

Update: Impact of 2019 Novel Coronavirus and Blood Safety

(last updated February 25, 2020 by AABB's Transfusion Transmitted Diseases Committee)

Update on SARS-CoV-2 (COVID-19)

The following report was developed based on data available on February 25, 2020:

1. **Epidemiology:** Little has change regarding estimates of basic epi parameters during the last two weeks.
 - a. There are 80,350 cases and 2705 deaths listed on the [Johns Hopkins dashboard](#) at 1200 EST 25 Feb 2020.
 - b. These are the locations and case counts for those areas with CDC travel alerts. The alert level is in parentheses.
 - i. 77,660 in mainland China (3)
 - ii. 977 in South Korea (3)
 - iii. 288 in Italy (2)
 - iv. 170 in Japan (2)
 - v. 95 in Iran (2)
 - vi. 84 Hong Kong (1)
 - c. Based on these travel alerts, sustained person-to-person transmission appears to be confined to areas of Asia, Italy and Iran.
 - d. Estimates of the basic reproductive number continue to be in the 2-3 range. On the Diamond Princess, a captive population, the estimate is 2.28.
 - e. The case fatality rate continues to be estimated in the 2-3% range but is most probably biased high by a lack of diagnosis and reporting of mild cases. A [WHO Situation Report from Feb. 20](#), estimates the infection fatality rate, which will be more informative in the long run, at 0.94% (95% CI, 0.37-2.9%), but that too is likely biased by case recognition and reporting.
2. **Transfusion Transmission:** There continue to be no reports of TTI. The data on RNAemia is unchanged from prior communications. Approximately 15% of clinically ill patients in one study had RNA in plasma or serum, but the presence or absence of infectious virus has not been reported and there remains no precedent for the occurrence of transfusion-transmitted respiratory viruses.
3. **Transmission by Pre- or Asymptomatic Infection:** These are the donors that we would be concerned about, productively infected but well.
 - a. On the Diamond Princess, at the end of quarantine, the following totals were disseminated via the Japanese Ministry of Health. Follow up is not complete enough to judge the significance of this high rate of asymptomatic infection.

- | | |
|---|------|
| i. Total crews and passengers at risk | 3011 |
| ii. SARS-CoV-2 positive (PCR) | 621 |
| iii. Positive and asymptomatic as of 19 Feb | 322 |
- b. Discounting the original German report of transmission from an asymptomatic index because of controversy about the quality of the evidence, there are two credible family clusters from China that suggest that pre-symptomatic transmission occurs (Yu P *et al. JID.* 2020. Tong Z-D *et al. EID.* 2020).
 - c. Of 126 individuals arriving by air in Germany, 11 who were contacts of confirmed or suspected cases or who were symptomatic were all PCR negative. Of 115 asymptomatic individuals without contact, 114 that throat swabs were done, 112 were negative and 2 were positive (Hoehl S *et al. NEJM.* 2020).

4. Precautionary Measures

- a. A short survey of US blood collection facilities will be available at week's end regarding the implementation, if any, of precautionary measures to reduce the theoretical transfusion transmission of SARS-CoV-2.
- b. The decision to implement optional precautionary measures resides with each responsible blood collection facility. [FDA's communication](#) does not specify the [type of CDC Travel Notices](#) that would prompt an update for self-deferral for travel. 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.
- c. To establish a consistent approach and simplify operations, some centers have decided to implement travel deferral when CDC issues a Level 2 travel alert for a country. The level 2 alerts posted to date contain this language “[country] is experiencing *sustained community spread* of respiratory illness (COVID-19) caused by the novel coronavirus” (emphasis added). This practice allows time for implementation of the change before the urgency that follows a Level 3 warning. Other centers may elect to implement a change based on a Level 3 warning.
- d. An excellent [summary of considerations for blood operators](#) from the Asia Pacific Blood Network is available and attached to this summary.

Conclusion: At this time, additional interventions are not necessary based on TTI risk data, but continued vigilance is important.

Last Updated February 20, 2020

AABB continues to closely monitor the outbreak of respiratory illness caused by a novel (new) coronavirus first identified in Wuhan, Hubei Province, China (2019-nCoV). This update provides insight into the current issues impacting blood safety.

Key Points

- The 2019-nCoV epidemic continues, with the number of cases growing rapidly in China and additional cases being reported outside China
- No transmissions by blood or other substances of human origin have been documented or alleged for 2019-nCoV. This is true, as well, for the other two coronaviruses that have emerged over the past two decades (SARS, the Severe Acute Respiratory Syndrome Coronavirus and MERS-CoV, causing Mideast Respiratory Syndrome).
- AABB, FDA, and CDC are not recommending any action by blood collection establishments at this time because there are no data or precedent suggesting risk of transfusion transmission
- Voluntary implementation of donor deferral for travel to China may address public concerns about the safety of the blood supply
- A range of options are available to blood collection establishments considering implementation of voluntary measures [POSTED 02 20 2020: [AABB's Optional Resources for FDA's Communication to Blood Establishments Regarding the COVID-19 Outbreak, February 2020](#)]
- AABB will continue to closely monitor the outbreak and will provide frequent updates
outbreaks
02 19 2020: [CDC identifies new Level 1 outbreak in Hong Kong.](#)

Novel Coronavirus Background

As [described by CDC](#), coronaviruses are a large family of viruses that are common in many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS and SARS. When person-to-person spread has occurred with MERS and SARS, it is thought to have happened mainly via respiratory droplets produced when an infected person coughs or sneezes, similar to how influenza and other respiratory pathogens spread. During the past 20 years, SARS, MERS-CoV and the 2019-nCoV have emerged to cause human disease, including substantial morbidity and mortality.

The outbreak of 2019-nCoV in Wuhan, China was initially associated with a large seafood and animal market, suggesting animal-to-person spread. A growing number of patients have not had such exposure, indicating person-to-person spread is occurring. At this time, estimates suggest each infected person in China is infecting 2-3 additional people by respiratory droplet spread and direct contact with infected secretions.

The CDC's latest situation summary updates are available on the web page [2019 Novel Coronavirus, Wuhan, China](#). Preliminary data suggest this virus may have arisen as a bat CoV, as did SARS before it jumped to palm civets and then to humans. Early reports have identified 2019-nCoV RNA in the blood of 15% of patients studied in a small Chinese series. The authors of that paper were careful to emphasize that RNA is *not synonymous* with infectious virus, which indicates there is no clear evidence for blood-borne transmission.

Current Outbreak

In addition to the China outbreak, there are 21 [countries with confirmed 2019-nCoV cases](#), almost all acquired during travel to China. Secondary cases without a history of exposure in China are now being recognized, and the extent of that person-to-person transmission will have important implications both generally for control of the outbreak(s) and specifically for any blood safety responses implemented by AABB member blood collection establishments in various locations.

As of January 30th, the World Health Organization declared the outbreak of 2019-nCoV [a global health emergency](#) after slightly more than 8000 cases in China had been recognized, with 171 deaths. At that time, there were:

- 21 [countries outside of China](#) that have reported imported infections with 2019-nCoV, and
- autochthonous transmissions from China travelers to nontravelers (reported in Germany, Viet Nam, and the US)
- one hundred and sixty five reported [investigations in the US](#), with 5 confirmed infections, 68 in which infection was ruled out and 92 pending.

The outbreak is evolving quickly and more current information on the outbreak will be [available](#) from the CDC where case counts are being updated on Monday, Wednesday, and Friday.

