EPIDEMIOLOGY SECTION

Connecticut Epidemiologist

STATE OF CONNECTICUT DEPARTMENT OF HEALTH SERVICES 1985

Douglas S. Lloyd, M.D., M.P.H., Commissioner

Vol. 4 No. 3

PUBLIC HEALTH SERVICE BLOOD SCREENING RECOMMENDATIONS

The U.S. Public Health Service recommended in the January 11, 1985 "Morbidity and Mortality Weekly Report" (MMWR) that all blood used for transfusion or the manufacture of blood products be screened for HTLV-III virus. The proposed method of screening was an ELISA test. Shortly thereafter, the Secretary of the Department of Health and Human Services (DHHS), Margaret Heckler, announced the impending licensure by the FDA of the ELISA test to detect antibodies to HTLV-III as a screening test to be used in blood and plasma centers.

Secretary Heckler also announced that in addition to testing at blood banks and plasma centers, alternative testing sites would be established through, or in cooperation with state and local public health departments and agencies, to provide an alternative to blood banks and plasma centers for those persons wishing to know if they had been infected with HTLV-III.

On February 7, 1985, the Association of State and Territorial Health Officials (ASTHO) -- the organization representing heads of the nation's state health departments and agencies -- convened a meeting in New York City to discuss the impact of these developments on state and local public health departments. At least three issues were of major concern:

1. The large number of individuals expected to have an ELISA test falsely positive and the resultant need for additional information and assistance. It has been estimated that the ELISA test may generate as many as 100,000 to 200,000 false positive results in persons who are truly not infected with the HTLV-III virus.

2. The ability of state and local health departments or others to quickly establish high quality alternate testing and counseling sites.

3. The diversion of scarce resources -- particularly laboratory and infectious disease control personnel -- to work on this program.

Of greatest concern to the nation's state health officers was the large number of false positives expected to be found through comprehensive screening of the nation's blood supply. The recently licensed ELISA test performs as accurately or better than many screening tests now in use by the medical community, (e.g., VDRL). However, unlike most of these other tests, currently no other reliable diagnostic tools are available to confirm the test result. In addition, the state of medical knowledge concerning the meaning of a positive result is limited, especially when no other signs, symptoms or risk factors are present. Simply stated, the long term prognosis for the development of AIDS in a person with antibody to HTLV-III is unknown. Given the very high case fatality rate associated with AIDS and resultant public fear and social stigma, implementation of this test without adequate preparation to respond to the large number of individuals with true and false positives was troubling.

ASTHO Consensus Meeting

In order to prepare themselves and other state and local health departments for the expected reactions to the licensure and widespread use of this test, ASTHO convened a meeting of its executive committee, together with state epidemiologists, private physicians experienced in dealing with AIDS, representatives of city and county health departments, gay rights groups and blood banks to recommend a course of action. The meeting was conducted at the Centers for Disease Control in Atlanta, Georgia, on March 1 and 2, 1985. The CDC also made available its technical staff to assist with the deliberations.

The recommendations in this document are the result of that meeting.

Additional detailed information on the technical aspects of the ELISA test; clinical evaluation of HTLV-III antibody-positive individuals; advice and requirements for blood banks; and laboratory requirements have been made available by the CDC and FDA to all state health departments. In addition, a "Dear Doctor" letter containing notification of licensure of the ELISA test for HTLV-III screening was mailed to all physicians in the country by the FDA. Copies of these materials are available directly from these agencies.

Recommendations

I. GENERAL PRINCIPLES

1. The HTLV-III antibody test is not a test to diagnose Acquired Immunodeficiency Syndrome (AIDS).

2. The HTLV-III antibody test is a useful tool that can assist in protecting the nation's blood supply, and is a valuable test to assist research efforts into the AIDS problem.

3. At the present time, the HTLV-III antibody test has extremely limited utility for purposes other than stated above, and is not a useful screening test for AIDS. The test does not have applicability except in specific medical circumstances. The HTLV-III test should not be used for generalized screening or as a precondition for employment, evidence of insurability, or admission to school or the military.

4. Because of the serious potential for harm to the individual resulting from the HTLV-III antibody test results, great care must be taken to inform the public and health care professionals about limitations in current understanding of the test results and of the entire disease process labeled Acquired Immunodeficiency Syndrome.

