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.

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.

05/29/20 AABB, ABC, ARC Urge Americans to Donate Blood

**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.

05/22/20 Pre-Print Data Suggest CCP Safe in Patients With COVID-19

**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.

05/22/20 Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'

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.

05/22/20 AABB Releases Latest Findings From Weekly Survey of Hospital Transfusion Services; Previous Findings Now Available Online

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 outdating 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.

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.

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**
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

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

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 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.”

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 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 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.”
05/15/20  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 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.

05/15/20  ARHQ to Award $5 Million for Health Services Research Related to COVID-19

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.
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.

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.

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 on 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.
05/08/20 HHS Begins Distributing Payments to Hospitals With High COVID-19 Admissions

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.

05/08/20 CMS Releases IFC on the Agency’s COVID-19 Response

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.

05/08/20 CMS Guidance Clarifies COVID-19 Testing Requirements, FDA Requires Serologic Test Manufacturers to Submit Accuracy Data

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

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

The Food and Drug Administration formally recognized AABB’s version 2.1 (v2.1) full-length Donor 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

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

This afternoon, the Food and Drug Administration formally recognized AABB’s version 2.1 (v2.1) full-length Donor History Questionnaire (DHQ) and abbreviated DHQ (aDHQ) in a level 2 guidance, 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 implementation of multiple updates, AABB is concurrently releasing 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 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. They should contact their FDA consumer safety officer with questions regarding implementation.

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 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 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

Updated by AABB Regulatory Affairs 05/29/20
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.

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

BARDA Announces Partnerships to Develop Investigational COVID-19 Therapies

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 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**

**AABB News Highlights COVID-19, Bleeding Disorders**

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 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**

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**

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.

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

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.
04/17/20 Reminder: Spanish Language Versions of COVID-19 Resources Available

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.

04/17/20 AABB Twitter Chat Explores COVID-19 Convalescent Plasma

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.

04/17/20 AABB Releases Summary of Weeks 1-4 Hospital Snapshot Survey Findings

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 intent 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.

**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.

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

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.
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.

04/03/20 FDA Issues Updated Considerations for HCT/P Establishments

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-CoV2, 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.

04/03/20 CCP Transfusion May Improve Clinical Outcomes for COVID-19 Patients

**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.”

04/03/20 ICCBBA Issues New Product Description Codes for COVID-19 Convalescent Plasma

**ICCBBA Issues New Product Description Codes for COVID-19 Convalescent Plasma**

ICCBBA has made available product description codes (PDCs) for COVID-19 convalescent plasma products. The new codes can be found in the latest release of ISBT 128 Standard Product Description Code Database available at the [ICCBBA website](http://iccbba.org). Inquiries and new PDC requests can be sent to iccbba@iccbba.org.

04/03/20 Wiley Offers Complimentary Access to COVID-19 Research

**Wiley Offers Complimentary Access to COVID-19 Research**

Wiley is offering members of the hematology and transfusion medicine community complimentary access to all COVID-19-related research published in the company’s journal portfolio. This includes content from AABB’s *Transfusion* journal, as well as content from the American Society for Apheresis, British Blood Transfusion Society, British Society for Haematology, International Society for Laboratory Hematology, International Society of Blood Transfusion and International Society on Thrombosis and Haemostasis. AABB, Wiley and its other journal partners aim to help the community continue providing the best possible care for their patients.

04/03/20 Wiley to Pause Print Edition of *Transfusion* During Pandemic

**Wiley to Pause Print Edition of *Transfusion* During Pandemic**

Wiley, the publisher of AABB’s peer-reviewed journal *Transfusion*, has suspended printing and distribution of all of its publications in response to production challenges resulting from the COVID-19 pandemic. During the pandemic, all articles and journal issues will be delivered solely via [Wiley Online Library](http://onlinelibrary.wiley.com), a platform that includes options for remote subscriber access. Wiley is working to help readers 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.
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.

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.

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.

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.
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.
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.

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.

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.
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 2020 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 2020 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.

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.

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.

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.

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.

03/27/20 Global Regulatory Workshop Explores Development of Novel Coronavirus Vaccine

**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.

03/27/20 CMS Releases COVID-19 Emergency CLIA Guidance FAQ Document

**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.

03/27/20 CDC Issues Interim COVID-19 Infection Control Guidance for Blood, Plasma Collection Personnel

**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.

03/27/20 CBER Pauses Some Lot Release Activities Due to Coronavirus

**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 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), 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) web page 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.

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.

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.

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.
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.

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.

03/20/20 AABB to Launch Weekly Hospital Snapshot Survey

**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.

03/20/20 REGULATORY UPDATE: AABB Releases Updated COVID-19 Toolkit

**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.

03/20/20 AABB Releases Association Bulletin #20-02 to Address Blood Donation During the COVID-19 Pandemic

AABB Releases Association Bulletin #20-02 to Address Blood Donation During the COVID-19 Pandemic

The AABB Board of Directors approved Association Bulletin #20-02 this week, which recommends strategies for blood collection establishments to implement to protect the availability of blood nationally during the 2019 coronavirus disease (COVID-19) pandemic. The bulletin contains information and strategies designed to promote a safe environment for blood donation necessary to protect both donors and staff; address public perception, misinformation, and growing concerns regarding the risk of infection transmission during donation; and encourage blood donation during the current COVID-19 outbreak through a demonstrable commitment to safety.

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.

Contact AABB:
Phone: +1.301.907.6977
Email: membership@aabb.org

**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**


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](https://www.cdc.gov/coronavirus/2019-ncov/pandemic-outbreaknotice.html) 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](https://www.cdc.gov/media/releases/2020/p0313-blood-donor-recruitment-letter.html), 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.

03/06/20 REGULATORY UPDATE: AABB Forms COVID-19 Working Group

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.
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.
- **AABB's regulatory updates for COVID-19**: master list of all Weekly Report resources for COVID-19.
- 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.

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.

**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.

**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.
WHO Names 2019 Novel Coronavirus ‘Covid-19’

The official name for the disease caused by the 2019 novel coronavirus is “Covid-19,” officials from the World Health Organization (WHO) announced in a media briefing on Tuesday. According to WHO Director General Tedros Adhanom Ghebreyesus, PhD, MSc, the organization had to select a name that did not refer to a geographical location, an animal, an individual or group of people, and which is also pronounceable and related to the disease. As of Feb. 13, there have been more than 46,997 confirmed cases of Covid-19 reported in China, along with 1,368 deaths. Outside China, there are 447 cases in 24 countries, and 1 death.

FDA Shares Information for Blood Establishments on Novel Coronavirus Outbreak

The Food and Drug Administration shared information for blood establishments regarding the novel coronavirus outbreak this week. The agency stated that the potential for transfusion transmission of the 2019 novel coronavirus (2019-nCoV) is unknown at this time, but noted that respiratory viruses are not known to be transmitted by blood transfusion and that there have been no reported cases of transfusion-transmitted 2019-nCoV at this time.

AABB’s Transfusion Transmitted Diseases Committee (TTD) continues to monitor the rapidly changing 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.

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

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.