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EDITORIAL VIEWS

Acquired Immunodeficiency Syndrome (AIDS) and Blood Products

SEVERAL GROUPS, including the Centers for Disease Control (CDC) and the Blood Products Advisory Committee of the Office of Biologics, the National Center for Drugs and Biologics, the Food and Drug Administration, have been meeting individually and together to consider the possibility that the acquired immunodeficiency syndrome, commonly called AIDS, may be transmitted by blood and blood products. This is an extremely important question because AIDS may be nearly 70% fatal within 2 years of diagnosis.

AIDS is a secondary immune deficiency often associated with opportunistic infections or a rare form of the malignancy, Kaposi's sarcoma, or both. Early in the course of AIDS, patients experience fatigue, cough, weight loss, and generalized lymphadenopathy. Later, patients with AIDS may present with disseminated Kaposi's sarcoma and pneumocystic carreni, or other opportunistic infections. Although a variety of manifestations can occur, the end result is extensive infections and uncontrolled tumor growth or wasting debility, or both, usually leading to death. Recently, apparent abnormalities of T-lymphocyte subsets (*e.g.*, reduced ratios of helper/inducer to suppressor/cytotoxic T lymphocytes) have been identified in patients with AIDS. However, these findings are not specific for patients with AIDS and therefore can be used only as a tool to help understand the disease process.

AIDS is found predominately in four groups of individuals: promiscuous gay males, persons who have resided in Haiti, intravenous drug abusers, and hemophiliacs. To date, all hemophiliacs with AIDS have been heavy users of antihemophiliac concentrate, suggesting a link between this product and AIDS. Considering this possibility, the National Hemophilia Foundation has recommended that cryoprecipitates be used in children under 4 years of age, newly identified hemophiliac patients, and those who require infrequent therapy. The Foundation further recommended that manufacturers of Factor VIII concentrates exclude donors who might transmit AIDS, which obviously includes the above four groups of patients. They advised further that donors from "hot spots" (currently New York, San Francisco, Los Angeles, and Miami) be excluded. These recommendations present tremendous logistic and obvious sociologic problems, but there is evidence that most manufacturers are attempting to comply with them.

A joint statement has been developed by the American Association of Blood Banks, the American National Red Cross, and the Council of Community Blood Centers with assistance from other affected groups. Seven recommendations evolved with full recognition that the cause of AIDS is unknown and evidence for its transmission by blood products is weak. This statement recommends development of a program to educate physicians on the risks of transfusion-transmitted diseases, including the possibility that AIDS may be one. They advocate consideration of autologous rather than allogeneic blood for elective surgery. Donors should be asked questions that would detect AIDS or exposure to patients with signs and symptoms suggestive of AIDS. Donor recruitment should not be directed toward

Although Dr. Bove is Chairman of and Dr. Miller is a member of the Blood Products Advisory Committee of the Food and Drug Administration (FDA), this article represents their personal opinions and should not be construed as representing the official policy of the Committee of the FDA.

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groups thought to have a high incidence of AIDS. A major dilemma was whether to limit voluntary blood donation by individuals from groups with a high incidence of AIDS (*e.g.*, gay males). Although considerable pressure had been exerted to restrict blood donation by gay males by either direct or indirect questioning, such an invasion of privacy seemed justified only if it demonstrated clear-cut benefits. Furthermore, the effectiveness of such a questioning program was debatable. The groups did not think that such a restrictor could be justified on the basis of currently available data.

The Centers for Disease Control (CDC) believe differently and on March 4, 1983, called on blood collecting agencies to request that members of high-risk groups, including sexually active homosexual or bisexual men with multiple partners, voluntarily refrain from donating blood. Their recommendations were accepted quickly by the blood collecting sector, and appropriate measures for voluntary screening now are in place in almost all areas of the country.

In January 1983, the American Blood Resources Association, which represents the plasma pheresis industry, recommended emphasis on donor education, donor screening, and surrogate laboratory testing for donors whose plasma will be used to manufacture products for treating hemophilia. In the educational area, individuals in high-risk groups should be advised as to how their risk of exposure can be reduced and to discourage such individuals from donating plasma. They also recommend that high-risk groups be excluded from donating plasma. The problem with this approach, however, is indicated above. In terms of laboratory testing, the Association recommended no large-scale testing at this time because the efficacy of such tests are doubtful. Because no test exists to detect persons with the prodromal signs and symptoms of AIDS, nonspecific screening tests have been proposed. For example, measurement of antibody to hepatitis B core antigen may be successful. The logic behind this approach is that hepatitis B is prevalent in the same populations that are at high-risk for AIDS. However, although this test has positive results in most patients with AIDS, it also has positive results in many potential donors who do not have AIDS. To enact such a test would cost millions of dollars. To expend that much personnel and financial resources with so little supporting data seems inappropriate.

It is obvious from this editorial that all concerned groups are attempting to arrive at responsible recommendations for coping with a disease that may have more far-reaching implications than are realized presently. The ability to make any intelligent decision and to evaluate its effect is complicated by the long (approximate 1 year) latency period. Therefore, decisions that are made now cannot be assessed for at least 1 year. The purpose of this editorial is to emphasize that AIDS is a highly fatal disease, for which the cause has not been identified, for which there is no diagnostic test, and for which the method of transmission is unknown. Although blood and blood products may be one possible method of transmission, this possibility still remains unproven. Only when the actual causative agent, if there is one, has been identified, responsible and definitive decisions can be made. Until then, increased caution in the use of blood and blood products is warranted.

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