Advancing Transfusion and
Cellular Therapies Worldwide

Advancing the U.S. Blood System: A Community-Based Approach to Address the Challenges of Today and Opportunities of Tomorrow

Recommendation: Establish a pre-competitive public-private partnership to proactively explore and advance specific, innovative, workable policy solutions that address some of the unique challenges that threaten the U.S. blood system. This important public health security effort would promote quality and efficiencies, encourage innovation and advance the continued safety and availability of the blood supply.

Background

A safe, available blood supply is a public health priority, and is critical to all health systems. Blood and blood components are irreplaceable essential medicines and unique health care resources. Blood transfusions are routine medically necessary treatments for patients with certain chronic health conditions and are frequently required for patients who lose blood during surgery or because of injury. In addition to these predictable uses, blood components must be immediately available in emergent situations characterized by severe bleeding, such as resuscitation after traumatic injuries or severe burns.

The U.S. blood system – from donor to use or from vein to vein – is comprised of a complex web of public and private stakeholders. In contrast to most other life-sustaining medicines, blood and blood components originate from altruistic, volunteer donors. Blood collection establishments collect, test, process and distribute blood components to hospitals and other settings of care where blood is transfused to patients. Blood components have short shelf lives and must be administered to patients within days or weeks, depending on the specific blood component. Other key stakeholders include device manufacturers, testing laboratories, clinicians, private standard setting and accreditation organizations, payors, the Food and Drug Administration, the Centers for Disease Control and Prevention, the National Institutes of Health, the Office of the Assistant Secretary for Health and the Office of the Assistant Secretary for Preparedness and Response, as well as other federal, state and local governmental agencies.

The U.S. blood system successfully responded to several significant stressors over the past year and a half, including developing, universally adopting and implementing tests to screen blood donations for the Zika virus, ensuring that the blood supply was safe, available and accessible in the aftermath of hurricanes Harvey and Irma and having sufficient capacity to meet the needs of the victims of the June 2016 Orlando nightclub shooting and the October 2017 Las Vegas shooting. These herculean, life-saving efforts required coordination and participation by all private and public stakeholders throughout the system.

Problem

Historical resilience cannot be equated with stability or future capacity. A recent Sounding Board article in the *New England Journal of Medicine* issues a critical call to action, highlighting ongoing trends

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and existing challenges that threaten to disrupt the blood system.[1] Changing medical practices, reduced blood utilization, a shrinking donor pool and consolidation throughout the health care system have stressed the blood community. Additionally, the blood sector faces mounting economic pressures from existing and emerging voluntary and mandatory safety measures, which are intended to protect the health of patients and donors but are costly to implement. Existing challenges limit the ability of the blood system to invest in research and development and adopt innovative technologies to maintain and improve the safety of transfusions and ensure an adequate supply of blood. In addition, these stressors interfere with the ability of the blood system to maximize its potential for preparing for and responding to emerging infectious diseases and unprecedented disasters and emergencies.

Solution

The broad array of stakeholders comprising the U.S. blood system have diverse, and often competing interests; however, there is widespread agreement on the critical need to ensure that the blood supply is safe and available. An inclusive public-private partnership can drive progress guided by these important goals by:

- Advancing regulatory science, which is defined as "the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products."[2]
- Serving as a forum for collaborative efforts aimed at reducing existing regulatory and reimbursement barriers, exploring mechanisms to facilitate research and development, encouraging the adoption of innovative technologies, and coordinating strategic investments in research, programs and tools intended to strengthen the blood system.
- Developing workable, novel policy solutions that promote a robust, stable blood system capable of meeting both anticipated and unforeseeable needs.

The blood community may consider modeling a partnership after the Medical Device Innovation Consortium (MDIC), a unique partnership between government, nonprofits and industry committed to advancing regulatory science to improve patient access to medical devices. MDIC's projects are intended to make new technologies available to patients, expedite the regulatory process and development of medical devices, reduce the risk and expense of research, and lessen the time and cost of developing medical devices.[3]

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AABB is a not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. For additional information, please contact Leah Stone, Director of Public Policy & Advocacy at 301-215-6554 or lmstone@aabb.org.

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[1] Klein HG, Hrouda JC, Epstein JS. Crisis in the sustainability of the U.S. blood system. N Engl J Med 2017; 377:1485-1488.

[2] Advancing Regulatory Science at the FDA: A Strategic Plan, August 2011, *available at* https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf (last visited November 1, 2017).

[3] Medical Device Innovation Consortium, *available at* http://www.mdic.org (last visited January 5, 2018).