Blood transfusion: advocacy, adequacy, and safety

When the United States discovered over 20 years ago that patients dependent on blood and component therapy could become infected with the human immunodeficiency virus (HIV) through blood transfusions, it paid significant attention to reducing that risk. Today, it is paying equal attention to making certain that the nation has an adequate and safe blood inventory.

Both of these concerns relate directly to the mission of the Center for Biologics Evaluation and Research (CBER), which is responsible for regulating biological products such as blood to ensure their purity, potency, safety, efficacy, and availability.

CBER seeks input on FDA-related activities

With the passage of the Food and Drug Administration (FDA) Modernization Act in 1997, CBER was given the mandate to seek the input of appropriate scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, and the regulated industry on FDA-related activities.

CBER currently works through three committees: the Blood Products Advisory Committee (BPAC), the Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC), and the Advisory Committee on Blood Safety and Availability (ACBSA). Specifically:

- The BPAC reviews and evaluates data concerning the safety, effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases. It also advises the FDA commissioner on related issues.
- The TSEAC reviews and evaluates data concerning the safety of products that may be at risk for transmission of spongiform encephalopathies having an impact on the public health. It also advises the commissioner.
- The ACBSA makes recommendations to the Secretary and Assistant Secretary of the U.S. Department of Health and Human Services regarding blood products. The range of issues includes the safety and availability of the blood supply; the broad public health, ethical, and legal issues related to the blood supply; and the implications for blood safety in terms of economic factors affecting product cost and supply.

Each committee regularly receives input from America’s Blood Centers, the American Red Cross, the AABB (formerly the American Association of Blood Banks), and consumer advocates.

These advisory committees, especially ACBSA, emphasize blood safety and availability from these different perspectives, but a newer one has emerged recently because of variant Creutzfeldt Jacob Disease and the possibility of its transfusion transmission. Protection of public health is a worldwide, rather than merely national, imperative. CBER’s new international vision is exemplified by its appointment as an official Collaborating Center to the World Health Organization.

Current safety of U.S. blood supply

Against this background of international collaboration, what can be said about the current safety of the blood supply? Progress is gratifying. Since the introduction of nucleic-acid testing for HIV and hepatitis C, the risk of transmission by transfusion has been reduced to about one in 2 million pints of blood.

This test closed the window of opportunity through which an individual would unknowingly donate infected blood. When screening tests for HIV were first introduced some 20 years ago, the average window was close to two months; currently, it is less than 11 days.

In terms of other infectious agents, screening for West Nile virus (WNV) in blood donors has been a remarkably successful effort between the FDA, the regulated blood-banking industry, scientists, and test-kit manufacturers. Once WNV was recognized as a transmission risk, it took only 10 months for implementation of nationwide donor screening. Prior to screening, 23 documented WNV transmissions took place in 2002 alone. There was only one transmission in 2004.

Investment in ID systems

While progress in screening blood for transmissible infection is gratifying, the major contribution to risk associated with transfusion still exists. Patient misidentification and the subsequent transfusion of incompatible blood require urgent attention.

Even though there are a number of positive-identification systems available to hospitals, they require capital investment. In these times of fiscal constraint and escalating healthcare costs, hospital administrators find it difficult to make the commitment to spend scarce dollars to prevent what they consider a remote possibility. CBER will continue to monitor this situation. For more information, contact CBER, FDA, 1401 Rockville Pike, Rockville, MD 20852-1448; telephone: 800-835-4709.

References


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