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ABSTRACT

A policy statement by a group of experts on screening blood donations for contamination by human immunodeficiency virus (HIV), the causative agent of acquired immunodeficiency syndrome (AIDS), is presented in this document. This document provides policy recommendations formed by a consensus conference sponsored by the National Institutes of Health and attended by biomedical investigators, blood bank specialists, clinicians, consumers, and representatives of public interest groups. The recommendations concern these areas: (1) tests that are currently being used to screen for AIDS and test performance characteristics; (2) what constitutes a positive test, how a positive HIV-antibody test should be interpreted, and how these tests should be used; (3) how to handle positive test results; (4) the psychosocial ramifications for blood donors of knowledge of a positive test result; (5) the impact testing has had on transfusion medicine; and (6) what research directions should be pursued. The conclusions in this report call for more sensitive tests to identify infectivity, better methods of discouraging possibly infected donors, and better methods of handling psychological problems occurring in those with positive tests. (ABL)

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THE IMPACT OF ROUTINE HTLV-III ANTIBODY TESTING ON PUBLIC HEALTH

National Institutes of Health
Consensus Development
Conference Statement

Volume 6 Number 5

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Introduction

The appearance of acquired immune deficiency syndrome (AIDS) has brought suffering and death to those who are afflicted and, at the same time, has posed daunting challenges to those who care for the sufferers, to biomedical scientists, and to those responsible for public health and public policy. Among these challenges is the protection of the nation's blood supply from contamination by human immunodeficiency virus (HIV),* the causative agent of AIDS. This challenge was met rapidly by the development of laboratory tests to detect the presence of antibody against the virus. The application of these tests makes it possible to determine whether the person has been infected by the virus at some time and thus to exclude persons from donating blood or to discard blood already donated. In the past 15 months, the widespread application of these tests along with self-deferral and removal of HIV-positive subjects from the pool of donors has sharply reduced the likelihood of the virus being spread by way of blood products.

Remarkable progress has recently been made in isolating the virus and in developing reasonably reliable tests for detecting its presence in blood by measuring the formation of antibodies against it. Mobilization of the whole scientific community, from government agencies and industry to the individual investigator, has brought about this progress, boding well for the eventual prevention of the disease. In fact, the prevention of posttransfusion AIDS is a typical example of the gains to be achieved by many years of supporting basic research.

However, the introduction of these tests has brought with it some problems. Questions can be raised about interpretation of the tests and their extension to purposes other than protection of the blood supply. As with almost every aspect of AIDS, the facts, opinions, and uncertainties of science are rapidly translated into public beliefs and social policy. Often, this translation has been inaccurate and incorrect. Policy has been made, or recommended, on the basis of an assumed scientific certitude that in fact may not exist. Conversely, scientifically sound information has been ignored or distorted by policymakers. Scientists have often failed to communicate their findings in ways that are useful for public policy.

The tests for evidence of infected blood are not yet optimally effective. There is still room for improved applications of the scientific method to identify methods with increased sensitivity, specificity, and predictive value. Because no test can be totally devoid of error, there must be continuing vigorous efforts to educate the public about who is a suitable donor of blood and to facilitate anonymous self-deferral at the time of blood donation.

To enhance understanding among scientists, those responsible for the health of individuals and of society, and the public at large, the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) and the NIH Office of Medical Applications of Research sponsored this Consensus Development Conference on the Impact of Routine HIV-Antibody Testing of Blood and Plasma Donors on Public Health. Other sponsors of the conference were the Centers for Disease Control; the Food and Drug Administration; the Clinical Center,

The National Institutes of Health urges that this summary statement be posted, duplicated, and distributed to interested staff.

*Previously referred to as HTLV-III/LAV, and subsequently referred to in this document as HIV in accordance with emerging and recommended usage.

NIH; the National Institute of Allergy and Infectious Diseases, NIH; and the National Institute of Mental Health.

The conference brought together biomedical investigators, blood bank specialists, clinicians, consumers, and representatives of public interest groups. Following 2 days of presentations by medical experts and discussion by the audience, the consensus panel worked hard to interpret the scientific evidence. Comments and recommendations are organized according to the following questions:

- What tests are currently being used? What are their performance characteristics?
- What constitutes a positive test? How should a positive HIV-antibody test result be interpreted? How should these tests be used?
- How should positive test results be handled?
- What are the psychosocial ramifications for blood donors of knowledge of a positive test result?
- What impact has testing had on transfusion medicine?
- What research directions should be pursued?

