AABB’s Regulatory Updates for COVID-19

Last updated March 17, 2020

03/13/20  AABB Temporarily Suspends Assessment Activities, Will Begin Remote Operations

AABB Temporarily Suspends Assessment Activities, Will Begin Remote Operations

In light of the ongoing 2019 novel coronavirus epidemic, AABB will temporarily suspend all assessments and begin remote operations effective Monday. This action will ensure that member facilities can focus on their own internal needs and challenges during the current outbreak, and it will also help protect the health and safety of AABB employees and volunteers. The Association’s other programs and services remain fully operational, and scheduled educational programs will continue as planned.

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03/13/20  AABB Releases Shareable Graphics on COVID-19 and Blood Donation

AABB Releases Shareable Graphics on COVID-19 and Blood Donation

AABB developed a shareable infographic about COVID-19 and the blood supply and a series of social media images to highlight the importance of continued blood donation during the ongoing outbreak. The infographic illustrates key messages that blood centers can use to address common misconceptions about novel coronavirus transmission, while the social media graphics emphasize the critical importance of an adequate national blood supply. AABB encourages members to utilize these tools in their own COVID-19 communications. Additional resources are available on AABB’s Coronavirus Resources web page. AABB encourages members to check this page regularly for updates.

03/13/20  FDA Updates Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

FDA Updates Information for Blood Establishments Regarding the Novel Coronavirus Outbreak


AABB is developing additional resources for the COVID-19 Toolkit based updated information from FDA.
and a [Centers for Disease Control and Prevention report](https://www.cdc.gov) 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](https://www.aabb.org), 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](https://www.fda.gov) (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](https://www.fda.gov) 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](https://www.aabb.org).

**03/13/20 FDA Postpones April 2-3 BPAC Meeting**

**FDA Postpones April 2-3 BPAC Meeting**

FDA will [postpone](https://www.fda.gov) 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](https://www.fda.gov) to seven companies for selling fraudulent products intended to treat COVID-19. The agencies noted that the products (including teas, essential oils, tinctures and colloidal silver) are unapproved drugs that pose significant risks to patient health, violate federal law and “may cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm.” FDA and FTC requested responses from the companies within 48 hours describing specific steps they have taken to correct the violations outlined in the respective letters. Companies selling products that fraudulently claim to prevent, treat or cure COVID-
19 may be subject to legal action. The agencies reiterated that there are no vaccines or drugs approved to treat or prevent COVID-19 at this time.

**03/13/20 DOJ Cautions Business Community Against Violating Antitrust Laws Regarding Health Products**

**DOJ Cautions Business Community Against Violating Antitrust Laws Regarding Health Products**

The Department of Justice (DOJ) will hold accountable anyone who violates antitrust laws in connection with the manufacturing, distribution or sale of public health products, the agency announced Monday. The agency also warned that individuals or companies that fix prices or rig bids for health protection equipment could face criminal prosecution. The announcement is part of a broader administration effort to ensure that federal, state and local health authorities; the private health care sector; and the public at large are in the strongest position to respond to the ongoing COVID-19 outbreak. DOJ’s Procurement Collusion Strike Force will be on alert for collusive practices in the sale of such products.

**03/13/20 WHO Declares Coronavirus Outbreak a Pandemic, CDC Issues Global COVID-19 Outbreak Notice**

**WHO Declares Coronavirus Outbreak a Pandemic, CDC Issues Global COVID-19 Outbreak Notice**

The World Health Organization (WHO) now considers the outbreak of novel coronavirus disease 2019 (COVID-19) to be a pandemic, Director General Tedros Adhanom Ghebreyesus, PhD, MSc, said during a Wednesday news briefing in Geneva. “All countries can still change the course of this pandemic. If countries detect, test, treat, isolate, trace and mobilize their people in the response,” he said.

Following WHO’s announcement, CDC issued a [Global COVID-19 Outbreak Notice](#) that classified the current situation as sustained community-level transmission. The notice encouraged travelers to practice enhanced safety precautions.

**03/13/20 AABB, ABC, ARC Urge CDC to Assist in Blood Donor Recruitment Efforts**

**AABB, ABC, ARC Urge CDC to Assist in Blood Donor Recruitment Efforts**

AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) urged CDC officials to encourage healthy individuals to donate blood to help limit the negative impact that social distancing is having on blood donation.

In a March 12 [letter](#), the organizations stated that while social distancing intended to limit the spread of COVID-19 is a necessary and appropriate public health measure, it has resulted in many canceled blood drives. Efforts to reduce non-essential blood component use can reduce the strain on the blood
supply, the letter states, but the impact of these blood management strategies is not big enough to make up for the loss of donors.

AABB, ABC and ARC also stressed that blood drives are not “mass gatherings,” but rather they are controlled events conducted using appropriate infection control mechanisms intended to assure the safety of the products, donors and staff. They emphasized that the entire blood community is united and undertaking massive efforts to educate the public about the safety and necessity for blood donation, but noted that governmental support is required to encourage blood donation and limit the negative impact that social distancing has on blood donation efforts.

