Advancing Transfusion and Cellular Therapies Worldwide

American Red Cross

June 18, 2020

Mr. James Berger
Designated Federal Officer
Office of Infectious Disease and HIV/AIDS Policy
U.S. Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW, Room L600
Washington, DC 20024
Attn: ACBTSA-PAHPAIA Sec. 209

**RE: RFI RESPONSE: ACBTSA – PAHPAIA Sec. 209**

Dear Mr. Berger,

AABB and the American Red Cross commend the Department of Health and Human Services for working with public and private-sector partners throughout the blood community to develop recommendations related to maintaining the national blood supply, which will be included in the report to Congress mandated by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAI). We urge HHS to include in the report to Congress a request for policymakers to use a legislative vehicle 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 will address each of the challenges highlighted by Congress, including (1) ensuring the adequacy of the blood supply in the case of public health emergencies; (2) identifying challenges and opportunities to strengthen the donor pool; (3) promoting safety and innovation; and (4) building upon the implementation and intent of the Transfusion-Transmissible Infections Monitoring System (TTIMS).

1. **A national data system that monitors the blood supply chain from vein to vein – or from donor to patient – is critical to our nation's preparedness infrastructure and is essential to ensuring the adequacy of the blood supply in the case of public health emergencies.**

The global COVID-19 pandemic has highlighted the fragility of the nation's blood supply chain. AABB and the American Red Cross are 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. For example, 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.

Additionally, there is no current mechanism in place to inform the health care community and policymakers about the availability and utilization of 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.

We urge HHS' report to Congress 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.

**2. A comprehensive data system that makes available data on the blood supply as well as changes in utilization would enable policymakers and organizations throughout the blood community identify challenges and opportunities to strengthen the blood donor pool.**

As illustrated above, changes in the blood donor pool directly impact the ability of the blood supply to meet patients' needs. Thus, real-time data on the blood supply and utilization would enable policymakers and the blood community to immediately identify challenges and opportunities to strengthen the donor pool.

For example, 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.

AABB and the American Red Cross acknowledge that data can inform practices, but education, outreach, and resources are also needed to strengthen the donor base. 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 including in its report to Congress a request for policymakers to 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.

**3. A holistic data system that captures data on hemovigilance and patient outcomes would promote blood safety and innovation.**

A national 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. While data is needed to support and monitor innovation, we also believe that HHS should recommend that Congress dedicate funds to support 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.

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.

Clinical practice would also improve by establishing a national red blood cell antigen typing patient database, which would advance patient outcomes by expediting access to compatible units of blood for individuals with special transfusion requirements, such as individuals with sickle cell disease. This innovative resource would be augmented by funding to support widespread molecular testing, which

would increase the number of potential donors for chronically transfused patients. These measures have the potential to significantly decrease transfusion associated morbidity and mortality for patients with unique transfusion needs, thereby improving patient safety and health outcomes.

Finally, payers can use data on transfusion outcomes and hemovigilance to inform coverage and reimbursement policies that support safety and innovation. For instance, payers would be able to use such data to develop and revise coverage and payment policies so they better align with transfusion practices, blood safety requirements and promoting patients' access to new technologies. As another example, the data can be used to advance innovative care by supporting payment policies for blood transfusions furnished in the hospital as well as in out-of-hospital settings of care.

4. **A comprehensive data system would be a critical part of the public health infrastructure, should be supported by Federal funds through a public-private partnership and should leverage and build upon existing platforms, including TTIMS.**

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 include in the report to Congress a recommendation that policymakers use their statutory authority to establish, maintain and fund a system that captures and make available data on the blood supply chain.

A comprehensive data system 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 should 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 and the American Red Cross encourage 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, including 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.

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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. AABB and the American Red Cross commend HHS for its work in making recommendations to Congress to support the adequacy of the blood supply and believes that a comprehensive data system is an important step in ensuring the endurance of this critical public health resource.

If you have any questions or need additional information, please contact Leah Stone, Vice President, Public Policy and Advocacy at 301-215-6554 or lmstone@aabb.org.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

J. Chris Hrouda
President, Biomedical Services
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