1.

What tests are currently being used? What are their performance characteristics?

There are three approaches to detecting HIV infection. Listed in decreasing order of difficulty and expense, these are:

1. Detection of the virus by culturing it.
2. Detection of antigens elaborated by the virus and present in blood.
3. Detection of HIV-specific antibodies that are produced by the infected person's immune system.

Two tests mainly support the entire current testing program. Both are of the third type. ELISA (enzyme-linked immunosorbent assay) reacts to the presence of antibodies in the donor's blood, showing a more intense color as larger quantities of the antibodies are present in the serum. A positive reaction is recorded where the observed intensity exceeds a cutoff value set by the manufacturer of the test kit. If the cutoff value is set low, so that relatively faint specimens are recorded as positive, the chance of detecting HIV cases with low levels of antibody are increased. At the same time, such a low threshold increases the chance of recording as positive samples that do not contain antibodies against HIV which can also produce color in the system. To protect the blood supply, it is prudent for a given test to set the threshold low, and accept the increase in false positives that must accompany that low threshold.

With a low threshold the ELISA test is quite sensitive; that is, truly infected persons are highly likely to give a positive reaction. But, uninfected persons—who are vastly more numerous—also occasionally give positive reactions to this test. This small fraction of uninfected donors produces many more of the positive reactions than arise from positive reactions of the few persons actually HIV-infected. That is, the odds are great that any single ELISA-positive reading comes from an uninfected person. Furthermore, low positive values are often not reproducible; that is, a repeated, independent sample from a donor whose first test was barely positive will likely turn up negative.

Current practice is that all donors are ELISA-tested. If the test is negative the unit of blood is acceptable. If there is a positive reaction, two further ELISA tests are performed on the same unit. If both are negative, the unit is acceptable. If either is positive, the unit is classified as "repeatably reactive" and is destroyed.

In the nonprofit blood banking system, there is further testing of the blood of a repeat reactor, aimed at clarifying the person's HIV status, which is still ambiguous since so many HIV false positives occur among the ELISA repeat reactors. The Western blot test is then applied. It, too, is an antibody detecting test, but it differs from the ELISA in several ways:

1. It gives information about particular antibodies among the several that HIV antigens may elicit; prominent among these are antibodies against p24 and gp41.
2. It uses electrophoresis and is thus more expensive and demanding of expertise than the ELISA.
3. It is less likely to give a false positive or false negative result.

If the specimen is Western-blot-positive, the donor is regarded as infected with HIV and notification of the donor is attempted. If the repeat reactor's Western blot test is negative, the donor may be informed that:

1. The blood is not, and will not be, usable.
2. The donor in all probability is not infected.

To protect the quality of the blood supply, it is essential to reduce the number of false negatives to a minimum. However, false negatives cannot be totally eliminated because

some sera contain too little anti-HIV antibody to be detected; they come primarily from donors who have been infected very recently, typically during the first 6 weeks of infection, or from individuals who for one reason or another form antibody very slowly. It is essential to increase the sensitivity of methods for detecting anti-HIV-antibody and to develop methods to detect and measure HIV antigens or infected T_4 cells.

Several versions of the ELISA test are on the market. They differ in their comparative sensitivity to the various antigens of HIV, and thus reflect somewhat different information about the antibodies in a given blood sample. They also presumably differ in sensitivity to sample constituents responsible for false positives. The cost-benefit ratio of simultaneously using ELISA tests from two different manufacturers on each sample to improve accuracy should be explored.

Several other methods of detecting anti-HIV antibodies are very useful for confirming and extending results obtained by the ELISA method, but are more time-consuming. Western blotting is difficult to standardize, but staining of p24 together with gp41 is unequivocally positive. Correlation with intermediate and high ELISA values is excellent. Radioimmune precipitation (RIP) and radioimmune assay (RIA) can be made both sensitive and specific by using very highly labeled antigens, but require skilled personnel and involve the use of radioactivity. HIV isolation is very difficult, time-consuming, and requires highly skilled personnel; it does not lend itself to analysis of large numbers of samples. It correlates highly with high ELISA values.