5. Information gathered from the testing or counseling of individuals should be kept strictly confidential.

6. State and local health departments, working in concert with the private medical and hospital communities, university systems, blood banks and plasma centers should establish a network and referral system (where not previously established) of physicians and other health care providers with expertise in dealing with AIDS.

7. For purposes of this document, persons tested for HTLV-III antibody will be classified in one of two ways prior to a medical assessment:

   - High Risk: Persons with known risk of exposure to AIDS. This group includes all men who have had sexual contact with another man, intravenous drug users, persons with hemophilia, and other persons who receive blood or blood products (excluding, at this time, immune globulin and hepatitis B vaccine), Haitian immigrants, and persons who have had sexual contact with a person who has AIDS or an AIDS-related condition or who is at increased risk of exposure to AIDS.

   - Low Risk: Persons with no known risk of exposure to AIDS or HTLV-III. This group includes all persons to whom the risk factors listed for the high risk group do not apply.

II. PUBLIC INFORMATION RECOMMENDATIONS

State and local public health departments, in concert with blood banks, plasma centers, commun organizations, and private health care providers, applicable, are urged to take appropriate measures to educate the public about the HTLV-III antibody test. More specifically, it is recommended that:

1. State and local health departments, together with blood banks, plasma centers, private providers and community groups, should strongly urge individuals not to donate blood or plasma for the purpose of determining their HTLV-III antibody status.

2. Where HTLV-III testing is performed in alternate testing sites, state and local health departments should assure that information is provided to the person prior to the test. This information should explain the intended use of the test, its limitations for other purposes, and the potential consequences to the individual of being identified as serologically positive. The statement prepared by CDC and included in this document is a recommended prototype for this information, (also see recommendation IV.(4)).

3. The HTLV-III antibody test is limited in its utility (other than for purposes of screening donated blood) to only a few clinical and research situations as an adjunctive diagnostic test. State and local health departments, blood banks, plasma centers and organi medical groups should urge health care p viders using the HTLV-III antibody test in these rare situations to explain the test's limitations and implications to their patients prior to its use.

III. RECOMMENDATIONS FOR NOTIFICATION OF POSITIVE RESULTS

State and local health departments are urged to work with blood banks, plasma centers, alternative testing sites, private providers, laboratories and others who may be performing anti-HTLV-III testing to assure that no results are released to an individual until the initial HTLV-III positive test result can be repeated. At a minimum, this requires another test on the same sample of blood. The Food and Drug Administration also recommends that a Western blot test be performed. Most laboratories are not capable of performing this test at the present time, but the FDA is requiring manufacturers of the ELISA test to perform the Western blot during the first year after licensure, if requested. (Presumably, a fee will be charged.)

After a test on the initial blood sample has been repeated and is again positive, state and local health departments are urged to:

1. Assure that blood banks, plasma centers a other providers using the HTLV-III test primarily low risk groups communicate information concerning all positive results in person by an individual with an understanding of the implications of a positive test result, and who can explain the additional steps necessary to

assess the meaning of such a positive test results. (See recommendation IV.(1) for the rationale for requiring a personal communication.)

2. Assure that the individual with a positive test result is either provided individualized counseling and medical assessment at the time of initial notification of positive results, or is referred to an organization or health care provider who can provide such counseling and assessment. (See additional requirements for alternative screening programs in Section IV.)

3. Assure that another test is performed on a different sample of blood drawn from the person with a positive test result, whether by providing the service directly or by referral.

4. Assure that if the repeat test is also positive on the second blood sample, a medical assessment and further counseling is offered, either directly or by referral. Included in the assessment and counseling should be the following requirements:

   a. A risk assessment to determine high risk or low risk sexual activity; drug use history, especially intravenous drug use; presence of hemophilia; blood transfusion receipt history; exposure to individuals that are in these high risk groups; and other potential risk factors.

   b. A sign and symptom inventory and clinical assessment, with focus on general systemic problems, including unexplained weight loss, fever, diarrhea, dyspnea and dysphagia.

   c. A physical examination with particular attention to lymph node examination, oral examination for thrush, splenic palpation, genital, rectal and fundoscopic examinations, and special attention to skin or mucous membrane lesions suggestive of Kaposi's sarcoma.

   d. A minimal laboratory examination, including a complete blood count, differential, WBC, VDRL and sedimentation rate. (Enumeration of the T-lymphocyte subset is an expensive test and not felt to be essential in this initial assessment, although in some areas of the country the test may be available at a reasonable cost).

