD Draft Guidance**

**REGULATORY UPDATE: AABB, ABC, ARC, ASBP Submit Joint Comments on CJD Draft Guidance**

AABB, ABC, ARC and the ASBP recently submitted joint comments to FDA on the January 2020 draft guidance, “Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components.” The organizations applauded CBER’s “new direction and the decision to restore donation opportunities for many new and returning donors, most notably those who were deferred for time spent in Europe during military service, along with their dependents.”

The comments also included a request for clarification on the rationale behind CBER’s risk-based decision to remove receipt of human growth hormone as a reason for donor deferral without permitting reentry options and similar rationale for potential iatrogenic exposures to sporadic Creutzfeldt-Jakob Disease.

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**03/20/20 AABB Highlights Urgent Need for Blood in National Media**

**AABB Highlights Urgent Need for Blood in National Media**

AABB continues to amplify the need for continuous blood donations in national, regional and local media outlets. Since the beginning of the outbreak, AABB representatives have stressed the importance of an adequate blood supply and urged the public to donate in articles from *The New York Times*, *The Los Angeles Times*, *USA Today*, *Kaiser Health News*, *Reuters* and more.

To assist member centers in publicizing the need for blood donations, AABB developed a social media campaign and released a media toolkit in partnership with ABC, ARC and the Armed Services Blood Program (ASBP). The toolkit includes a press release and several pre-recorded media statements. As the pandemic unfolds, AABB will continue to use every opportunity to highlight the importance of the blood supply and of the critical work of the blood community.

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**03/20/20 Government Officials Urge Americans to Donate Blood**

**Government Officials Urge Americans to Donate Blood**

Surgeon General Vice Admiral Jerome Adams, MD, MPH, and Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research (CBER), issued separate statements this week urging
Americans to donate blood in response to the COVID-19 pandemic. In a Thursday news conference, Adams reminded the public that blood donation is safe and highlighted several of the extra precautions blood centers have implemented to prevent the spread of COVID-19 based on CDC recommendations.

Marks reiterated the need for blood donors and emphasized that blood centers are skilled in infection control practices and have procedures in place to prevent the spread of infections. “Blood donation centers always take steps to prevent staff and donors who are not feeling well or who have a fever from reaching the donor area,” Marks said. “And they are now taking additional social distancing precautions wherever possible.”

Last week, AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) wrote a joint letter to CDC Director Robert R. Redfield, MD, stressing that governmental support is necessary to encourage all healthy individuals to donate blood and to limit the negative impact that social distancing has on blood donation efforts.

03/20/20 CMS Recommends Delays for Elective, Non-Essential Surgeries

CMS Recommends Delays for Elective, Non-Essential Surgeries

The Centers for Medicare & Medicaid Services (CMS) announced on Wednesday that all elective surgeries, non-essential medical, surgical and dental procedures should be delayed during the COVID-19 pandemic. The recommendation is part of a broader framework for hospitals and clinicians to implement immediately during the COVID-19 response. The recommendations outline factors that should be considered for postponing elective and non-essential surgeries, including patient risk factors, availability of beds, staff, personal protective equipment and the urgency of the procedure. The recommendations will help providers to focus on addressing more urgent cases and preserve resources needed for the COVID-19 response.

03/20/20 FDA Issues Guidance for Conducting Clinical Trials During COVID-19 Outbreak

FDA Issues Guidance for Conducting Clinical Trials During COVID-19 Outbreak

FDA issued a guidance on Wednesday for industry, investigators and institutional review boards conducting clinical trials during the COVID-19 pandemic. The guidance outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity. These considerations include sponsors evaluating alternative methods for assessments, such as phone contacts or virtual visits, and offering additional safety monitoring for those trial participants who may no longer have access to the investigational product or the investigational site.
**FDA Postpones Domestic Routine Surveillance Facility Inspections**

FDA has temporarily postponed all domestic routine surveillance facility inspections in response to the COVID-19 outbreak, FDA Commissioner Stephen M. Hahn, MD, announced on Wednesday. The postponement will not affect inspections that FDA considers "mission critical," and the agency will continue to respond to natural disasters, outbreaks and other public health emergencies involving FDA-regulated products. FDA is evaluating additional ways to conduct inspectional work that would not jeopardize public safety.

**AABB Releases New COVID-19 Cellular Therapy Resource**

AABB's Center for Cellular Therapies released a new resource this week that compiles the latest information from FDA, AABB and partner organizations related to cellular therapy products and COVID-19. AABB continues to monitor the COVID-19 situation closely and update the resource as new information becomes available.

