

# **STATEMENT OF LEO DEBANDI**

## **VICE CHAIR**

### **AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism**

### **HHS Advisory Committee on Blood and Tissue Safety and Availability**

**AUGUST 18, 2021**

My name is Leo Debandi, and I am responsible for analytics, production and inventory planning at the American Red Cross. Additionally, I am the vice chair of the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism (Task Force). I am pleased to provide this statement to the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) in my capacity as the vice chair of the Task Force.

Last year, Brian Gannon, chief executive officer of Gulf Coast Regional Blood Center and the chair of the Task Force shared with the Advisory Committee background about the Task Force as well as strengths and challenges that the Task Force experienced during the COVID-19 pandemic. On behalf of the Task Force, Brian offered recommendations to improve our preparedness and care for patients. Today, I will provide the Committee with supplemental information about the Task Force, describe the data that currently informs the Task Force's activities, and highlight challenges with the data as well as opportunities for improvement.

#### **BACKGROUND**

I have been active with the Task Force since it was established in the aftermath of the 9/11 attacks. Immediately after 9/11, the nation experienced an unprecedented surge of blood donations, which stressed the blood collections system, led to a national blood surplus, and resulted in significant wastage. The Task Force was established to coordinate the blood system by helping to ensure that blood collection efforts resulting from disasters are managed properly and delivering clear and consistent messages to the public regarding the status of America's blood supply.

The Task Force is composed of representatives from U.S. blood services, associations and commercial entities, as well as liaisons from governmental agencies. The members of the Task Force work together to prepare for disasters by ensuring that safe and adequate blood product inventories are always in place. In addition, the Task Force operates as a mechanism to assess the need for collections or transportation of blood should a disaster occur.

AABB serves at the designated coordinating entity for the Task Force. Members of the Task Force's Critical Events Assessment Group (CEAG) include America's Blood Centers, the American Red Cross, and Blood Centers of America as well as liaisons from the Armed Services Blood Program and the U.S. Department of Health and Human Services/Office of the Assistant Secretary for Health (OASH). Additional members of the Task Force include the American Hospital Association, the College of American Pathologists, AdvaMed, the National Marrow Donor Program and the Plasma Protein Therapeutics Association as well as liaisons from the Centers for Disease Control and Prevention and the Food and Drug Administration.

In the event of an emergency, AABB immediately convenes a meeting of a subgroup of the Task Force, including the CEAG, FDA and CDC. Local blood centers are responsible for ascertaining medical blood needs based on estimates using pre-determined formulas, assessing available local supply, and communicating that information to the Task Force through a reporting organization.

Additionally, a blood collector experiencing a disaster or emergency may submit a request for assistance to the Task Force. The blood collector may note that an event has impacted collections or distributions, indicate that it is not able to meet hospitals' demands, or share that it is unable to meet patients' needs. By the time a request is elevated to the Task Force, individual members of the Task Force have already started working together to try and identify the requested product but have not been successful. The Task Force evaluates each request and works to meet the specific needs.

The subgroup of the Task Force determines the strategy and coordination efforts, including: (1) constructing a message to blood community and donors; (2) coordinating a broad public message in conjunction with HHS; (3) transporting and coordinating needed blood to the affected area; and (4) determining next steps until event has been resolved. They communicate their findings to the other members of the Task Force and help advance the identified activities.

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## **CURRENT DATA USED BY THE TASK FORCE**

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While the current data provides a benchmark for the Task Force's work to prepare for and respond to disasters and emergencies, it is limited. Before I address challenges with the data, it is important to recognize that many blood centers and hospitals consider their blood inventories to be proprietary and confidential.

There are three organizations that submit data on blood inventories that is used by the Task Force, including the American Red Cross, Blood Centers of America, and America's Blood Centers. The blood inventory reports are often manual and are not uniform across the industry, with differences in some of the formulas used to assess the number of days' supply on hand. For instance, while most blood centers report inventory levels based on distribution, some reports are based on projected collections. As another example, while most blood centers report inventory daily, on any

given day, there may be centers that do not submit a daily report. America's Blood Centers, the American Red Cross, and Blood Centers of America are currently working with AABB to improve the quality and consistency of the blood supply data, but we anticipate that some amount of center-to-center variation may continue.

There are several other limitations with the data used by the Task Force. The national estimate of blood does not allow for visibility into regional blood availability. Also, the data only accounts for red blood cells and does not capture platelet availability. However, during disasters, platelet availability becomes challenging because of the short shelf life of the product.

The Task Force does not receive data on blood collected by hospital-based blood collection establishments; most hospital-based collectors are not licensed by FDA since they generally limit their distributions to their own institutions. Therefore, these hospital-based collectors would not be able to ship their blood inventory across state lines in response to a disaster or emergency.

In addition to the current limitations of the data received from blood collectors, the Task Force does not have access to data that reflects hospitals' inventories, which is significant because hospitals hold most of the nation's blood. The inventories held by hospitals are important for disaster planning and response because the blood immediately available for responding to disasters is the blood already on hospitals' shelves. While blood centers do not often have real time visibility into hospitals' inventories, the Task Force relies on blood centers for that assessment. Therefore, while the Task Force makes assessments based on macro-trends derived from the available information, the current data limits the ability of the Task Force to precisely assess the status of the blood supply in real time at national or regional levels.

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## **OPPORTUNITIES FOR IMPROVEMENT**

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The Task Force supports the ACBTSA's efforts related to exploring solutions that improve the data infrastructure related to the blood supply. When Brian presented to the Advisory Committee last year, he noted that the most significant challenge the Task Force faced while responding to the COVID-19 pandemic was the absence of accurate, comprehensive, and timely data on the blood supply. He recommended that HHS dedicate funding to modernize the system used to report the available blood supply and to maintain an automated system that includes real-time, comprehensive, accurate data on blood inventories. A data infrastructure to monitor the status of the blood supply in real-time can be designed to inform the Task Force's operations, which will strengthen the nation's preparedness capabilities and significantly improve our ability to ensure that blood is continuously available to meet patients' needs.

The nation had a unique opportunity to appreciate the benefits of comprehensive, transparent data through its experience developing and managing the inventory of COVID-19 convalescent plasma (CCP). All blood collectors that collected CCP submitted automatically generated, uniform data

in real-time to centralized reporting organizations. As a result, it was possible to know how much CCP was collected throughout the country as well as details on each unit of CCP, including the collection date, the expiration date, the ABO type, and the location of the unit. This type of collaboration and coordination facilitated patients' timely access to CCP. In short, data on CCP was gathered, validated, funneled, and housed centrally.

The Advisory Committee may consider lessons learned from the blood community's experience with data related to CCP to understand the benefit, help anticipate challenges and inform a data infrastructure. While the data system that accompanied the CCP program supports that such an infrastructure can be valuable, there were some unique attributes related to CCP. The collections-based funding model for developing and managing the inventory of CCP helped support the establishment of a uniform, automatic reporting infrastructure. This is different from the funding model for other blood products, and the nation has not yet made a similar investment in the data infrastructure related to the blood supply. Also, as I previously mentioned, blood centers and hospitals consider their blood inventories to be proprietary and confidential. Therefore, it is essential that any data infrastructure is designed to protect the confidentiality of details about standard products and the security of the data.

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## **ADDITIONAL CONSIDERATIONS FOR THE ACBTSA**

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While data is important for disaster preparedness, when the Task Force is responding to a disaster, we generally confront logistical challenges, such as transportation and infrastructure as well as limited blood inventories. When Brian presented to the ACBTSA, he explained how the Task Force was activated at the beginning of the pandemic after a blood center in Washington state reported that the blood supply was threatened. The Task Force contacted and coordinated with blood centers across the nation and helped avoid a blood shortage in the impacted area by directing blood to the affected blood center. At the same time, blood donation across the country declined due to blood drives and blood donation appointments being cancelled amid social distancing policies and remote working arrangements.

Over the past year, the Task Force has had to respond to several events beyond the direct impact of the pandemic. Last summer, wildfires plagued the western states and in the fall hurricanes and other storms disrupted the collection of blood. Severe winter storms brought debilitating snow, ice and cold to much of the United States, and caused power outages or weather conditions that limited the ability of donors to travel to donate blood. Transportation difficulties, including dangerous roads and closed airports, complicated the ability to transport blood to hospitals.

Therefore, we encourage the ACBTSA to recommend that the Assistant Secretary for Health work with the Assistant Secretary for Preparedness and Response (ASPR) and other policymakers to ensure that blood collection establishments, the Task Force and considerations related to the safety and availability of the blood supply are integrated into federal, state, and local pandemic and

disaster preparedness and response policies. For instance, blood collection establishments and the Task Force can be incorporated into existing programs, such as the Hospital Preparedness Program and the National Disaster Medical System, as well as the regional disaster health response system that is currently being established.

Finally, we urge the ACBTSA to recommend that HHS dedicate funding to support the Task Force's infrastructure to enable innovation, support its evolution and ensure that it continues to meet the needs of the blood community and the nation.