After this medical examination and counseling, patients with repeat positive HTLV-III tests should be divided into two groups:

- High risk -- those persons felt to be at high risk for developing AIDS based on risk assessment or symptoms.

- Low risk -- those persons with no apparent risk factors, normal laboratory and examination findings, and no symptoms.

Further counseling and medical follow-up is indicated for both groups, but as detailed in Sections V and VI, should be different as a result of this evaluation.

IV. RECOMMENDATIONS FOR ALTERNATIVE TESTING SITES

State and local health departments and agencies are strongly urged to work with blood banks, plasma centers, community groups, laboratories and private providers where alternative testing sites are established. The location and assignment of administrative responsibility for alternative sites must be determined within each jurisdiction to best fit local needs and circumstances. Where such sites are established, it is recommended that state and local health departments assure that the following conditions are met.

1. Each person tested for HTLV-III antibody at an alternative site should be provided the results in person from a counselor during a scheduled return visit. A personal presentation of the test results (whether positive or negative) is the only method which:

   - Does not involve potentially serious risk to the privacy of the individual;

   - Permits the counselor to assess the individual's emotional reaction and provides an opportunity for a private and sensitive explanation of the implications of the results; and

   - Permits persons in recognized risk groups for AIDS who have a negative test result to understand the limitation of the test, and to be counseled on methods of reducing their personal risk, and the risk to others, of exposure to HTLV-III.

2. Counselors must be trained and experienced in assessing and responding to people about sensitive and potentially life-threatening issues. Such counselors need not be persons with academic credentials. However, referral relationships with trained professionals should be established.

3. Strictest confidentiality must be maintained. This can be done in a number of ways, including use of the procedures followed for research protocols (including an Institutional Review Board protocol); strict adherence to standard procedures for confidentiality in clinical settings; or use of a patient number rather than name to assure complete record anonymity. No information about an individual should be shared with any other organization or individual without the signed permission of the individual who was tested. However, summary statistical information without individual identifiers should be provided to public health authorities if requested.

4. Persons should be fully informed about the limitations and implications of the test prior to providing the test. In addition, the person should be informed of how the results will be communicated or made available to him/her; how and where the results will be recorded; where the results might be reported; and who

may have access to them. Any possible future uses of the person's name for medical follow-up or research should require a signed consent and should be considered separately to avoid confusion.

5. A record of the information provided to the patient, including counseling when applicable, should be maintained in a confidential patient record containing the results of the HTLV-III testing.

6. All alternative testing sites for antibody to HTLV-III must be medically supervised. In addition, physicians, nurses and mental health professionals with additional specific training should be an integral part of a referral network for any counseling effort.

7. All alternative test sites should have access to a referral list or a system of referral to physicians and other health care providers specializing in treatment of AIDS or AIDS-related conditions, and should establish, to the extent possible, working relationships with these providers.

8. Referral for medical follow-up for all persons with positive test results must be assured, and all persons at an alternative test site wishing further information should be informed of a referral network of health care providers with expertise in dealing with AIDS.

V. FOLLOW-UP RECOMMENDATIONS FOR HIGH RISK INDIVIDUALS WITH REPEAT POSITIVE TEST RESULTS

State and local health departments are urged to work with blood banks, plasma centers, private providers, community organizations and others providing HTLV-III testing to assure that high risk individuals be advised to establish a relationship with a physician who can, by reason of training and experience, continue to evaluate the patient for signs and symptoms of AIDS or related conditions. High risk individuals are defined as persons with known risk of exposure to HTLV-III, or of high risk of acquiring or transmitting the HTLV-III virus as previously defined. It is also recommended that:

1. High risk individuals be advised of the early clinical manifestations of HTLV-III infection, AIDS, and AIDS-related conditions and advised to seek immediate medical attention if any of them occur.

2. High risk individuals be advised that the prognosis for an individual infected with HTLV-III (the probable cause of AIDS) over the long term is not known. However, available studies conducted among homosexual men indicate that most persons will remain infected, but asymptomatic.

3. High risk individuals be advised to seek medical evaluation and follow-up at least twice annually, and more frequently as indicated for an individual who develops signs or symptoms suggestive of HTLV-III infection, AIDS, or AIDS-related conditions.

4. High risk individuals be advised that although the person may be asymptomatic, there is a risk of infecting others by sexual intercourse, sharing needles, and possibly through saliva or exposure through oral-genital contact or intimate kissing. The efficacy of condoms in preventing infection with HTLV-III is unproven, but the consistent use of them may reduce transmission.