**AABB to Launch Weekly Hospital Snapshot Survey**

AABB hospitals are encouraged to be on the lookout next week for a quick survey asking about new or changed blood bank practices in light of the COVID-19 pandemic. Questions include whether hospitals have changed transfusion medicine practices, such as whether indication thresholds for red blood cells and platelets have been lowered, whether prophylactic platelet transfusions have been discontinued, and similar questions. The survey, to be administered weekly, is intended to provide a weekly snapshot into the impact of the blood supply on patient care during the COVID-19 pandemic. AABB will report the results out to participating hospitals on a weekly basis during the coming months.

**REGULATORY UPDATE: AABB Releases Updated COVID-19 Toolkit**

AABB’s Regulatory Affairs posted an updated COVID-19 toolkit in response to the Food and Drug Administration’s March 11 communication, Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak. AABB urges members to carefully review the information from FDA and the updated toolkit, including "Notes to Consider" which may be helpful as they determine the appropriate approach for rapidly changing events and to avoid unnecessary donor deferrals if blood availability is a concern.

In response to member questions, the toolkit clarifies the following compliance responsibilities:
1. COVID-19 is not a “transfusion-transmitted infection, nor an RTTI, under 21 CFR 630.3 which provides a significant part of the regulatory framework for donor screening requirements” throughout 630.10.

2. For example, 630.10(a) states “To be eligible, the donor must be in good health and free from transfusion-transmitted infections…” which means the donor is eligible, according to current FDA regulations, if “feeling healthy and well” when asked on the day of donation.

3. The FDA issued “considerations, but not recommendations, to be implemented at the discretion of the Medical Director.

Because COVID-19 is not a TTI, compliance with the considerations listed in the March 11 communication is not expected, except the requirement under 630.10 to establish the donor is “feeling healthy and well” at the time of donation. The establishment may determine if additional precautionary measures should be taken.

Three key changes from FDA are highlighted in the toolkit:

1. FDA has removed the reference to optional self-deferral for travel that was in the Feb. 4 communication.

2. FDA’s considerations on post-donation information (PDI) include a “subsequent diagnosis” only and do not include close contact/lived with a person diagnosed with COVID-19. FDA has never referenced PDI for travel in the precautionary measures.

3. FDA considerations for retrieval and quarantine are also precautionary measures. As such, retrieval and quarantine for a subsequent diagnosis of COVID-19 or close contact/lived with a person diagnosed with COVID-19 (which is not listed as a PDI consideration) are not required.

AABB is actively reviewing FDA’s new guidance process “to rapidly disseminate Agency recommendations and policies related to COVID-19 to industry, FDA staff and other stakeholders. The Association urges members to review the AABB’s Coronavirus Resources web page for updates. Questions about the toolkit or other regulatory concerns may be sent to regulatory@aabb.org.
These recommendations, developed by AABB’s COVID-19 Working Group, are based on a review of Centers for Disease Control and Prevention recommendations to protect individuals from the spread of the virus and current practices shared by AABB members. The adoption of some or all of these strategies will help to demonstrate the commitment of blood collection organizations to the safety of their donors. As new recommendations emerge, and as warranted by the current pandemic, AABB will continue to urge adoption of these and other practices by the blood collection community.

03/13/20 AABB Temporarily Suspends Assessment Activities, Will Begin Remote Operations

**AABB Temporarily Suspends Assessment Activities, Will Begin Remote Operations**

In light of the ongoing 2019 novel coronavirus epidemic, AABB will temporarily suspend all assessments and begin remote operations effective Monday. This action will ensure that member facilities can focus on their own internal needs and challenges during the current outbreak, and it will also help protect the health and safety of AABB employees and volunteers. The Association’s other programs and services remain fully operational, and scheduled educational programs will continue as planned.

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03/13/20 AABB Releases Shareable Graphics on COVID-19 and Blood Donation

**AABB Releases Shareable Graphics on COVID-19 and Blood Donation**

AABB developed a shareable infographic about COVID-19 and the blood supply and a series of social media images to highlight the importance of continued blood donation during the ongoing outbreak. The infographic illustrates key messages that blood centers can use to address common misconceptions about novel coronavirus transmission, while the social media graphics emphasize the critical importance of an adequate national blood supply. AABB encourages members to utilize these tools in their own COVID-19 communications. Additional resources are available on AABB’s Coronavirus Resources web page. AABB encourages members to check this page regularly for updates.

