



Advancing Transfusion and
Cellular Therapies Worldwide

AABB's Resources for: FDA's Updated Information for Blood Establishments Regarding the Novel Coronavirus (COVID-19) Outbreak March 2020

This toolkit (posted 03 18 2020) was updated to align with FDA's March 11th [Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#).

The 2019 novel coronavirus has been named "SARS-CoV-2" and the disease it causes has been named coronavirus disease 2019 (abbreviated COVID-19). The situation is changing rapidly as the outbreak spreads to the US. The toolkit provides considerations as blood establishments revise policy to address the evolving outbreak.

FDA has issued these optional precautionary measures for COVID-19 but continues to state:

"Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation ([21 CFR 630.10](#))."

This toolkit continues to provide information on the optional precautionary measures which are not regulatory requirements.

*FDA has removed any mention of self-deferral for travel.
Evolving options may be considered.*

AABB's Resources Supporting: FDA's Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

AABB's Regulatory Affairs is issuing this updated toolkit in response to FDA's [March 11th communication](#):

- To assist blood establishments by highlighting **new information** and changes;
- To offer "Notes to consider" as you evaluate the considerations, address concerns with community spread of the virus and its impact on blood availability;
- To assist you with the evolving options based on FDA's removal of self-deferral for travel;
- To identify CDC's resources, including the [sustained/on-going transmission in the US](#); and
- To provide example documents to consider when updating policy.

FDA continues to report:

- ✓ "The potential for transfusion transmission of SARS-CoV-2 is unknown at this time."
- ✓ Respiratory viruses, in general, are "not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus."
- ✓ "Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10)."

[NOTE to consider:

- *The FDA does not consider COVID-19 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 in [630.10](#).*
- *Therefore, the agency has issued considerations, but **not recommendations**, to be implemented at the discretion of the Medical Director. FDA has no expectations for compliance with the March 11th communication.]*

FDA provided the following new information:

- 1- "FDA recognizes that deferral solely for travel to areas with cases of COVID-19 may not be feasible."

[NOTE to consider:

- *FDA no longer references the optional use of "donor educational materials to instruct individuals to self-defer" for travel to "areas with COVID-19 outbreaks" which was included in the [February 4th communication](#). (Refer to pages 3 and 4)*
- *With [sustained/on-going transmission in the US](#), FDA has made clear that the optional deferral for travel may be discontinued. (Refer to page 9)]*

- 2- "Laboratory testing to screen asymptomatic blood donors is not recommended by FDA at this time because detection of SARS-CoV-2 is only seen in severely ill patients, not in asymptomatic individuals."
- 3- "Blood centers should prepare and evaluate their emergency plans to address possible challenges, such as effects on the availability of blood donors and staff."
 - **[NOTE to consider:** *This is required of all AABB Accredited facilities in accordance with AABB Standards for Blood Banks and Transfusion Services. Refer to the [AABB's COVID-19 Planning Checklist on the Coronavirus Resources webpage](#).]*
- 4- FDA "supports the recommendations of [AABB's Interorganizational Task Force on Domestic Disasters and Acts of Terrorism](#), encouraging healthy individuals to make plans to donate blood to maintain the adequacy of the nation's blood supply."
 - The agency also provided contact information, "encouraging healthy individuals to make plans to

donate blood to maintain the adequacy of the nation's blood supply.”

FDA has made the following changes in the March 11th updated considerations:

- 1- “Blood establishments may wish to consider donor educational materials to instruct individuals to self-defer and refrain from blood donation if they have:
 - **cared for, lived with, or otherwise had close contact** with individuals diagnosed with or suspected of having COVID-19...” OR
 - “been diagnosed with or suspected of having COVID-19.”

[NOTE to consider:

 - *FDA removed the reference to travel that was in the February 4th communication, leaving these two considerations for self-deferral. (Refer to page 4, and the Travel Flowchart, page 9, Evolving Options)]*
- 2- **NO CHANGE HERE:** “Based on limited information available, FDA suggests individuals refrain from donating blood for at least 28 days after resolution of symptoms after a diagnosis of COVID-19 or 28 days after the last possible close contact exposure to a person with COVID-19.” The blood establishment’s responsible physician must evaluate the prospective donor and determine eligibility [[21 CFR 630.5](#)].
- 3- **NO CHANGE HERE:** “Updating post-donation instructions provided to all donors of blood and blood components to ask donors to report a subsequent diagnosis of COVID-19 as soon as possible to the blood establishment.”

[NOTE to consider:

 - *FDA only refers to PDI for a “subsequent diagnosis” and does not refer to PDI for close contact/lived with a person diagnosed with COVID-19, nor PDI for travel.]*
- 4- “Consider retrieval and quarantine of blood and blood components collected in the 28 days prior to or after COVID-19 **symptom** onset or collected in the 28 days prior to or after possible exposure to patients with COVID-19. FDA remove the word “infection”

[NOTE to consider:

 - *Each establishment may consider precautionary measures for retrieval and quarantine of collections from individuals (1) with a subsequent diagnosis of COVID-19 and (2) who have had close contact/lived with a person diagnosed with COVID-19 (which is not a listed as a PDI consideration in item 3 above).]*

SUPPORTING DOCUMENTS

- _____ **FDA Communications** on March 11th and February 4th, **with changes highlighted** (pages 3-4)
- _____ **Poster/Website Messaging and COVID-19 Handout** (examples 1 and 2 on pages 5-6)
- _____ **Flowcharts for Diagnosis, Close Contact and Travel**, (examples 3-5 on pages 7-9)
 - The flowcharts provide assistance with follow up questions on COVID-19 risk if needed for self-deferral AND/OR information elicited by the following questions on the [v2.0 DHQ](#):
 - Q1: Are you feeling healthy and well today?
 - Q2: Are you currently taking an antibiotic?
 - Q3: Are you currently taking any other medication for an infection?
 - Q5: Have you read the educational materials today?
 - Q27: In the past three years, have you been outside the United States or Canada?
 - IF performing donor screening for COVID-19 – the flowcharts can be revised for use with questions [added to the area designated](#) for additional questions at the end of the [v2.0 DHQ](#).

Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

March 11, 2020 **Yellow = NEW Information**

FDA is working closely with CDC and other federal and international agencies to monitor the evolving outbreak of the 2019 novel coronavirus that was first identified in Wuhan, Hubei Province, China. The virus has been named “SARS-CoV-2” and the disease it causes has been named coronavirus disease 2019 (abbreviated COVID-19). The potential for transmission of SARS-CoV-2 by blood and blood components is unknown at this time. However, respiratory viruses, in general, are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus.

Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10).

As communities are affected, it is imperative that healthy individuals continue to donate blood.

Considerations

FDA supports the recommendations of AABB’s Interorganizational Task Force [External Link Disclaimer](#), encouraging healthy individuals to make plans to donate blood to maintain the adequacy of the nation’s blood supply.

