Blood Donor Screening for Chagas Disease --- United States, 2006--2007

Chagas disease, a zoonotic disease caused by the bloodborne parasite *Trypanosoma cruzi*, affects an estimated 11 million persons throughout much of Latin America. In endemic areas, *T. cruzi* is transmitted primarily by triatomine insects (i.e., kissing bugs); infection also can occur via blood transfusion, congenital transmission, organ transplantation, laboratory incident, and ingestion of triatomine-contaminated food or drink (1). To evaluate an investigational assay for detecting *T. cruzi* infection in blood donations, the American Red Cross conducted a clinical trial during August 2006--January 2007, screening 148,969 blood samples at three blood-collection centers in the United States. In January 2007, after the new assay was licensed by the Food and Drug Administration (FDA), other centers began screening donors for *T. cruzi*. This report describes the results of the American Red Cross study, which identified 32 donations (approximately one in 4,655) as confirmed positive for *T. cruzi* antibodies. As blood-donation screening for Chagas disease becomes more widespread, public health officials and health-care providers should anticipate increased numbers of questions regarding the diagnosis, evaluation, and management of Chagas disease.

Chagas disease has an acute stage, typically asymptomatic or with mild symptoms (e.g., fever, malaise, swelling at the site of inoculation and lymphadenopathy) during the first 6--8 weeks after infection. If not treated, infection is lifelong with low-level, intermittent parasitemia. The majority of infected persons remain asymptomatic in the chronic indeterminate phase (i.e., a prolonged period of clinically silent infection that follows acute primary infection). However, an estimated 30% will have onset of chronic symptomatic disease, usually decades after the initial infection, with cardiac manifestations (e.g., cardiomyopathy, arrhythmias, and sudden death) or gastrointestinal involvement (e.g., megaesophagus or megacolon).

In the United States, vector-borne transmission of Chagas disease is rare (2). However, one study revealed an increasing Chagas seroprevalence among blood donors in Los Angeles County, California, from 1996 (one in 9,850 donors) to 1998 (one in 5,400 donors) (7). In 1991, a questionnaire was introduced to screen blood donors; those reporting a history of Chagas disease are deferred, but most persons with Chagas disease likely are unaware of their infections. Seven cases of transfusion-associated transmission have been documented in the United States and Canada during the past 20 years; all occurred in immunosuppressed recipients (3--6). Because acute infections often are asymptomatic and the level of awareness of Chagas disease among clinicians is low, cases of transfusion-associated transmission can go undetected.

In 2005, a new commercial test for blood-donation screening for Chagas disease was developed. The test, manufactured by Ortho-Clinical Diagnostics (Raritan, New Jersey), is an enzyme-linked immunosorbent assay (ELISA) that uses epimastigote lysate antigens for detection of antibodies to *T. cruzi* in serum and plasma (8). In clinical trials evaluating the test, including the American Red Cross study, blood donor specimens with initially reactive results were retested twice and considered repeat
reactive if one or both of the repeat tests were reactive. Repeat reactive specimens from the clinical trials underwent further testing using a radioimmunoprecipitation assay (RIPA); those with positive RIPA results were considered confirmed positive. However, FDA has not licensed a supplemental test as a confirmatory assay in blood donation screening for T. cruzi antibodies.

After a clinical trial in 2005 with approximately 40,000 blood donors resulted in only one repeat reactive specimen (which tested negative with RIPA) (8), the American Red Cross conducted a larger study of the new screening assay in areas where Chagas was expected to be more prevalent. The study was conducted in three collection facilities of the American Red Cross, including the Southern California Region (Los Angeles, California), the Northern California Region (Oakland, California), and the Arizona Region (Tucson, Arizona). Blood donations collected during August 28, 2006--January 28, 2007, were tested with the screening assay for those blood donors willing to participate in the study. All donors were asked to participate; 78.5% agreed, and their specimens were tested.

A total of 148,969 blood-donation specimens were tested; 63 specimens from 61 donors were repeat reactive for T. cruzi antibodies (approximately one in 2,365 donations). Among the 61 donors with repeat reactive specimens, 40 (66%) were male; the age range was 17--84 years, with a mean age of 47 years and a median of 50 years. Of the 63 repeat reactive specimens, 50 (79%; one in 1,993 donations) were collected from the Los Angeles center, nine (14%; one in 3,258 donations) were collected from the Oakland center, and four (6%; one in 5,995 donations) were collected from the Tucson center. Fifty-five (90%) of the 61 donors were allogeneic donors; the remaining six included five autologous donors (two with two reactive donations each) and one directed donor. Of the 55 allogeneic donors, 18 (33%) were first-time donors, and 37 (67%) had donated blood previously. All of the 63 repeat reactive donations were tested with RIPA, of which 32 (51%) were positive and 31 (49%) were negative.