03/13/20 FDA Updates Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

**FDA Updates Information for Blood Establishments Regarding the Novel Coronavirus Outbreak**

The Food and Drug Administration issued a series of updated safety and availability considerations for blood establishments in response to the ongoing outbreak of the 2019 novel coronavirus (SARS-CoV-
2), which causes the illness known as coronavirus disease 2019 (COVID-19). The updated web page addresses the use of laboratory screening tests, donor education and deferral, prospective donor evaluations and post-donation instructions.

AABB is developing additional resources for the COVID-19 Toolkit based updated information from FDA and a Centers for Disease Control and Prevention report of “community spread of the disease” in the United States. The toolkit will identify all changes in the March 11 communication. AABB will post the information as soon as possible.

In addition, FDA reemphasized its support for recommendations developed by the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, which encourage healthy individuals to make plans to donate blood to maintain the adequacy of the nation's blood supply. The agency also encouraged blood centers to prepare and evaluate their emergency plans to address possible challenges, such as the availability of donors and staff.

03/13/20 FDA Launches COVID-19 FAQ Web Page

FDA Launches COVID-19 FAQ Web Page

FDA launched a new web page on Tuesday to answer frequently asked questions (FAQs) related to COVID-19. The page includes a section on vaccines, biologics, human tissues and blood products and addresses concerns related to donor screening, transmission risk and potential treatments. The FAQ page reemphasizes information that FDA shared on the Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak web page and the Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak web page. Additional tools and resources are available on AABB’s Coronavirus Resources web page.

03/13/20 FDA Postpones April 2-3 BPAC Meeting

FDA Postpones April 2-3 BPAC Meeting

FDA will postpone the April 2-3 meeting of the Blood Products Advisory Committee (BPAC). The postponement is part of a larger government decision to cancel or postpone all non-essential meetings through the month of April. FDA will reassess on an ongoing basis for future months and leverage technology to host remote meetings where possible.

03/13/20 FDA, FTC Warn Companies for Selling Fraudulent COVID-19 Products

FDA, FTC Warn Companies for Selling Fraudulent COVID-19 Products

FDA and the Federal Trade Commission (FTC) issued warning letters to seven companies for selling fraudulent products intended to treat COVID-19. The agencies noted that the products (including teas, essential oils, tinctures and colloidal silver) are unapproved drugs that pose significant risks to patient
health, violate federal law and “may cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm.” FDA and FTC requested responses from the companies within 48 hours describing specific steps they have taken to correct the violations outlined in the respective letters. Companies selling products that fraudulently claim to prevent, treat or cure COVID-19 may be subject to legal action. The agencies reiterated that there are no vaccines or drugs approved to treat or prevent COVID-19 at this time.

03/13/20 DOJ Cautions Business Community Against Violating Antitrust Laws Regarding Health Products

DOJ Cautions Business Community Against Violating Antitrust Laws Regarding Health Products

The Department of Justice (DOJ) will hold accountable anyone who violates antitrust laws in connection with the manufacturing, distribution or sale of public health products, the agency announced Monday. The agency also warned that individuals or companies that fix prices or rig bids for health protection equipment could face criminal prosecution. The announcement is part of a broader administration effort to ensure that federal, state and local health authorities; the private health care sector; and the public at large are in the strongest position to respond to the ongoing COVID-19 outbreak. DOJ’s Procurement Collusion Strike Force will be on alert for collusive practices in the sale of such products.

03/13/20 WHO Declares Coronavirus Outbreak a Pandemic, CDC Issues Global COVID-19 Outbreak Notice

WHO Declares Coronavirus Outbreak a Pandemic, CDC Issues Global COVID-19 Outbreak Notice

The World Health Organization (WHO) now considers the outbreak of novel coronavirus disease 2019 (COVID-19) to be a pandemic, Director General Tedros Adhanom Ghebreyesus, PhD, MSc, said during a Wednesday news briefing in Geneva. “All countries can still change the course of this pandemic. If countries detect, test, treat, isolate, trace and mobilize their people in the response,” he said.

Following WHO’s announcement, CDC issued a Global COVID-19 Outbreak Notice that classified the current situation as sustained community-level transmission. The notice encouraged travelers to practice enhanced safety precautions.