- Those interested in donating blood may contact the following organizations to find a local blood collection site and to schedule an appointment:
 - AABB: www.aabb.org [External Link Disclaimer](#); +1.301.907.6977
 - America’s Blood Centers: www.americasblood.org [External Link Disclaimer](#)
 - American Red Cross: www.redcrossblood.org [External Link Disclaimer](#); +1.800.RED CROSS (+1.800.733.2767)
 - Armed Services Blood Program: www.militaryblood.dod.mil [External Link Disclaimer](#); +1.703.681.8024
- Blood centers should prepare and evaluate their emergency plans to address possible challenges, such as effects on the availability of blood donors and staff.
- At this time, FDA does not recommend using laboratory tests to screen asymptomatic blood donors. Based on available information, detection of SARS-CoV-2 in blood samples has only been seen in severely ill patients, not in asymptomatic individuals.
- FDA is aware that some blood establishments are considering donor education and/or donor deferral measures in response to COVID-19. FDA recognizes that deferral solely for travel to areas with cases of COVID-19 may not be feasible.
- Blood establishments may wish to consider donor educational materials to instruct individuals to self-defer and refrain from blood donation if they have:
 - cared for, lived with, or otherwise had close contact with individuals diagnosed with or suspected of having COVID-19;
 - been diagnosed with or suspected of having COVID-19.
- The blood establishment’s responsible physician must evaluate the prospective donor and determine eligibility (21 CFR 630.5). Based on the limited information available at this time, we suggest individuals refrain from donating blood at least 28 days after resolution of symptoms after a diagnosis of COVID-19 or 28 days after the last possible close contact exposure to a person with COVID-19.
- Blood establishments may wish to consider updating post-donation instructions provided to all donors of blood and blood components to ask donors to report a subsequent diagnosis of COVID-19 as soon as possible to the blood establishment. Blood establishments may wish to consider retrieval and quarantine of blood and blood components collected in the 28 days prior to or after COVID-19 symptom onset; or collected in the 28 days prior to or after possible exposure to patients with COVID-19.
- FDA will continue to monitor the situation and issue updated information as it becomes available.

Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

February 4, 2020 **Red** = Information that FDA DID NOT include in the March 11 document

FDA is working closely with CDC and other federal and international agencies to monitor the evolving outbreak of the 2019 novel coronavirus (COVID-19) that was first identified in Wuhan, Hubei Province, China. The potential for transmission of COVID-19 by blood and blood components is unknown at this time. However, respiratory viruses, in general, are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus.

Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10).

Considerations

FDA is aware that some blood establishments are considering donor education and/or donor deferral measures in response to COVID-19. As a precaution, blood establishments may wish to consider whether to provide donor education, encourage self-deferral, and manage post-donation information about COVID-19.

- Blood establishments may wish to consider updating donor educational materials to instruct individuals to self-defer and refrain from blood donation if they have:
 - ✓ traveled to areas with COVID-19 outbreaks, as defined by CDC;
 - ✓ lived with individuals diagnosed with or suspected of having COVID-19 infection;
 - ✓ been diagnosed with or suspected of having COVID-19 infection.

The blood establishment's responsible physician must evaluate the prospective donor and determine eligibility (21 CFR 630.5). Based on the limited information available at this time, we suggest individuals refrain from donating blood at least 28 days after resolution of symptoms after a diagnosis of COVID-19 infection or 28 days after the date of departure from an outbreak area or the last possible close contact exposure to a person with COVID-19 infection.

- Blood establishments may wish to consider updating post-donation instructions provided to all donors of blood and blood components to ask donors to report a subsequent diagnosis of COVID-19 infection as soon as possible to the blood establishment. Blood establishments may wish to consider retrieval and quarantine of blood and blood components collected in the 28 days prior to or after COVID-19 disease onset; or collected in the 28 days prior to or after possible exposure to patients with COVID-19 infection.

FDA will continue to monitor the situation and issue updated information as it becomes available.

Example 1- OPTIONAL POSTER

Per your policy, you:

- May use this poster to encourage donors to self-defer.
- Should revise the poster to reflect your current policy.
- Will determine when and where to use this poster based on your policy.

COVID-19

Do Not Donate Blood Today IF IN THE PAST 28 DAYS:

- You have **cared for**, lived with, **or otherwise had close contact with** an individual(s) diagnosed with or suspected of having COVID-19.
- You have been diagnosed with or suspected of having COVID-19.
 - Use this bullet if you continue to defer for travel after the FDA's [March 11th communication](#) and CDC's reports of [sustained community spread](#):
- You have traveled to an area impacted by an outbreak of COVID-19:
 - Add countries here, per your policy – refer to the [CDC's website](#) and the travel flowchart, page 9.

If you think you should not donate based on this information, you may leave at this time.

For more information on Coronavirus and Blood Donation visit FDA's webpage:

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/updated-information-blood-establishments-regarding-novel-coronavirus-outbreak?utm_campaign=What%27sNew2020-03-11&utm_medium=email&utm_source=Eloqua

For more information on Coronavirus and travel visit CDC's

- Travel Health Notices webpage: <https://wwwnc.cdc.gov/travel/notices>
- Coronavirus webpages: https://www.cdc.gov/coronavirus/2019-ncov/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2Fnovel-coronavirus-2019.html

Example 2 - OPTIONAL HANDOUT

Per your policy, you:

- May use this handout to encourage donors to self-defer.
- Should revise the handout to reflect your current policy.
- Will determine when and where to use this handout based on your policy.

COVID-19

Do Not Donate Blood Today IF IN THE PAST 28 DAYS:

- You have **cared for**, lived with, **or otherwise had close contact with** an individual(s) diagnosed with or suspected of having COVID-19.
- You have been diagnosed with or suspected of having COVID-19.
 - Use this bullet if you continue to defer for travel after the FDA's [March 11th communication](#) and CDC's reports of [sustained community spread](#):
- You have traveled to an area impacted by an outbreak of COVID-19:
 - Add countries here, per your policy – refer to the [CDC's website](#) and the [travel flowchart](#), page 9.

If you think you should not donate based on this information, you may leave at this time.

For more information on Coronavirus and Blood Donation visit FDA's webpage:
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/updated-information-blood-establishments-regarding-novel-coronavirus-outbreak?utm_campaign=What%27sNew2020-03-11&utm_medium=email&utm_source=Eloqua

For more information on Coronavirus and travel visit CDC's

- Travel Health Notices webpage: <https://wwwnc.cdc.gov/travel/notices>
- Coronavirus webpages: https://www.cdc.gov/coronavirus/2019-ncov/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2Fnovel-coronavirus-2019.html

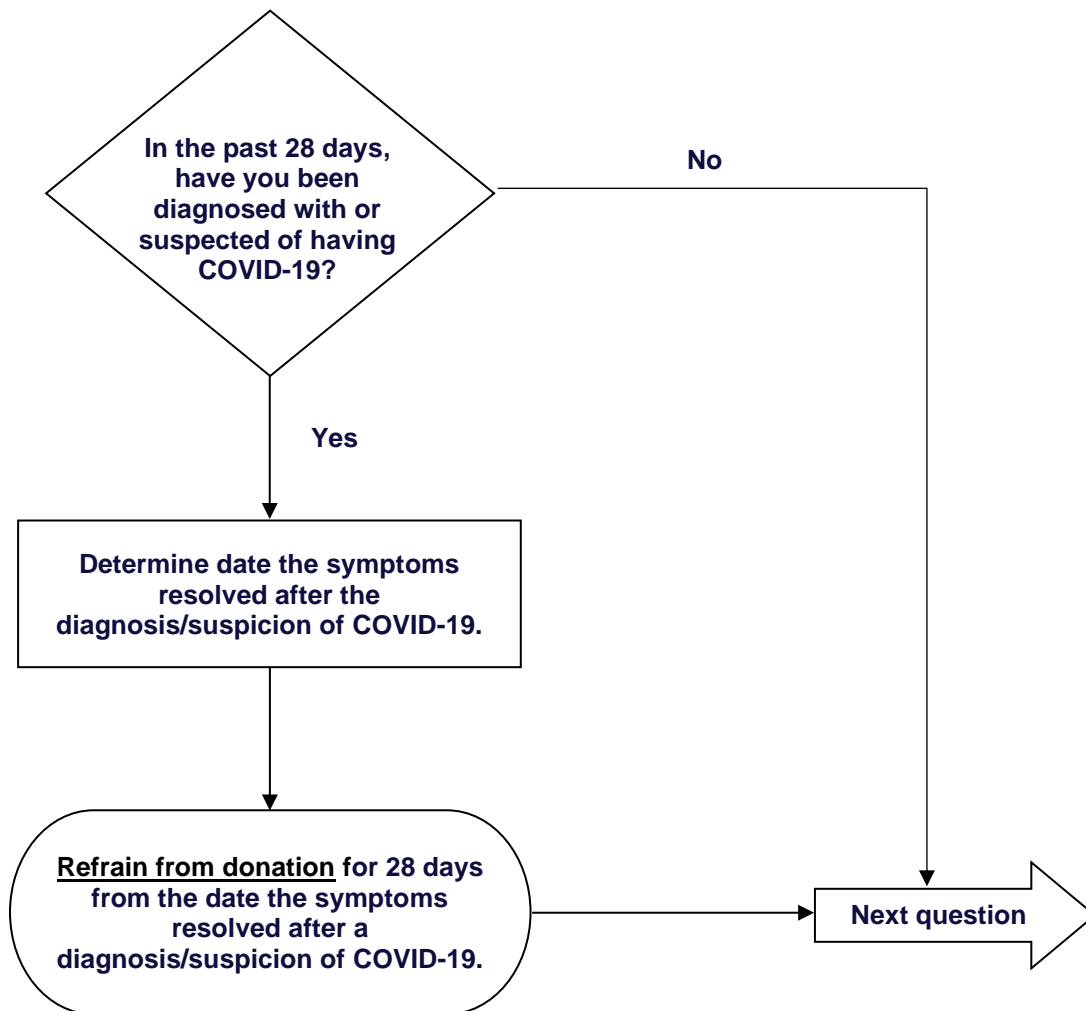
Example 3 – FLOWCHART – SELF DEFERRAL FOR DIAGNOSIS/SUSPECTED INFECTION

