



# Coronavirus Disease 2019 (COVID-19) Poses Challenges for the U.S. Blood Supply

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The current Coronavirus Disease 2019 (COVID-19) outbreak may pose significant challenges for the United States' blood supply. Mitigation strategies to prevent the spread of COVID-19, such as closures of schools and workplaces, have led to blood drive cancellations, resulting in a critical blood supply shortage in the Pacific Northwest (specifically, western Washington and Oregon). School closures, event cancellations, and other mitigation strategies in other areas of the country may provide challenges for maintaining a sufficient blood supply. The management and distribution of the U.S. blood supply is largely coordinated by private organizations, with some oversight by the Department of Health and Human Services (HHS). Congress may consider how best to address critical storages, such as through HHS or the U.S. Food and Drug Administration's (FDA) authority over blood safety and donation guidance.

# **Industry and Blood Center Response**

The nation's blood supply is managed by a network of independent blood centers and the American Red Cross. On March 9, 2020, one blood center, Bloodworks Northwest, headquartered in Seattle, Washington, issued a press release warning that the Pacific Northwest blood supply is at the risk of collapse in coming days due to COVID-19 concerns. The release notes that the closure of schools, businesses, and events has led to the cancellation of blood drives in the area.

Immediate risk of blood supply collapse due to the COVID-19 outbreak is currently limited to the Pacific Northwest. However, blood drives may potentially be cancelled in other areas of the country as containment and mitigation strategies increase, which may lead to blood supply shortages in additional areas. Blood centers are also concerned that potential donors may choose not to donate over fears of contracting COVID-19 while at the blood center. Blood centers throughout the country and organizations representing the industry are urging individuals to donate blood to mitigate potential shortages. (For examples, see Kentucky Blood Center, New York Blood Center, and LifeServe Blood Center.)

Blood products have a limited shelf-life, and therefore ongoing donations are necessary. Blood can be mobilized and distributed regionally by blood center networks when a shortage exists at a blood center,

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but only to a certain extent given the limited shelf-life. HHS supports blood availability preparedness and response coordination through a number of roles and responsibilities.

## **Blood Donation and Transfusion Safety**

The industry is reinforcing the notion that blood donation is a safe activity. Bloodworks Northwest, for instance, relayed in its press release on the outbreak that it routinely sanitizes its facilities and equipment, and staff regularly implement infection control precautions. Furthermore, staff, donors, and volunteers are encouraged to stay home if they feel unwell. Other blood centers are including similar reassurances in their calls to donate.

On the day of donation, donors must have a normal temperature and present other signs of good health (21 C.F.R. § 630.10(f)). Blood centers are asking donors to follow-up after donating if diagnosed with COVID-19, as recommended by FDA.

FDA reports that there are no known cases of respiratory virus transmission by blood transfusion and there have been no reported cases of transfusion-transmitted COVID-19, but has issued recommendations to guide the blood donation activities of persons who may have been exposed.

## FDA Recommendations on Blood Donation

On March 11, 2020, FDA published updated information for blood establishments regarding donation during the outbreak. The March 11 information suggests that some blood establishments may want to consider donor education, encourage self-deferral, and manage post-donation information about COVID-19. The March 11 information recommends that individuals self-defer from donating blood for 28 days after either (1) resolution of symptoms after a diagnosis of COVID-19 or (2) the last possible contact exposure to a person with a COVID-19 infection. Donors are also directed to report a subsequent diagnosis after donation.

Previous, now-outdated FDA information published on February 4, 2020, also recommended that individuals self-defer from donating blood for 28 days following travel to a location with a COVID-19 outbreak. However, some blood centers are still instructing potential donors to self-defer from donating if they recently traveled to areas with COVID-19 cases (for examples, see LifeServe Blood Center and Bloodworks Northwest). If these instructions remain in effect, they could potentially limit supply in areas that have the most critical need as many potential donors may meet the self-deferral criteria.

The March 11 information also recommends that blood centers "prepare and evaluate emergency plans to address challenges, such as effects on the availability of blood donors and staff." FDA did not provide any specific guidance for the preparation of emergency plans for blood centers.

## **Implications for Congress**

Congress may direct FDA to issue more specific information to help blood centers educate potential donors as the outbreak evolves, to prevent travel deferrals, and to guide the development of emergency plans. Congress may also direct HHS to ensure that measures are in place to mobilize and distribute blood to blood centers, as needed. In addition, individual members of Congress may wish to communicate the safety of blood donation to constituents and to encourage donations at the local level.

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