The most promising new approaches will be the development of fluorescent antibody (FA) techniques for detecting infected T_4 lymphocytes and the development of techniques for detecting viral proteins, based either on antigen capture or on reverse transcriptase (RT) activation and synthesis of HIV DNA, which can then be detected with high sensitivity and specificity.

2.

What constitutes a positive test? How should a positive HIV-antibody test result be interpreted? How should these tests be used?

The virus thought to cause AIDS has been isolated and its genome and gene products are largely characterized. Tests have been developed for the detection of virus, virus-coded proteins, and antibodies directed against those proteins. These developments have facilitated large-scale screening of blood and blood products for viral antibodies. Clearly, the tests in use have enhanced the safety of transfusion procedures.

Current procedures utilize an ELISA test for detecting antibodies against HIV as an initial screen. An additional test, the Western blot, is used to test sera found repeatably reactive in the ELISA test. Extensive experience has demonstrated that many sera that are repeatably reactive in the ELISA test do not react when tested by Western blot analysis. These discordant results indicate that many of the sera that are repeatably reactive in the ELISA test do not represent combinations with virus-specific proteins and often may not indicate the presence of an HIV infection. Resolution of this problem is difficult because of limitations in currently available information. This is partly because investigators often use different methodologies, and licensed tests from different manufacturers probably differ in subtle yet possibly important ways. There are few published comparative analyses of the tests used in the field. Further, Western blots have generally been carried out by personnel who are aware of the fact that the sera they are testing have reacted in the ELISA test. In addition, it often is not possible to estimate the specificity of these tests because ELISA-negative sera are not being routinely tested by Western blot. Consequently, there is still a need for rigorous studies to clarify many issues regarding interpretation of test results.

The most specific test for infectivity remains virus isolation; however, because of the complexity and difficulty of isolating HIV in cell culture, this is an impractical method for large-scale use. Some form of the ELISA test with enhanced sensitivity and specificity remains the most practical and feasible procedure for large-scale screening of the blood supply. Improved confirmatory methods should be developed that can be used in conjunction with such a test. Even with currently available tests, however, it is essential that confirmatory studies be performed without the laboratory personnel knowing the prior ELISA results. Specimens should be identified by a code number only and a suitable number of ELISA-negative specimens should be included in each test run.

For the purposes of notifying the donor, a confirmatory test such as the Western blot should be applied to resolve the actual HIV status because the repeated reaction may be caused by factors such as autoimmune or cell-line-specific antibodies. Currently, however, blood banks are obliged to exclude sera that test repeatably reactive in the ELISA regardless of any confirmatory test results. Many of these almost certainly represent false positive reactions. It is unfortunate that a considerable number of donors are functionally excluded from donation because of their questionable test status. Efforts should therefore be made to find ways to identify ELISA-positive individuals who are not infected so that their true serological status may be defined and their return to the blood donor pool expedited.

Available data indicate that the presence of virus precursors or antibodies in the blood reflects the continuing presence of HIV in the host. Thus, detection of such components represents a sign of continued infectivity of the blood. Like many other chronic viral infections, the period very shortly after exposure is often likely to be characterized by lack of antibody and by levels of virus proteins below the threshold of detection. In addition, biologic variation of both host and pathogen suggest that some chronically infected individuals do not synthesize virus-specific antibodies or make quantities of viral proteins that can be detected by assays currently in use. Nevertheless, such individuals are potentially infectious. Thus, while total elimination of infected blood from the national supply is not immediately feasible, it remains a desirable goal.

3.

How should positive test results be handled?

A positive test* has the following significance as currently understood:

1. Such persons are infected with HIV.
2. Most persons infected with retroviruses such as HIV are infected for life.
3. All persons who are antibody-positive for HIV, whether they are symptom-free or ill, must be considered to be potentially infectious to others by sexual transmission, by sharing of drug injection equipment, by childbearing, or by donation of blood, semen, or organs.
4. Antibody positivity is not synonymous with having AIDS. However, by current estimate, as many as 35 percent of HIV-antibody-positive persons may experience progression to AIDS over 6 to 8 years.
5. We cannot precisely predict who among persons with antibody positivity will be ill or fatally ill in the future and it is not possible at present to prevent such outcomes.
6. All antibody-positive persons should seek information and advice on how to protect their sexual contacts and future children from infection.