03/06/20 Trump Signs Emergency Coronavirus Funding Package

**Trump Signs Emergency Coronavirus Funding Package**

President Trump *signed* an $8.3 billion emergency aid package on Friday in response to the novel coronavirus. The bipartisan package, negotiated and *passed by Congress* this week, includes more than $3 billion for research and development of vaccines and other treatments. The bill also includes $2.2 billion in public health funding, including grants of $4 million or more to allow each state to prepare for and respond to the coronavirus; $836 million for the National Institutes of Health; and $1.25 billion for the Department of State and the United States Agency for International Development, including money for evacuations and humanitarian assistance. The bill authorizes $500 million for telemedicine, although Congress would need to pass legislation to specifically appropriate this funding.

03/06/20 Interorganizational Disaster Task Force Encourages Continued Blood Donation to Maintain Adequate Blood Supply

**Interorganizational Disaster Task Force Encourages Continued Blood Donation to Maintain Adequate Blood Supply**

The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism issued a *statement* on Tuesday urging healthy, eligible individuals to donate blood to help maintain an adequate blood supply for patients in need. In its statement, the Task Force reminded the public that individuals are not at risk of the novel coronavirus through the blood donation process or via a blood transfusion, since respiratory viruses are generally not known to be transmitted by donation or transfusion. The statement also emphasized that routine blood donor screening measures — which may include travel deferrals — are already in place to help prevent individuals with clinical respiratory infections from donating blood. The Task Force and the blood community will continue to work with FDA and CDC as the situation evolves to further protect the safety and maintain availability of the blood supply.

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.

03/06/20 REGULATORY UPDATE: AABB Launches New Web Page for COVID-19 Resources

REGULATORY UPDATE: AABB Launches New Web Page for COVID-19 Resources

AABB launched a Coronavirus Resources web page to serve as a comprehensive hub for the Association’s latest information and tools related to coronavirus disease (COVID-19). The new web page includes the following resources:

- AABB’s COVID-19 outbreak planning checklist.
- COVID-19 resource list: the most current information from the Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, the World Health Organization (WHO) and other public health authorities.
- A list of key messages, developed by the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, that health care professionals can use when discussing COVID-19 with blood donors, patients and members of the public.

Previously released information, such as the updates from the Transfusion Transmitted Diseases Committee and the optional resources toolkit for FDA’s communication to blood establishments.

02/28/20 REGULATORY UPDATE: COVID-19 and Blood Donation

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.

02/14/20 WHO Names 2019 Novel Coronavirus ‘Covid-19’

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.

02/07/20 FDA Shares Information for Blood Establishments on Novel Coronavirus Outbreak

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.
**01/31/20 REGULATORY UPDATE: AABB Issues Update on Novel Coronavirus Outbreak**

**REGULATORY UPDATE: AABB Issues Update on Novel Coronavirus Outbreak**

AABB is closely monitoring the outbreak of 2019-nCoV, including all communications from the Centers for Disease Control and Prevention, Food and Drug Administration and other public health authorities. AABB issued an update, "Impact of 2019 Novel Coronavirus and Blood Safety," to provide new information and insight into the current issues effecting blood safety.

At this time, AABB, CDC or FDA are not recommending interventions since there are neither data nor precedents suggesting risk for transfusion transmission of the 2019-nCoV. However, AABB recognizes that some blood collections establishments may elect to take action in advance of recommendations from FDA and CDC. This update includes important information on the range of options available.

The Transfusion Transmitted Diseases Committee (TTD) will continue to monitor the rapidly changing information for evidence suggesting risk for 2019-nCoV as a transfusion-transmitted infection (TTI). The TTD will advise the Donor History Task Force regarding TTI risk and deferral options as the Task Force prepares potential donor screening strategies in advance of such TTI risk. AABB will provide frequent communication. Members with questions may contact Regulatory Affairs at regulatory@aabb.org.

**01/22/20 AABB Newsflash, AABB Update on Novel Coronavirus Outbreak, Jan. 22**

**AABB Newsflash, AABB Update on Novel Coronavirus Outbreak, Jan. 22**

AABB’s Transfusion Transmitted Diseases (TTD) Committee is continuously monitoring developments for the novel coronavirus (called 2019-nCoV), which has recently been identified in Wuhan, Hubei Province, China. The TTD Committee’s summary of the expanding information describes the background and data available as of Jan 22. AABB advises readers to pay close attention to updates from the Centers for Disease Control and Prevention (CDC) and other public health resources because the increasing number of case counts and clinical and epidemiological information are extremely labile. Rapidly changing information is anticipated.

The 2019-nCoV infection is generally associated with unexplained pneumonia following an incubation period that appears to be in the range of 2 to 14 days, based on limited data. Given the potential similarities of this virus to Severe Acute Respiratory Syndrome (SARS) and the Mideast Respiratory Syndrome coronavirus (MERS-CoV), the TTD Committee has been in contact with both the Food and Drug Administration (FDA) and CDC to assess any need for interventions to ensure the safety of the blood supply.

A rapid risk assessment from the European Centers for Disease Control recommends a brief travel deferral for donors returning from Wuhan. The CDC confirmed the first U.S. case of 2019-nCoV on Tuesday; however, the CDC and FDA have not yet recommended a travel deferral.
AABB will continue to monitor the situation and issue updates as necessary, including new information from CDC and FDA as it becomes available. Individuals may contact AABB’s Regulatory Affairs staff with questions.

01/10/20 Chinese Officials, WHO Monitoring Pneumonia Cases Caused by New Coronavirus

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.