



Advancing Transfusion and
Cellular Therapies Worldwide

July 8, 2020

Via Electronic Mail

The Honorable Admiral Brett Giroir, MD
Assistant Secretary for Health
Office of the Assistant Secretary for Health
U.S. Department of Health & Human Services
Mary E. Switzer Building
330 C Street SW, Room L600
Washington, DC 20024
Attn: OASH Comments
OASHcomments@hhs.gov

**RE: RFI RESPONSE – LONG-TERM MONITORING OF HEALTH CARE SYSTEM
RESILIENCE, 85 Fed. Reg 34,644 (June 5, 2020)**

Dear Assistant Secretary Giroir,

AABB is submitting this letter in response to the “Request for Information - Long-Term Monitoring of Health Care System Resilience.” We applaud the Department of Health and Human Services (HHS) for soliciting feedback on opportunities to strengthen the U.S. health care system and are especially pleased with HHS’ focus on public-private partnerships in data sharing and comprehensive analytics. AABB recently submitted a letter to your office in response to a request for information to inform a report to Congress on the adequacy of the national blood supply. AABB believes that a safe, available blood supply is a critical component of health care system resilience and we encourage HHS to use the report to Congress to support this effort as well. We believe that the priority we set out in our previous letter – including the establishment of a national data infrastructure that monitors the blood supply chain from vein to vein – or from donor to patient – is critical to health system resiliency and preparedness in the United States and is essential to ensuring the adequacy of a safe blood supply before, during, and after public health emergencies.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. The association is committed to “improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.” AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

A safe and adequate blood supply is critical to medical practice, patient safety and the public’s health. Blood transfusions make up roughly 15% of all hospitalizations, with blood products needed for major surgeries and trauma management. Blood is used to treat diseases such as sickle cell anemia and some cancers, and to treat victims who have injuries caused by accidents or natural disasters. Every day, the United States needs approximately 36,000 units of red blood cells, nearly 7,000 units of platelets, and 10,000 units of plasma. AABB is proud that despite significant challenges, the blood community - including blood donor centers, transfusion medicine services, device and testing manufacturers,

government regulators and the public - continues to ensure that patients have access to safe, available blood.

We urge HHS to work with Congress and private stakeholders to establish, implement and support a sustainable public-private system that captures and makes accessible real-time data on blood availability and utilization, transfusion outcomes and hemovigilance. A comprehensive data system is needed to reinforce and organize the blood supply chain and strengthen the U.S. healthcare system.

Barrier and Opportunities for Health System Resilience

1. What have been the most significant barriers to assessing, monitoring, and strengthening health system resilience in the U.S.?

The lack of data has been a significant barrier to assessing, monitoring, and strengthening health system resilience. For example, the healthcare system does not have an infrastructure to monitor real-time data on blood availability and utilization, transfusion outcomes and hemovigilance.

The global COVID-19 pandemic has highlighted the fragility of the nation's blood supply chain. AABB is proud that despite significant challenges, the blood community - including blood donor centers, transfusion medicine services, device and testing manufacturers, government regulators and the public - continues to ensure that patients have access to safe, available blood. However, now more than ever we recognize that the absence of real-time data on the blood supply chain jeopardizes the public's health.

The availability of the blood supply and blood utilization are dynamic and must be continuously harmonized to ensure that blood is available to meet patients' needs. At the beginning of the COVID-19 pandemic, blood donation centers experienced a sharp decline in blood donation due to travel restrictions and social distancing efforts, such as remote working and school arrangements, which resulted in cancelled blood drives and fewer donation appointments. There was an urgent national effort to encourage blood donation to ensure that the blood supply remained adequate to meet patients' needs. As the pandemic progressed, hospitals stopped performing non-emergent procedures, which resulted in a steep reduction of blood utilization. Then, as the country resumed non-emergent and elective services amid prolonged social distancing practices, utilization quickly escalated, and the blood supply was once again strained.