5. High risk individuals be advised that blood, plasma, body organs, other tissue or sperm should not be donated.

6. High risk individuals be advised that toothbrushes, razors, or other implements that could become contaminated with blood should not be shared.

7. High risk individuals be advised that children born since 1979 to women with a positive HTLV-III test should be clinically evaluated.

8. High risk individuals who are women, or women who have a high risk sexual partner who has a positive test, be advised that they are at increased risk of acquiring AIDS, and that any offspring is at increased risk of acquiring AIDS.**

9. High risk individuals be advised that in the absence of close or intimate contact, household contacts need not be referred for testing at this time.

10. High risk individuals be advised that after accidents resulting in bleeding, contaminated surfaces should be cleaned with household bleach freshly diluted 1:10 in water.

11. High risk individuals be advised that devices that have punctured the skin, such as hypodermic and acupuncture needles, should be steam sterilized by autoclave before reuse or safely discarded. Whenever possible, disposable needles and equipment should be used.

12. High risk individuals be advised that when seeking medical or dental care for illness, they should inform those responsible for their care of the positive HTLV-III results so that appropriate evaluation can be undertaken and precautions taken to prevent transmission to others.

13. High risk individuals be advised that most persons with positive HTLV-III test results need not consider a change in employment. However, those persons whose work involves significant potential of exposing others to his or her blood or other body fluids should, at a minimum, be advised to act prudently and take precautions such as wearing gloves.

14. High risk individuals be advised that when they are employed in medical, dental or other health care professions and performing invasive procedures or if they have skin lesions, should take precautions similar to those recommended for hepatitis B to protect their patients from the risk of infection.

15. High risk individuals be advised that any sexual or needle-sharing partner of a person with a positive test should be advised to seek clinical evaluation of potential risk factors, symptom history, and physical findings.**

**Because there was no current consensus on recommendations 8 and 15, these decisions should be left to the discretion of the evaluating physician.

VI. FOLLOW-UP RECOMMENDATIONS FOR LOW RISK INDIVIDUALS WITH REPEAT POSITIVE TEST RESULTS

State and local health departments are urged to work with blood banks, plasma centers, private providers, community organizations and others providing alternative testing and counseling sites to assure that low risk persons with repeat positive HTLV-III antibody tests be provided with counseling. These persons are defined as those with repeat positive results who are not members of known risk groups, have no signs or symptoms of immune deficiency disease, and have a normal physical and laboratory examination. It is recommended that:

1. Low risk individuals be advised about interpretation of these test results. This should include an understanding that the prevalence of false positives in the low risk group may be high, and that the patient's particular result may be of questionable significance. The person should also understand that a positive test -- if it is not a false positive -- measures only antibodies to the virus which may indicate past or present exposure to HTLV-III or a related virus. In addition, the person should be counseled that he/she does not appear to have AIDS, and that the risk of developing AIDS in the future, if the test is not a false positive, is small.

2. Low risk individuals be advised that, as a precautionary measure, they should not donate blood, plasma, sperm or body organs.

3. Low risk individuals be advised that if no known risk factors are present, currently there is insufficient evidence to warrant a broad restriction on sexual relations. However, advice on sexual relations and practices should be individualized.

4. Low risk individuals be advised that until more is known about the status of a positive test in a low risk population, that testing the patient's regular sexual partner may provide better or more information to determine if the test result may be a true or false positive. However, testing of other family members of low risk patients is not advised.

5. Low risk individuals be advised that there is insufficient evidence to warrant advising blanket postponement of pregnancy at this time. However, each circumstance should be carefully evaluated.

6. Low risk individuals be advised that they should notify their personal physicians and dentists that they have had repeat positive HTLV-III screening tests but were considered as having no known risk of exposure to AIDS.

7. Low risk individuals be advised there is no need for any restrictions on employment, education, or other social contacts.

8. Low risk individuals be advised that additional counseling or referral is available if they have further questions or concerns.

9. Low risk individuals be advised to seek medical follow-up assessment within six months in order to identify any potential changes in their medical status or recommendations.