Options for Blood Safety Interventions

As there are no data or precedent suggesting an impact on blood safety, CDC and FDA have not provided guidance or recommendations to blood establishments. AABB is also not recommending implementation of any measures at this point. However, blood collection establishments may choose voluntary interventions as a precaution, such as deferrals for travel to China. As such, AABB's Transfusion Transmitted Diseases (TTD) Committee has provided an assessment of the outbreak to help inform blood collection establishments that are contemplating voluntary interventions. TTD members expressed support for a range of approaches, recognizing that public perception may be an important consideration during this outbreak. In the absence of FDA recommendations, approaches include but are not limited to:

1) Voluntary Implementation of Travel deferrals

- Blood collection establishments can implement more restrictive donor eligibility and deferral policies based on local concerns, such as this outbreak.
- In the absence of sustained person-to-person transmission locally, some blood collection establishments are considering or have implemented a travel deferral. The mechanisms

for deferral include: 1) self-deferral based on donor education information provided by blood centers or 2) temporarily revising the flowchart for the travel capture question on the [donor history questionnaire](#) (DHQ) to identify individuals who have traveled to China in the past 28 days.

- A 28 day deferral covers twice the maximum incubation period of 2019-nCoV.
 - Data from a 2015-6 travel survey suggest this would impact approximately 1/500 US blood donors overall.
- A donor deferral strategy can be implemented using the current travel question in the [DHQ \(question 27\)](#) and adds a new path to defer prospective donors for 28 days after their exit from China. This approach has the advantage that additional countries can be added as needed. Alternatively, the question can be added to the end of the DHQ. As described in the [User Brochure for the DHQ](#), [flowcharts](#) may be revised to reflect local policy, and questions may be added to the DHQ *as long as deferrals are not made less strict than those required by AABB and FDA*. [Example flowcharts](#) are provided for this approach.

2) **Combination of deferrals related to illness and contact and enhanced education**

If an area experiences sustained local transmissions, blood collection establishments may consider a more aggressive set of interventions, similar to those used at the time of the SARS outbreak (i.e., a combination of donor education, travel deferrals, deferrals for contact with SARS and for a diagnosis of SARS.) AABB is actively working with the Donor History Task Force to prepare documents and resources to support the adoption of these measures if needed.

If FDA and CDC determine there is evidence indicating risk for transfusion transmission of 2019-nCoV, FDA may issue recommendations. If this occurs, blood collection establishments should implement the new recommendations that are deemed necessary to protect blood safety. Until such time, a decision to implement additional interventions resides at the local level.

Additional Considerations:

Blood collection establishments in Canada, Australia and the European Union have implemented travel deferrals of 21-28 days. Canada routinely defers donors for 21 days following international travel which addresses potential risks posed by emerging infectious disease agents, such as 2019-nCoV. As noted, the deferral period of 28 days represents twice the maximum reported incubation period (14 days) from exposure to onset of symptoms and is the surveillance interval being used in public health reporting by CDC.

If the evidence indicates risk for transfusion transmission of 2019-nCoV, pathogen reduction may be another option available. The TTD Committee is reviewing data on available pathogen reduction measures for labile components and recognized that methods with valid data demonstrating coronavirus inactivation would be acceptable safety approaches for 2019-nCoV.

The multiple pathogen removal and inactivation steps involved in plasma fractionation were considered adequate to maintain their safety, and the committee understood that the Plasma Protein Therapeutics Association would be considering that evidence in the coming days.

Conclusion

The ultimate course of the epidemic is not known. AABB is working closely with FDA and CDC and will continue to monitor the situation and will expedite the development of tools and other informational resources as needed. Accordingly, the TTD committee endorsed the development by staff and committee members of a Coronavirus Tool Kit [POSTED 02 20 2020: [AABB's Optional Resources for FDA's Communication to Blood Establishments Regarding the COVID-19 Outbreak, February 2020](#)] based on the approaches used during the SARS epidemic that could be adopted as needed in the future. The AABB is taking additional measures to provide rapid staging of additional interventions for the protection of blood safety and the safety of staff in blood collection establishments should they be needed.