The panel believes that there is a clear ethical responsibility on the part of blood- and plasma-collection centers to notify individuals with repeatably reactive blood in a sensitive, humane, and supportive manner. Consideration should be given to the donor's cultural and linguistic background. The need to maintain confidentiality of the information creates a duty on the part of blood-collection centers to assume primary responsibility for notifying positive donors of their test results.

Notification of donors serves two purposes:

1. It contributes to controlling the spread of HIV by encouraging self-deferral and changes in sexual practices.
2. It provides circumstances for optimizing the health and well-being of the affected individual.

Differences exist across communities with respect to the process by which notification is accomplished, the nature of the information provided, and the extent of counseling that is provided. The panel does not believe that any single approach would be universally applicable.

*Positive: describes a repeatably reactive sample which is determined to contain antibody by an additional, more specific test, such as Western blot, radioimmunoprecipitation, and the like. Persons who have positive sera are termed "seropositive."

Notification should be followed by education. The panel believes that the central component to education is person-to-person interchange between the donor and the counselor. Additional techniques such as videotape presentations and printed materials may supplement, but not substitute for, personal interchange. Appropriate elements of a supportive counseling program for persons who are seropositive include education about the natural history of HIV infection and the meaning of a positive test, advice on behavioral changes that will protect one's sexual partner(s) from infection, and referral to additional resources.

While blood collection centers will rarely have the trained personnel or assets to provide extensive and specialized counsel, we believe that they have a duty to cooperate with community agencies that can provide the necessary supportive services and to make effective referrals. These referrals would include the person's physician and other long-term counseling services, and such community agencies as local health departments, alternate test sites, AIDS service organizations, social service agencies, and others.

Confidentiality should be carefully and strictly maintained due to the sensitive nature of the information. Test results should be released to parties other than the patient only when there is a scientifically valid and legitimate need to know for public health purposes and, in principle, with the patient's specific consent.

Current practice in many centers is to enter the names of persons whose blood is repeatably reactive but negative by Western blot into lists of deferred donors. We believe that it is inappropriate to enter a person's identity into such a list without his knowledge and without giving him the personal advantage of sharing that knowledge and its meaning. It is common practice to allow such individuals to donate again, but to discard their blood without their knowledge. This practice should not continue; these donors have a right to be advised of their status.

Blood-collection agencies currently maintain lists of deferred donors onto which are entered the names of HIV-antibody-positive donors. The agencies believe that such lists increase the likelihood that infectious units of blood will be screened out in the future should positive donors not self-defer. On the other hand, such lists are a potential source of loss of confidentiality for donors should their identity be inadvertently revealed. We believe that a balance of interests supports the entry of the names of those who are believed to be truly positive or whose status cannot be satisfactorily resolved but only if such donors are informed initially that their name will be listed, if the list is very securely held, and the list is used only for the limited purpose of protecting the quality of the blood supply. The actual utility of such lists should be regularly evaluated as technology improves.

Persons found to be seropositive may have a history of previous blood donations. For such persons, the question then arises about their past donations that have already been transfused into patients. In these cases, the blood bank has a serious responsibility to notify the hospital to which that blood was sent. It is the responsibility of the hospital, directly or through the patient's physician, to notify the patients of the possibility of having received seropositive blood and to educate them about the meaning of this. It is our opinion that, while the blood banks do not have the primary responsibility for the notification and counseling of recipients, they should, within their means, assist hospitals and physicians with accurate and effective information.

The repeatably reactive donors (by ELISA) in the plasmapheresis setting cannot be characterized without additional testing as being either positive or negative for anti-HIV-antibody. If the plasmapheresis industry is unwilling to test these donors further, the situation should be explained to the donor and the donor should be referred to an agency where such testing and pretest and posttest counseling are available.

4.

What are the psychosocial ramifications for blood donors of knowledge of a positive test result?

Everyone involved in blood and plasma collecting is aware of the potential psychosocial ramifications of the knowledge of a positive test result. Nevertheless, current data do not reveal the magnitude and nature of the short- and long-term psychosocial adjustment problems that seropositive donors and their sexual partners and family members experience. Possible outcomes include the effects on the individual's psychological and physical health, subsequent sexual behavior, [illegible] of self-deferral behavior, and functioning in one's work and other social roles. Other research concerned with risk factors in health and illness has suggested that these outcomes will vary with the social and political climate of the community, the sociodemographic characteristics of the subpopulations at risk, the individual's personality traits, social support system, and characteristic mode of coping.