On December 13, 2006, based in part on preliminary results from the American Red Cross study, FDA licensed the Ortho T. cruzi ELISA Test System to screen blood donors in the United States. The new assay also is labeled for testing plasma and serum samples from living cell and tissue donors and from heart-beating organ donors, but is not labeled for general clinical diagnostic use.

Reported by: SL Stramer, PhD, American Red Cross, Gaithersburg; RY Dodd, PhD, DA Leiby, PhD, American Red Cross, Rockville, Maryland. RM Herron, MD, American Red Cross, Los Angeles; L Mascola, MD, Los Angeles County Dept of Public Health; LJ Rosenberg, MD, California State Health Dept. S Caglioti, Blood Systems Laboratories, Tempe; E Lawaczeck, DVM, RH Sunenshine, MD, Arizona Dept of Health Svcs. MJ Kuehnert, MD, Div of Health Care Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases (proposed); S Montgomery, DVM, C Bern, MD, A Moore, MD, B Herwaldt, MD, Div of Parasitic Diseases, National Center for Zoonotic, Vector-Borne, and Enteric Diseases (proposed); H Kun, PhD, JR Verani, MD, EIS officers, CDC.

Editorial Note:

Findings from the American Red Cross study described in this report provided evidence to support FDA approval of the first blood donor screening test for Chagas disease in the United States. Use of this test by blood centers to screen for T. cruzi antibodies is not required. However, both the American Red Cross and Blood Systems, Inc., blood-collection organizations that are responsible for approximately 65% of the U.S. blood supply, began screening all donations for T. cruzi on January 29, 2007, and providing testing services for smaller blood-collection centers and hospitals that requested testing. FDA is expected to recommend implementation of the test by all blood-collection establishments.

The AABB (formerly known as the American Association of Blood Banks) has issued recommendations to its member facilities regarding how to use the new test.* AABB recommends that all components from blood donations that are repeat reactive by the ELISA test should be quarantined
and removed from distribution, and the donor should be deferred from making donations indefinitely. Recipient tracing should be conducted to identify and test recipients of blood components collected previously from donors who are confirmed positive (i.e., repeat reactive by ELISA and positive by RIPA). AABB also suggests testing at-risk family members of donors who are confirmed positive or family members with a similar history of exposure to vectors in an endemic area (e.g., the children of seropositive women). Deferred donors, at-risk family members, and potentially infected recipients should be referred to health-care providers for evaluation and management.

Screening blood donations for *T. cruzi* antibodies can identify persons with previously undiagnosed Chagas disease and further enhance the safety of the U.S. blood supply. However, as with any screening test, limitations exist. Although available data regarding the performance of the new assay have suggested high sensitivity and specificity (8,9), some false-negative results have occurred with this assay (8) and with other assays used to screen for *T. cruzi* antibodies (10). In addition, when a screening assay is used in a population with low disease prevalence, a greater proportion of false-positive results can be expected. Donors with reactive screening assay results require further clinical diagnostic testing to verify *T. cruzi* infection and to guide clinical management.

For clinical purposes, no single laboratory test is adequately sensitive and specific to diagnose Chagas disease. Diagnosis generally is made by using at least two different serologic tests (e.g., diagnostic ELISA tests, immunofluorescence assay, or indirect hemagglutination) (1) and by considering clinical findings and exposure risk. Clinical diagnostic testing for Chagas disease is available through commercial laboratories and the Division of Parasitic Diseases (DPD) at CDC. After diagnosis, health-care providers should conduct a thorough clinical evaluation to determine the stage of disease, develop an appropriate treatment plan, and provide information regarding prognosis. CDC is preparing guidance for the clinical evaluation, staging, management, and treatment of patients with Chagas disease.

Cases of Chagas disease likely will be increasingly identified as a result of screening blood donors for infection with *T. cruzi*. In addition, requests for diagnostic testing might become more frequent as awareness of Chagas disease increases among clinicians and the general public. Most identified cases likely will represent chronic infections that were acquired years earlier.

Chagas treatment options are limited and are most effective during the acute stage of infection. However, increasing evidence suggests that treatment of persons with chronic infections can result in seroreversion and prevent progression of cardiac morbidity (1). Treatment of women of childbearing age with Chagas disease can decrease the risk for congenital transmission. Antitrypanosomal medication in the United States is currently available only through CDC under an investigational new drug protocol.

Questions regarding laboratory diagnosis, evaluation, and management of Chagas disease can be posed to DPD by telephone, 770-488-7775. Additional information regarding Chagas disease is available at [http://www.cdc.gov/ncidod/dpd/parasites/chagasdisease/default.htm](http://www.cdc.gov/ncidod/dpd/parasites/chagasdisease/default.htm).

**References**

American Society of Hematology, San Francisco, California; December 1--5, 2000.

* Available at http://www.aabb.org/content/members_area/association_bulletins/ab06-08.htm.

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