



**America's Blood Centers
Comments for the Blood Product Advisory Committee
Meeting Date: November 4, 2021**

Thank you for the opportunity to provide an update on the status of independent blood centers for the November 4, 2021 meeting of the Blood Product Advisory Committee (BPAC).

The ongoing work of America's Blood Centers member centers during the COVID-19 pandemic is reflective of the blood community's commitment to meet any challenge, and we have faced many during the last 18 months.

Severe, Sustained Blood Shortage

Today, we are facing a severe, sustained blood shortage. The emergence of the Delta variant has once again disrupted our traditional methods for collecting blood in our communities, at schools and at businesses. Increases in trauma cases, gunshot wounds, and cardiac events (stemming from deferred care) are just a few examples of what is driving an increased utilization of blood components, and straining the fragile national blood inventory. The Interorganizational Disaster Task Force has reported the blood inventory at a status of "red" (less than 1 day's supply of blood) each week consecutively since September 15, 2021.

At the start of the pandemic, ABC submitted options to the FDA for extending the blood supply - recommendations with the highest potential for increasing supply and the lowest risk to donors and patients. We very much appreciate the actions taken by FDA to finalize the vCJD guidance, and implement the following three temporary guidances (April 2020) that made a significant impact on the ability of centers to provide blood products to hospitals in support of patient care, while experiencing significant challenges in collections:

- Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency
- Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria

Our member centers have been very responsive and agile during the course of the pandemic. The operational changes necessary to implement these three guidances, while swiftly applied, involved substantial changes to SOP and blood establishment computer systems. Additionally, donors have shown appreciation for the revised qualifications, and many units were saved with the allowance for release of blood components that would previously have required discard regardless of whether safety of the donor or patient was unaffected.

Making Temporary Blood Guidances Permanent

We continue to urge transitioning all three guidances to a permanent status (beyond the expiration of the public health emergency). We strongly encourage FDA to ensure the timing avoids any "gap" as it would place an undue burden on centers, if they were required to revert back to previous pre-

pandemic requirements then reimplement. In addition to the above, we urge the FDA to consider protocols for implementing additional temporary measures to augment the blood supply during a disaster. Options would include:

- Lower donor hemoglobin requirements
- Shortened inter-donation interval for whole blood and double red cell collections
- Allowing therapeutic donors with secondary polycythemia due to benign conditions to be collected and not labeled with the disease condition
- Waiving the Medical Director examination blood pressure requirements of 21 CFR 630.10(f)(2)
- Temporarily raising the total annual platelet donations for platelet donors
- Temporarily raising the rolling RBC/plasma annual limits for platelet donors
- Temporarily allowing interstate shipment of platelets without licensure
- Allowing the labeling of platelets with $< 3.0 \times 10^{11}$ yield with standard label

These measures would have the highest potential for increasing supply with the lowest risk to donors and patients. Having guidance in advance to be triggered during a disaster will allow blood centers to have the operational changes (such as creating the necessary SOPs) ready to be implemented during a disaster. While we appreciate the temporary guidances to extend the supply during the pandemic, the substantial operational changes were time challenging and had centers known what changes would occur during a disaster, it would improve efficiency and ensure a safe and adequate blood supply remains available.

COVID-19 Convalescent Plasma

In April 2020, the Biomedical Advanced Research and Development Authority (BARDA) established a contract with ABC for the coordination of convalescent plasma collection and distribution. Nearly all U.S. independent blood collectors participated, allowing for necessary standardization and equity across the industry.

Convalescent plasma (CP) is an established therapeutic that has been utilized in previous novel diseases including past coronaviruses such as SARS and MERS. The experience of these previous coronaviruses should be added to the lessons learned during COVID-19 to establish protocols that can be easily adapted to a future pandemic. Such protocols can significantly expedite the implementation of CCP and reduce confusion associated with evolving FDA recommendations (e.g. the switch to high titer units, restrictions on vaccinated donors, etc.) for the collection and use of the therapeutic.

We recommend that protocols or generic licensing for convalescent plasma be developed now, for the next novel disease, to incorporate the following factors:

- Prioritization of early development of titer testing from multiple manufacturers
- Early establishment of consistent guidelines for donor qualifications
- Physician and hospital education programs and clear guidelines for clinical use
- Research designs that will provide data as quickly as possible while still allowing for compassionate use
- Labeling requirements including ISBT component codes

Conclusion

Thank you again for this opportunity to share America's Blood Centers experiences and the role of independent blood centers during the COVID-19 pandemic. We look forward to continuing the work of evaluating lessons learned and finding solutions for the critical work we do.