Due to issues of confidentiality, the education and initial notification of donors of confirmed reactive and positive tests is the responsibility of

plasma- and blood-collecting institutions and begins prior to blood donation. Anticipation of the donor's fear and distress is not a valid basis for not informing the donor. The content and manner in which the message is delivered may play a role in modifying the stress of being informed subsequent to a positive test result. In the notification procedure it is critical to differentiate between the ELISA test defined as repeatably reactive, and the individual defined as seropositive based on additional confirmatory tests. It is also the responsibility of these centers to offer followup support and counseling through referral to the health care system.

There is a need for rigorous psychosocial research that will provide such data necessary to determine behavioral outcomes and to design and evaluate appropriate intervention strategies. The literature on the psychosocial outcomes of other life-threatening chronic conditions should be useful in this endeavor and will enhance research concerned with psychosocial ramifications for blood donors with positive tests.

5.

What impact has testing had on transfusion medicine?

HIV testing has important implications for blood donors, patients, practicing physicians, blood banking operations, and manufacturers of blood products and devices.

Donors

The panel unanimously affirms that the primary means of preventing AIDS and protecting the public health is through the responsible behavior of individuals. Thus, the primary public health measure is education regarding what constitutes risky behavior and ways in which such behavior might be modified. With regard to safety of the blood supply, this responsible behavior consists of persons who are likely to be infected refraining from blood donation. This behavior must be encouraged in every reasonable way. It is our belief that punitive and threatening measures against groups that are at increased risk are counterproductive; they drive individuals away from responsible behavior and make education almost impossible.

Voluntary blood donors have the right to expect confidentiality of records of blood donation and anonymity with respect to the recipient of their blood. They should receive an explanation of tests to be performed, consequences of a positive test, and details of any lists on which their name may be entered.

Two widespread misconceptions regarding HIV infection exist among potential donors. The idea that blood donation places a donor at risk for AIDS is patently false. It is also incorrect that all infected donors will be detected by screening tests. Informational programs to dispel these ideas are needed.

Because of real or perceived social pressures, some persons at risk to transmit HIV may feel compelled to donate blood. Procedures should be adopted by all blood banks to allow donors to indicate confidentially that their blood should not be transfused (self-deferral). Persons at risk for AIDS should be advised through programs of public education not to donate blood.

Alternative test sites should be available to allow anonymous access to testing without the need for voluntary blood donation.

Practicing Physicians

Blood utilization in the United States has declined significantly since 1982, the first such change in more than three decades. Much of this reduction appears to be the result of more judicious use of blood transfusion therapy by physicians. Preoperative autologous blood donation and intraoperative blood salvage have increased significantly and should be encouraged. These developments have reduced patient exposure to homologous blood and reflect good transfusion practice. Efforts should be made to increase the knowledge of practicing physicians about transfusion medicine and to make consultation readily available to them. Recipients should be adequately informed about the risks of blood transfusion. Effective peer review of transfusion practices should be maintained, and recording of the indications for blood transfusion in patient charts should be encouraged. All possible steps should be taken to avoid unnecessary blood transfusion. This is especially critical for neonates, who may be uniquely susceptible to HIV infection.

Blood Banks

There is uniform agreement that autologous blood is the safest form of transfusion therapy. Blood banks and blood centers should make this option available to all qualified healthy people with a scheduled elective operation, simplify the donation process to the extent possible, and inform physicians and patients about the advantages and mechanics of this approach. However, stockpiling of autologous blood without an imminent need should not be countenanced. In some areas, blood banks and blood centers have acceded to requests by individual patients for "directed donations," that is, donations by persons known to the prospective recipients.

Although no evidence was presented to show that directed donations are any more or any less safe than donations from the general public for individual patients, the panel heard persuasive arguments against directed donations based on social and ethical considerations.

Transfusion medicine is emerging as a sophisticated individual discipline. Additional physicians well-trained in this specialty are needed to meet educational needs, assure appropriate transfusion practices, and encourage research and training programs.