The nine recommendations above apply only to individuals who have no abnormal physical or laboratory findings other than repeat positive HTLV-III tests, and are not in a known risk group for acquiring AIDS. All other individuals with repeat positive HTLV-III tests, whether with known risk factors (including being a sexual partner of a person in a high risk group) but otherwise free of findings, or with no known risk but some clinical findings, should be counseled as "high risk" patients. There will be cases where low risk individuals desire to know all recommended precautions concerning the transmission of HTLV-III infection, AIDS, and AIDS-related conditions. In these cases, it is suggested that the recommendations for high risk individuals also be given to the individual. In addition, where the individual clinician is uncertain as to the risk status of the person who has been tested, it is suggested that both sets of recommendations be given to the individual.

Suggested Information to be Provided
Prior to Testing at Alternative Test Sites
(Centers for Disease Control)

(For use by physicians and clinics in counseling individuals BEFORE testing at alternative sites. You should know whether laws in your state require reporting of positive test results to the State Health Department when advising persons requesting the test.)

WHAT IS THE ANTIBODY TEST FOR HTLV-III?

This is a test to identify antibodies to the HTLV-III virus; it is not a test to detect the virus itself. When a person is infected by a virus, the body's immune system normally begins to fight the infection through white blood cells which produce substances called antibodies. Antibodies, therefore, indicate that a person has been infected by a specific virus. Antibodies to the HTLV-III virus may indicate that the virus is still present. Research has shown that antibodies to the virus are frequently found in the blood of persons who have AIDS or AIDS-related conditions, and in members of high risk groups.

WHAT IS AIDS?

Acquired Immunodeficiency Syndrome (AIDS) is a serious disease which reduces the body's ability to fight certain infections. Over the past several years, increasing numbers of persons have developed

the disease. The HTLV-III virus is the cause of AIDS. A blood test to detect antibodies to this virus is now available.

WHY IS THE ANTIBODY TEST BEING USED?

The primary purpose of this new antibody test is to screen blood and plasma that are donated for transfusion or for production of blood products. Because a positive antibody test means that a person has probably been infected with the HTLV-III virus, it is now possible to use the test to identify blood which should not be used for transfusion. By not using this blood, transfusions will be safer by keeping other people from being exposed to the AIDS virus.

SHOULD I BE TESTED FOR HTLV-III ANTIBODY?

You should consider the following factors, and discuss your particular situation with your physician in attempting to answer this question:

- A positive antibody test, if it's a true positive, indicates infection with HTLV-III -- the virus that causes AIDS. However, only a portion of persons with HTLV-III antibodies have AIDS.

- An antibody test does NOT identify the HTLV-III virus and cannot be used to diagnose AIDS. Nor can the test totally exclude infection with HTLV-III, the virus that causes AIDS.

- Antibody test results are difficult to interpret, especially when the positive test occurs in a healthy person who is not in a high risk group for AIDS.

- A negative test result in a member of a high risk group does not guarantee that the person has never been infected with the virus or is not currently infected with the virus.

- A positive antibody test result can have a significant psychological impact on both the person tested and those who are close to him or her. At the present time, the consequences for persons who are infected with HTLV-III are unpredictable, since no treatment is currently available for the infection.

- It has been suggested by some that insurance companies or employers may seek information about positive test results as a condition of coverage or employment.

- In some states, positive test results may have to be reported to the State Health Department.

Alternating Tesiting Sites in Connecticut

It has been decided to initially limit approval to perform HTLV-III testing in Connecticut to laboratories which comply with the following requirements. To receive approval, laboratories will be required to submit a protocol to the Commissioner of Health. Protocols must include methods for 1) obtaining informed consent from each individual tested, 2) assuring availability of another test method to confirm positive ELISA test results (the Western Blot test at the present time), 3) provision of pre- and post-test counseling, and 4) maintaing confidentiality of patient information during the testing and reporting process. Protocols must be approved by the Department of Health Services and by the human investigations committee at the laboratory's institution. An emergency regulation on restriction on the performance of HTLV-III antibody testing has been developed to enforce these requirements.

Information describing protocol requirements have been sent to directors of all approved hospital and licensed independent clinical laboratories. A list of laboratories approved to perform HTLV-III testing will be available through the Epidemiology Section (566-5058).

James L. Hadler, M.D., M.P.H., Chief Matthew L. Cartter, M.D.
Patricia J. Checko, M.P.H., Editor
Leonard Gilmartin, Coordinator, Public Health Education Section

EPIDEMIOLOGY SECTION
PREVENTABLE DISEASES DIVISION
State of Connecticut Department of Health Services

150 Washington Street
Hartford, CT 06106

Bulk Rate
U.S. Postage
PAID
Permit No. 4313
Hartford, Conn.