03/13/20 AABB, ABC, ARC Urge CDC to Assist in Blood Donor Recruitment Efforts

AABB, ABC, ARC Urge CDC to Assist in Blood Donor Recruitment Efforts

AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) urged CDC officials to encourage healthy individuals to donate blood to help limit the negative impact that social distancing is having on blood donation.
In a March 12 letter, the organizations stated that while social distancing intended to limit the spread of COVID-19 is a necessary and appropriate public health measure, it has resulted in many canceled blood drives. Efforts to reduce non-essential blood component use can reduce the strain on the blood supply, the letter states, but the impact of these blood management strategies is not big enough to make up for the loss of donors.

AABB, ABC and ARC also stressed that blood drives are not "mass gatherings," but rather they are controlled events conducted using appropriate infection control mechanisms intended to assure the safety of the products, donors and staff. They emphasized that the entire blood community is united and undertaking massive efforts to educate the public about the safety and necessity for blood donation, but noted that governmental support is required to encourage blood donation and limit the negative impact that social distancing has on blood donation efforts.

03/06/20 Trump Signs Emergency Coronavirus Funding Package

Trump Signs Emergency Coronavirus Funding Package

President Trump signed an $8.3 billion emergency aid package on Friday in response to the novel coronavirus. The bipartisan package, negotiated and passed by Congress this week, includes more than $3 billion for research and development of vaccines and other treatments. The bill also includes $2.2 billion in public health funding, including grants of $4 million or more to allow each state to prepare for and respond to the coronavirus; $836 million for the National Institutes of Health; and $1.25 billion for the Department of State and the United States Agency for International Development, including money for evacuations and humanitarian assistance. The bill authorizes $500 million for telemedicine, although Congress would need to pass legislation to specifically appropriate this funding.

03/06/20 Interorganizational Disaster Task Force Encourages Continued Blood Donation to Maintain Adequate Blood Supply

Interorganizational Disaster Task Force Encourages Continued Blood Donation to Maintain Adequate Blood Supply

The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism issued a statement on Tuesday urging healthy, eligible individuals to donate blood to help maintain an adequate blood supply for patients in need. In its statement, the Task Force reminded the public that individuals are not at risk of the novel coronavirus through the blood donation process or via a blood transfusion, since respiratory viruses are generally not known to be transmitted by donation or transfusion. The statement also emphasized that routine blood donor screening measures — which may include travel deferrals — are already in place to help prevent individuals with clinical respiratory infections from donating blood. The Task Force and the blood community will continue to work with FDA and CDC as the situation evolves to further protect the safety and maintain availability of the blood supply.
**REGULATORY UPDATE: AABB Forms COVID-19 Working Group**

AABB formed a COVID-19 Working Group this week to help blood collection centers and transfusion services respond to the potential adverse impact on blood collections due to the ongoing outbreak of COVID-19. The COVID-19 Working Group will provide education and tools to support planning and preparation, donor and staff safety, communications, and continuity of operations necessary to promote blood safety and availability during the outbreak.

AABB will coordinate the activities of the COVID-19 Working Group, which includes representatives from AABB, America’s Blood Centers, the American Red Cross (ARC) and the Association of Donor Recruitment Professionals. AABB recognizes the hard work and dedication of these volunteers.

Individuals with questions AABB’s COVID-19 response or the Working Group should contact regulatory@aabb.org.

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**REGULATORY UPDATE: AABB Launches New Web Page for COVID-19 Resources**

AABB launched a Coronavirus Resources web page to serve as a comprehensive hub for the Association’s latest information and tools related to coronavirus disease (COVID-19). The new web page includes the following resources:

- AABB’s COVID-19 outbreak planning checklist.
- COVID-19 resource list: the most current information from the Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, the World Health Organization (WHO) and other public health authorities.
- A list of key messages, developed by the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, that health care professionals can use when discussing COVID-19 with blood donors, patients and members of the public.

Previously released information, such as the updates from the Transfusion Transmitted Diseases Committee and the optional resources toolkit for FDA’s communication to blood establishments.

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**REGULATORY UPDATE: COVID-19 and Blood Donation**

**AABB Releases Member Toolkit**

As announced in a News Flash last week, AABB, in collaboration with the Donor History Task Force and with support from the Transfusion Transmitted Diseases (TTD) Committee, has developed a toolkit to
support the Food and Drug Administration’s recently released “Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak.” The toolkit is intended to assist blood collection centers considering optional precautionary measures related to COVID-19 and blood donation. The toolkit aligns with FDA’s current thinking, provides examples of optional documents and reminds donor centers how to stay informed by following updates on the CDC Travel Notices page. Additional information, including the TTD’s most recent COVID-19 update are posted on AABB’s Regulatory Affairs web page.