Impact on Manufacturers of Blood Products and Devices

The plasma fractionation industry uses large pools of plasma for the preparation of certain lots of clotting factor concentrates. Despite highly sensitive tests for anti-HIV-antibody used to screen individual units of plasma, final products may contain infected units not detected by these assays. Reasonably successful methods have been developed to inactivate virus in these products. Recent reports of HIV seroconversion in previously seronegative hemophiliacs receiving heat-treated factor VIII concentrates suggest the need to develop better procedures for removal or inactivation of virus. Production of certain clotting factors by recombinant DNA techniques and by monoclonal antibody methods is now in progress and should be encouraged.

Devices have been developed to salvage patients' blood during operations, following trauma, and in other selected conditions. Recognizing the advantages of autologous blood, the panel recommends that industry continue to improve blood salvage devices.

6.

What research directions should be pursued?

It is remarkable that in the few years since AIDS was recognized, the human immunodeficiency virus has been characterized and tests for specific antibody have been developed and implemented for the protection of blood donors and transfusion recipients. However, the ELISA screening tests in current use fail to detect some infectious donors and yield positive reactions with many donors who are HIV-negative. It is essential that more sensitive tests be developed to detect low levels of antibody. Highly specific confirmatory tests capable of distinguishing false positive from true positive reaction and that can be performed in a blood center are also required. In the early stage of HIV infection, virus may be present without antibody. In rare individuals with infection of longer duration, antibody levels may be too low to be detected with any test. Highly specific methods for detecting HIV in donor blood are available, but these are time-consuming, expensive, and lacking in sensitivity. Since direct detection of virus offers the most specific way of identifying donors who carry HIV, emphasis should be placed on the development of improved methods for detecting the HIV genome and virus-specific proteins in blood samples.

No definitive measures are yet available to predict which persons infected with HIV will develop AIDS, and much remains to be learned about modes of infection and the best ways of preventing the spread of HIV to personal contacts. Longitudinal studies of seropositive persons are needed to define outcomes in these individuals. Even in the absence of a cure for AIDS, better information on these issues would be invaluable to blood transfusion recipients and those carrying HIV.

AIDS presents enormous challenges for psychosocial research. Persons in high-risk groups must be informed about the danger of transmitting HIV by transfusion and persuaded to comply with blood donor regulations. Effective methods of counsel and support for HIV-positive persons should be characterized and implemented. Considering that the next great threat from AIDS may come from heterosexual spread, means should be found to educate young, sexually active persons about the hazard of AIDS and the changes in behavior required to reduce the risk of contracting or transmitting this disease.

Since no methods of donor screening are likely to eliminate all risk of HIV transmission by blood, better methods of inactivating or removing HIV from blood products, especially those produced from plasma pooled from many donors, should be sought. Production of such products by recombinant DNA methods eventually should eliminate the risk of transmitting HIV and other infections with them.

Finally, and most obviously, the extensive efforts now under way to develop effective therapeutic agents for AIDS and methods for immunization against HIV should be sustained until these goals are achieved.

Conclusions

Remarkable progress has been made in applying the fruits of basic research to the development and

detection of antibodies against HIV in blood collected for transfusion. Although test sensitivity is constantly improving, there is never a perfect test and exclusion of possible infected donors remains important. A procedure should be adopted by all blood banks to allow donors to indicate confidentially that their blood should not be transfused (self-deferral).

As a result of the policy of minimizing the chances of positive blood slipping through the screen, false positive tests will always occur. Extra efforts will be required to reassure donors and to salvage blood now discarded because of a false positive reaction.

Confirmed positive tests mean that the donor is infected and has an unknown but real chance of developing AIDS. Disease will continue to be recognized in those who received infected blood before universal testing began and in the rare instance of transfusion of a blood product that for whatever reason falsely tested negative.

A policy of protection of the individual donor's privacy should be vigorously pursued; however, blood banks must be responsible for properly informing the individual and arranging for counseling. Much needs to be learned about the short- and long-term psychosocial adjustment problems of healthy people who are told they have an infection that may prove life-threatening.

Every aspect of the problem requires continuing research. More sensitive tests that more specifically identify infectivity must be developed and tested in epidemiologically sound ways. Better methods of discouraging possibly infected donors and handling the psychological problems occurring in those with positive tests must be discovered through sound research projects.

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