There are no changes to this flowchart as a result of the [New information from FDA](#)

Follow Up Question: In the past **28 days**, have you been diagnosed with or suspected of having COVID-19?

Donor Eligibility: A person who has been diagnosed with or suspected of having COVID-19 should self-defer or refrain from donation for 28 days after resolution of symptoms.

This flowchart may be modified if implementing donor screening with the v2.0 DHQ.



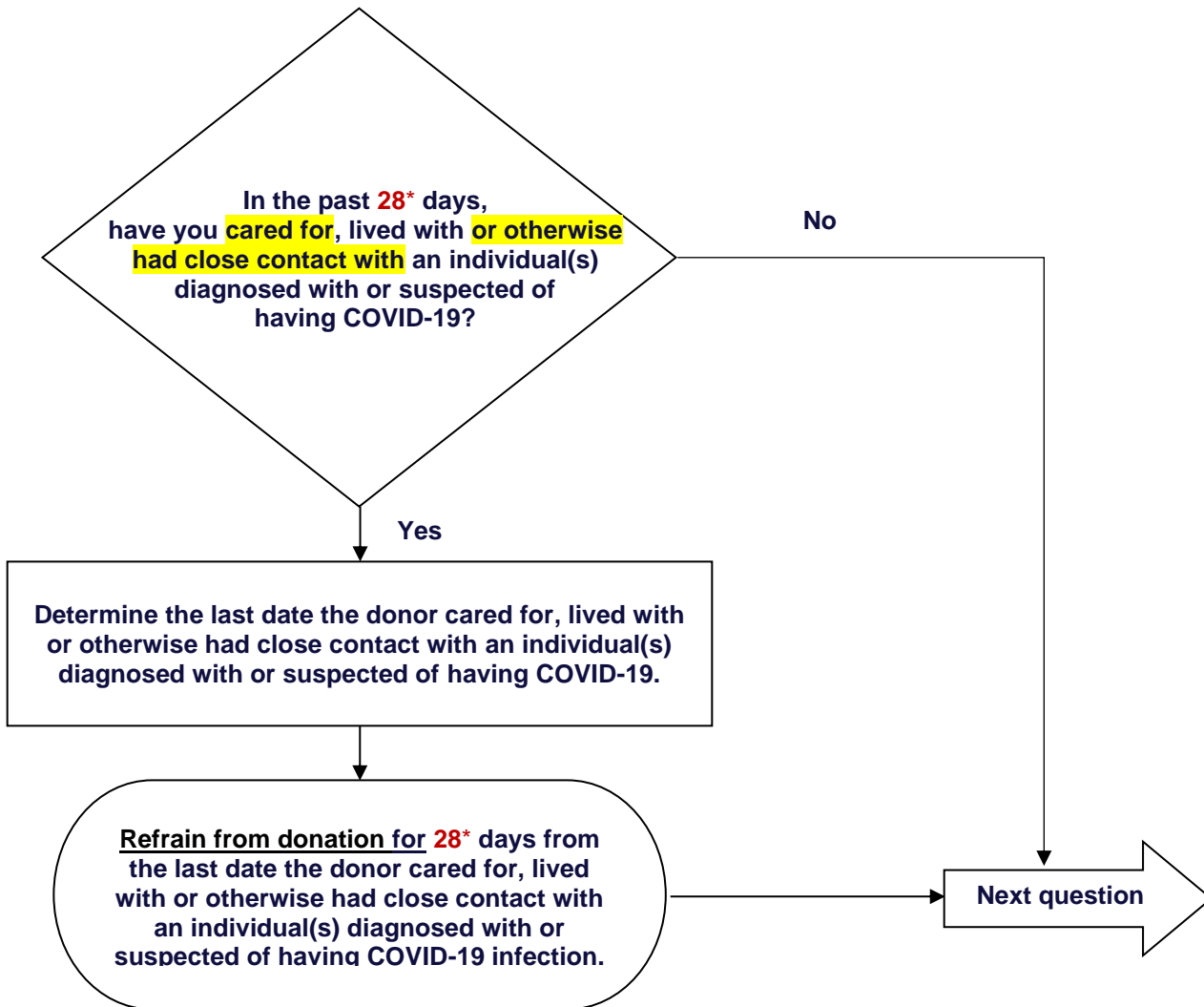
Example 4 – OPTIONAL FLOWCHART SELF DEFERRAL FOR “CLOSE CONTACT”
New information from FDA is highlighted

Follow Up Question: In the past 28* days, have you **cared for**, lived with **or otherwise had close contact with** an individual(s) diagnosed with or suspected of having COVID-19?

Donor Eligibility: A person who has lived with an individual(s) diagnosed with or suspected of having COVID-19 should refrain from donation for 28* days from the last date of exposure from living with a person with COVID-19.

* FDA has issued these optional precautionary measures for COVID-19, which has not been named a transfusion transmitted infection (TTI). As such, each establishment may determine if the [14-day quarantine model for returning travelers](#) used by federal authorities to protect the public health can also be applied to this “close contact” risk. This decision could minimize the impact of unnecessary deferrals. **REFER to Flowchart 5 on travel for more on these evolving options.**

This flowchart may be modified if implementing donor screening with the v2.0 DHQ.



Example 5 – TRAVEL FLOWCHART

Follow Up Question: In the past 28* days, have you traveled to areas impacted by COVID-19 outbreaks as listed below?

***EVOLVING OPTIONS** – FDA no longer lists self-deferral for travel based on the growing risk for local transmission in the US.

Establishments may wish to discontinue this deferral when the risk is no longer solely related to travel outside the US and Canada but also includes [sustained community spread in the US](#).

➤ **IF you continue the travel deferral, you may wish to consider** that virus is not known to be a TTI, and

- *Implement a shorter deferral period based on the [14-day quarantine model for returning travelers](#) used by federal authorities to protect the public health, and
- Avoid unnecessary deferral.

This flowchart may be modified if implementing donor screening with the v2.0 DHQ.