The blood community currently monitors changes in supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. While individual institutions and hospital systems have data on their own blood use, general changes in utilization are not monitored or reported in real-time. The absence of comprehensive national data accounting for supply and utilization impedes the ability of blood donor centers, hospitals, clinicians, the broader health care community, and policymakers to take data-driven actions to ensure that the blood supply is continuously available to meet patients' needs. The lack of real-time data on fluctuations in supply and utilization is particularly challenging for the blood system since blood generally has a short shelf life of between days and weeks, depending on the specific blood component.

2. What policies and programs can be improved to mitigate the risk of COVID-19 and avoid negative impacts on patient outcomes?

We recommend that HHS encourage Congress to use a legislative vehicle to establish, implement, and support a sustainable, public-private infrastructure that captures and makes accessible real-time data on blood availability and utilization, hemovigilance and transfusion outcomes. A comprehensive data system is critical to our nation's health care and preparedness infrastructure and is

essential to mitigating the risk of COVID-19, avoiding negative impacts on patient outcomes, and ensuring the adequacy of a safe blood supply.

Blood Availability and Utilization

We urge HHS to address the current lack of visibility into the health and status of the blood supply chain by recommending that Congress establish, implement and support a comprehensive, sustainable, minimally burdensome system that monitors and makes available data on the blood supply as well as utilization. Significantly, the system would need to be designed in a manner that accounts for the confidential and proprietary nature of the data. Real-time transparency into the status of the blood supply chain is the only way to ensure the adequacy of the blood supply, including during public health emergencies.

Such a system would be able to inform the health care community and policymakers about the availability and utilization of blood, including individual blood components. For instance, COVID-19 convalescent plasma (CCP) was identified as a first line investigational treatment for certain patients with COVID-19. Blood centers shifted their operations and worked tirelessly to build the national inventory of CCP without having a system capable of monitoring the constantly changing national demand. Likewise, clinicians seeking access to this investigational therapy were not able to clearly ascertain the evolving availability of the product.

Additionally, the data would enable blood donor centers, transfusion medicine services and policymakers to assess whether the available blood supply is able to meet the needs of specific patient populations, such as chronically transfused individuals with sickle cell disease who must have access to and receive antigen-matched or antigen-negative blood. Similarly, the data would clarify whether the current supply of specific blood components or blood types is adequate to satisfy patient needs. Blood donor centers could use the data to adjust their operations and transfusion medicine services could use the data to guide clinical practices.

We acknowledge that data can inform practices, but education, outreach, and resources are also needed to strengthen the donor base, which is essential to ensuring an adequate blood supply. We appreciate that Congress included in the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act requirements that HHS carry out a national blood donor awareness campaign and report back to Congress on the impact of that campaign. We encourage HHS to build upon this effort by requesting that policymakers appropriate funding to support this initiative as well as funding that can be awarded to blood centers to enable them to pilot novel approaches to donor recruitment, increasing awareness of blood donation and promoting diversity among blood donors.

Hemovigilance and Transfusion Outcomes Data

While COVID-19 is not transmitted by blood, it is possible that a future virus would be transfusion-transmitted. A system capturing comprehensive, real-time hemovigilance data and patient outcomes would advance safety and innovation by (1) promoting evidence-based policymaking, (2) informing the development and adoption of new blood safety technologies, and (3) enabling continuous practice and quality improvement by blood donation centers, hospital transfusion services, testing and device manufacturers and other organizations throughout the blood system.

For instance, thorough hemovigilance data would provide the blood community and regulators with a vehicle to monitor the incidence and prevalence of transfusion transmitted diseases (TTDs) in current blood donations as well as the potential risk of emerging infectious diseases, such as arboviral

infections. Thus, policymakers would be better equipped to continuously update policies, ensuring that they reflect current data on emerging infectious diseases, changes in the epidemiology of all TTDs, and the capabilities of novel processes and technologies. Additionally, hemovigilance data have the potential to help advance an individual risk assessment approach for blood donation, as policymakers and the blood community would have a tool to monitor the continued safety of the blood supply in real-time. Importantly, hemovigilance data would serve as an early warning system for policy failure or emerging infectious diseases.