AABB continues to monitor the COVID-19 outbreak and will keep members informed as necessary. AABB is also working with the Interorganizational Task Force on Domestic Disasters and Acts of Terrorism to determine if the outbreak is impacting the blood supply. Additionally, the Public Relations Subgroup of the Disaster Task Force is developing communication materials for the public regarding coronavirus and the blood supply, which will be forthcoming soon.

**CDC Updates COVID-19-Related Resources**
The Centers for Disease Control and Prevention has developed numerous resources on COVID-19, including the Coronavirus Disease 2019 (COVID-19) page and a new page consolidating Travel Notices for COVID-19. CDC provides definitions for the three types of travel notices and details for each location affected by a travel notice. These two pages provide links to a broad range of resources for clinical professionals. A short document offering COVID-19 resources is also available.

CDC recently updated the Travel Health Notices web page to include Japan, Iran, Italy and South Korea, underscoring the importance of reviewing its updated information frequently. Those who are interested can subscribe to receive CDC updates to the Travelers' Health website through an RSS feed. In addition, CDC invites the public to “stay current with this rapidly evolving situation” by signing up for the newly launched COVID-19 “What’s New” Weekly Update via CDC’s Sign Up for CDC.gov Email Updates page. CDC also provides updates via social media on Facebook, Instagram, Twitter and YouTube.

**Asia Pacific Blood Network Releases Recommendations For Updating Optional Documents Regarding COVID-19 (also referred to as SARS-CoV-2)**
The Asia Pacific Blood Network’s February 17 "Rapid Brief White Paper 2019 Novel Coronavirus (SARS-CoV-2): Expected challenges and risks to blood safety" provides a comprehensive update and recommends specific factors to consider when developing an effective risk reduction strategy. The briefing document suggests, for “the emerging SARS-CoV-2 epidemic it is vital that blood services consider their response to the epidemic carefully. An overly precautionary response early, given the theoretical blood safety risk, may contribute to community misinformation on the risk and make it more difficult to maintain the blood supply if sustained community transmission has occurred. A precautionary approach may be acceptable if it has the ability to be flexible and change with emerging evidence and a changing epidemiology.” The November 2010 FDA Guidance, Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application has important information to consider when
preparing for and updating strategies to respond to the COVID-19 outbreak. The November 2010 guidance states the recommendations, “are applicable regardless of the existence of a pandemic or other emergency situation.”

The decision to implement precautionary measures and flexible options for updating self-deferral and donor education as Covid-19 spreads are left to the discretion of each responsible medical director. FDA’s Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak provides a flexible model for considering precautionary measures. FDA’s communication refers to “areas of outbreak” and without specifying the type of CDC Travel Health Notice (Watch, Alert or Warning) that would prompt an update to the precautionary measures. Similarly, blood centers electing to implement donor screening questions and travel deferrals have the flexibility to determine the type of travel notice that would trigger a travel deferral.

AABB will continue to work closely with FDA, CDC and other public health authorities to monitor the evolving outbreak of COVID-19.

AABB encourages members to contact its Department of Regulatory Affairs with questions.

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**02/28/20** FDA Posts New Information for HCT/P Establishments Regarding the 2019 Novel Coronavirus Outbreak

**FDA Posts New Information for HCT/P Establishments Regarding the 2019 Novel Coronavirus Outbreak**

FDA released new information for establishments involved in the collection of human cells, tissues or cellular or tissue-based products (HCT/Ps) in response to the Covid-19 outbreak. While noting that routine screening methods are currently in place to evaluate HCT/P donors for respiratory infection, FDA suggests that establishments in the United States that are considering additional donor screening measures in response to the virus consider the following donor history in the 28 days prior to HCT/P recovery:

- Travel in areas with COVID-19 outbreaks.
- Living with individuals diagnosed with or suspected of having COVID-19 infection.
- Diagnosis with or suspicion of having COVID-19.

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**02/20/20** AABB News Flash, Regulatory Update: Information on COVID-19 and Blood Donation

**AABB News Flash, Regulatory Update: Information on COVID-19 and Blood Donation**

AABB developed a member toolkit in response to the Food and Drug Administration’s Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak (FDA’s
communication) and provided updated COVID-19 information. Both are posted on AABB’s Regulatory Affairs web page.

FDA has stated that “there have been no reported cases of transfusion-transmitted coronavirus” and “routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood.” The optional resources in the toolkit can be used by blood collection centers that elect to implement additional precautionary measures. The toolkit provides examples of optional documents that align with FDA’s communication. These documents were developed in collaboration with AABB’s Donor History Task Force.

The Centers for Disease Control and Prevention recently updated the Travel Health Notice web page. In addition to the Level 3 outbreak identified earlier in China, CDC has identified Level 1 outbreaks of COVID-19 in Hong Kong and Japan. CDC updates are also available by email through an RSS feed to those who subscribe. AABB will continue to work closely with FDA, CDC and other public health authorities to monitor the evolving outbreak of COVID-19.

AABB encourages members to contact Regulatory Affairs with questions.
information for evidence suggesting risk for 2019-nCoV as a transfusion-transmitted infection (TTI). The TTD is also advising the Donor History Task Force regarding TTI risk and deferral options as the Task Force prepares potential donor screening strategies.

Individuals with questions may contact AABB’s Regulatory Affairs staff at regulatory@aabb.org.

**01/31/20 REGULATORY UPDATE: AABB Issues Update on Novel Coronavirus Outbreak**

**REGULATORY UPDATE: AABB Issues Update on Novel Coronavirus Outbreak**

AABB is closely monitoring the outbreak of 2019-nCoV, including all communications from the Centers for Disease Control and Prevention, Food and Drug Administration and other public health authorities. AABB issued an update, "Impact of 2019 Novel Coronavirus and Blood Safety," to provide new information and insight into the current issues effecting blood safety.

At this time, AABB, CDC or FDA are not recommending interventions since there are neither data nor precedents suggesting risk for transfusion transmission of the 2019-nCoV. However, AABB recognizes that some blood collections establishments may elect to take action in advance of recommendations from FDA and CDC. This update includes important information on the range of options available.

The Transfusion Transmitted Diseases Committee (TTD) will continue to monitor the rapidly changing information for evidence suggesting risk for 2019-nCoV as a transfusion-transmitted infection (TTI). The TTD will advise the Donor History Task Force regarding TTI risk and deferral options as the Task Force prepares potential donor screening strategies in advance of such TTI risk. AABB will provide frequent communication. Members with questions may contact Regulatory Affairs at regulatory@aabb.org.

**01/22/20 AABB Newsflash, AABB Update on Novel Coronavirus Outbreak, Jan. 22**

**AABB Newsflash, AABB Update on Novel Coronavirus Outbreak, Jan. 22**

AABB’s Transfusion Transmitted Diseases (TTD) Committee is continuously monitoring developments for the novel coronavirus (called 2019-nCoV), which has recently been identified in Wuhan, Hubei Province, China. The TTD Committee’s summary of the expanding information describes the background and data available as of Jan 22. AABB advises readers to pay close attention to updates from the Centers for Disease Control and Prevention (CDC) and other public health resources because the increasing number of case counts and clinical and epidemiological information are extremely labile. Rapidly changing information is anticipated.

The 2019-nCoV infection is generally associated with unexplained pneumonia following an incubation period that appears to be in the range of 2 to 14 days, based on limited data. Given the potential similarities of this virus to Severe Acute Respiratory Syndrome (SARS) and the Mideast Respiratory
Syndrome coronavirus (MERS-CoV), the TTD Committee has been in contact with both the Food and Drug Administration (FDA) and CDC to assess any need for interventions to ensure the safety of the blood supply.

A rapid risk assessment from the European Centers for Disease Control recommends a brief travel deferral for donors returning from Wuhan. The CDC confirmed the first U.S. case of 2019-nCoV on Tuesday; however, the CDC and FDA have not yet recommended a travel deferral.

AABB will continue to monitor the situation and issue updates as necessary, including new information from CDC and FDA as it becomes available. Individuals may contact AABB’s Regulatory Affairs staff with questions.

01/10/20 Chinese Officials, WHO Monitoring Pneumonia Cases Caused by New Coronavirus

Health authorities in China have made a preliminary determination of a novel coronavirus, identified in a hospitalized patient with pneumonia in Wuhan, Hubei Province. Investigators conducted gene sequencing of the virus using an isolate from one positive patient sample. Officials notified the China country office of the World Health Organization (WHO) of a cluster of pneumonia cases of unknown cause last week. Of the 44 cases reported, 11 are severely ill, while the remaining 33 patients are in stable condition. WHO does not recommend any specific measures for travelers and advises against the application of any travel or trade restrictions on China based on the information currently available.

AABB’s Transfusion-Transmitted Diseases Committee continues to monitor this and other emerging infectious diseases.