As another example, policymakers, private-sector organizations and individuals could use hemovigilance and outcomes data, together with data on the blood supply and utilization, to determine whether new safety requirements or the implementation of novel processes or technologies successfully advance blood safety while ensuring that the blood supply continues to meet patients' needs. Hemovigilance and outcomes data can highlight continued challenges related to blood safety, which can help identify areas that would benefit from further innovation.

Outcomes data has the potential to improve patient safety and the quality of care since it can be used to update transfusion practices and policies. Similarly, comprehensive data on non-infectious complications, such as transfusion-associated circulatory overload (TACO), the transfusion-related acute lung injury (TRALI), and transfusion of an incompatible unit of blood, can inform policies and improve clinical practice.

3. What scientific advances are needed to assess and address vulnerabilities in the U.S. healthcare system during the COVID-19 response and in future disturbances to the healthcare system?

While data is needed to support and monitor innovation, we also believe funds must be dedicated to supporting research and development related to innovative blood products, such as cold stored platelets, lyophilized plasma and thrombosomes, which are going to be important interventions to improve blood safety and accessibility. The COVID-19 pandemic has highlighted the vulnerability of the blood supply and supporting innovation around new product development could meaningfully alter the nation's susceptibility to situations where blood collection efforts are temporarily jeopardized.

Key Indicators & Data Sources of Health System Resilience

1. What is your definition of health system resilience within the context of your organization? Does the definition of resilience need to be defined differently based on geographic region and/or the domain of healthcare being assessed?

A safe, available blood supply is a key component of health system resilience. The blood community's extraordinary efforts continue to ensure that patients benefit from a safe, available, accessible blood supply every day, even in the aftermath of severe hurricanes, mass casualty events and in the face of emerging infectious diseases and a worldwide pandemic. While there are regional and blood center-specific variations in blood availability, the nation has never faced widespread blood shortages.

However, we cannot assume that historical successes will translate into a stable, available blood system in the future. Prior to the COVID-19 pandemic, the blood supply was fragile due to historical trends and challenges, such as difficulties with blood donor recruitment, changing medical practices, reduced blood utilization, costs associated with implementing new safety measures, and consolidation throughout the health care system. COVID-19 has exacerbated some of the existing challenges and has reinforced the need for the nation to invest in the security of the blood supply chain.

2. *What key indicators or data sets are being used within your organization to assess health system resilience?*

As explained above, blood system resilience is assessed through indicators including blood availability, utilization, transfusion outcomes and hemovigilance.

There are several data systems, existing platforms and programs that different public and private stakeholders in the blood community use to evaluate blood availability and utilization, transfusion outcomes and hemovigilance. However, none of the data systems are comprehensive, many of them are manual and they often do not reflect real-time data. For instance, the blood community currently monitors changes in supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. While individual institutions and hospital systems have data on their own blood use, general changes in utilization are not monitored or reported in real-time.

As another example, participation in the hemovigilance module of the National Healthcare Safety Network (NHSN) is voluntary except if required by state law and is burdensome since the system is manual and staff must report adverse transfusion-related events. Thus, only some hospitals participate, which limits the utility of the data. The Transfusion-Transmitted Infections Monitoring System (TTIMS) captures the incidence and prevalence of infectious disease data, demographic variables and behavioral risk factors on approximately 60 percent of the blood supply. Additionally, the National Blood Collection and Utilization Survey (NBCUS) is retrospective and does not reflect real-time data.

3. *What existing methods, data sources, and analytic approaches are being used to assess and monitor health system resilience in private healthcare systems?*

Private-sector organizations have developed and use a variety of programs, platforms and solutions to monitor blood availability and utilization, transfusion outcomes and hemovigilance.

4. *What selected health conditions should be used as indicators of healthcare availability, access, timeliness, and quality, in terms of treatment and preventive services?*

The availability of blood to meet patients' needs should be an indicator of healthcare availability, access, timeliness, and quality.

Public/Private Data Sources

1. *What data sources does your organization use to assess the resilience of the health system? What demographic populations are covered by these data systems? Do these data systems capture urban-rural and other geographic differences?*

AABB monitors changes in the blood supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations. AABB also reviews manuscripts and data about the safety and availability of the blood system that is generated through a variety of private and public sources. Because the systems do not focus on inventory held by hospitals, they do not address urban-rural and other geographic differences.

2. *How are you using these data sources to inform your public health response?*

The AABB Interorganizational Disaster Task Force (Task Force) brings together the private sector blood community and the government to support the nation and ensure the availability of the blood supply during disasters. AABB uses data to help inform the Task Force's activities. When acute

shortages with the potential to impact public health are reported, the Task Force may be convened to coordinate a community response. For example, throughout the COVID-19 pandemic, the Task Force has convened the blood community, worked to assess the status of the blood supply and coordinated public messaging about the need for blood donation.

Public-Private Partnerships

1. Provide ideas of the form and function of a public-private partnership model to continually assess and monitor health system resilience and individual as well as population health outcomes?

A comprehensive data system for the blood supply chain must: (1) be created and implemented in a cost-effective manner; (2) be sustainable; (3) contain information from a maximum number of blood donor centers and institutions/individuals that utilize blood products; and (4) provide useful data to regulators, payers and other organizations and professionals throughout the blood community. For these reasons, we encourage HHS to recommend that Congress use its statutory authority to establish, maintain and fund a system that captures and make available data on the blood supply chain.

A comprehensive data infrastructure should be designed through a public-private partnership to ensure that the data supports the needs of blood donor centers, transfusion medicine services, testing and device manufacturers, accreditors, regulators, payers and other organizations throughout the blood community. It should protect the confidential and proprietary nature of the data, while imposing minimal new burdens on organizations and individuals.

One way to maximize efficiencies and minimize burdens is to leverage and coordinate any new data system with existing platforms, data systems and programs. For example, HHS may consider recommending that the Transfusion-Transmitted Infections Monitoring System (TTIMS) serve as the foundation for a hemovigilance system since it captures the incidence and prevalence of infectious disease data, demographic variables and behavioral risk factors on approximately 60 percent of the blood supply. Additionally, it is intended to provide data on the impact of shifts in the donor base, which can inform evidence-based policies. We recommend that HHS consider whether TTIMS can be expanded to cover all blood donations, and whether other data, such as supply data, can be incorporated into the system.

AABB encourages HHS to shape a comprehensive data system by working with the private sector to consider the successes and challenges of other existing platforms, data systems and programs, such as the hemovigilance module of the National Healthcare Safety Network (NHSN), the Biologics Effectiveness and Safety (BEST) Sentinel Initiative, the National Blood Collection and Utilization Survey (NBCUS), and other programs developed by public and private-sector organizations.

Similarly, public and private partners should evaluate challenges with the nation's hemovigilance efforts, which illustrate the benefit of having a comprehensive data effort rooted in statute. For example, participation in the hemovigilance module of the NHSN is voluntary except if required by state law and is burdensome since the system is manual and staff must report adverse transfusion-related events. Thus, only some hospitals participate, which limits the utility of the data. In contrast, policymakers have recognized the benefit of using legislation to establish mandatory data systems for other areas of medicine, such as hematopoietic cell transplants, solid organ transplants and end stage renal disease. It is paramount for the nation to make a similar investment in the foundation of its blood system to improve the data used to inform policies, clinical practices and decisions that impact blood safety, blood availability and patient outcomes.

2. *What private and public sectors should HHS engage as part of such a collaborative effort?*

HHS should engage with blood donor centers, transfusion medicine services, testing and device manufacturers, accreditors, regulators, payers and other organizations throughout the blood community as part of a collaborative effort to design a comprehensive data system that supports the resiliency of the nation's blood system.

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Thank you for the opportunity to offer these comments on the RFI. We look forward to continuing to work with HHS on recommendations related to maintaining a safe and adequate national blood supply. If you have any questions or need additional information, please contact Leah Stone at lmstone@aabb.org or at 301-215-6554.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB