



Advancing Transfusion and
Cellular Therapies Worldwide

**Blood Products Advisory Committee
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Approaches to Blood Donor Deferral for Travel to Malarious Areas

**Steven Kleinman, MD
AABB Transfusion Transmitted Diseases Committee**

AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For more than 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, and developing and delivering programs and services to optimize patient and donor care and safety.

The AABB Transfusion Transmitted Diseases Committee – that includes representatives from other blood, plasma and tissue organizations such as American Association of Tissue Banks, American Red Cross, America's Blood Centers, Armed Services Blood Program Office, Plasma Protein Therapeutics Association – is charged with monitoring the status of current and emerging infectious diseases that could be transmitted through transfusion or tissue or cellular transplantation, to include tests and screening procedures for infectious diseases and potential adverse outcomes for patients, and re-entry protocols that would return deferred blood donors to the eligible donor pool. We appreciate the opportunity to comment today on the issue of donor deferral for travel to malarious areas.

Transfusion-transmitted malaria is very uncommon in the United States, with only two definitive cases reported since 1999. However deferral for travel to malarious areas is the second most frequent cause of deferral, exceeded only by unacceptable hemoglobin levels. In a recent publication, Leiby has shown that, for the period 2000-2006, the American Red Cross deferred an average of 41,000 donors each year for travel to malarious areas, but only 3,900 for residence in such areas, and 90 for a history of malaria. Since the Red Cross collects about 45% of blood in the US, we believe that travel deferrals would result in the loss of approximately 100,000 donors and all of their donations every year. REDS-II data for 2006 project that this number may be as high as 150,500 donors. Similarly, in a survey of 52 ABC blood centers in the US (presented by

8101 Glenbrook Road
Bethesda, MD 20814-2749
301.907.6977 MAIN
301.907.6895 FAX
www.aabb.org

Dr. Bianco), 72,437 donors were deferred in 2007 due to travel to a malarial area; this projects to greater than 140,000 donors annually in the entire US. Travel deferrals appear to be increasing at a rate of 3.5% annually. Based on ARC data, once a first-time donor is deferred for malaria-related travel, he or she has only a 22-25 percent chance of returning for future donation (Leiby et al, Transfusion in press). In addition, the donor questions related to travel to malaria endemic areas are confusing for the health historians who administer the questions in regards to the detail required for proper decisions in specific geographic locations (e.g., 7 states in Mexico have a city named Monterrey of which 4 are considered malarious and 3 are not). Further, these questions are often answered incorrectly by donors and thus are a frequent source of post-donation information resulting in regulatory risk to the collection organization.

Recent studies (REDS-II data) indicate that 41 percent of all travel deferrals are for travel to Mexico, and a further 22 percent for travel to Central America. However, Mexico accounts for only 0.6% percent of imported cases of malaria and Central America for 6 percent. In contrast, Africa and Asia, although representing only 3.7 and 15.3 percent of deferrals, are the source of 71 and 11 percent of all imported malaria cases. The relative risk of transfusion malaria from donors traveling to Africa or Asia is respectively 1116 and 129 as compared to that for travelers to Mexico. Finally, only a very minor proportion of actual cases of transfusion malaria (3 of 64 in the past 45 years) are attributable to US civilian travelers to any region: all recent cases have been traced to former residents of malarious areas (Mungai et al., NEJM 2001).

The TTD Committee strongly supports the approval of alternative approaches to assuring the safety of the blood supply from malaria. We appreciate the FDA's willingness to consider reducing the deferral period by the use of a serologic test, but believe that this approach does not go far enough and that it is unlikely to substantially increase blood availability. Another downside to a decrease in the deferral period by the use of testing of deferred donors is the additional complexity added to an already extremely complicated system of varying donor deferral periods for travel, residence or having had malaria. Furthermore, we are concerned that limited testing would discourage manufacturers from making the investment necessary to develop and license tests with appropriate properties for donor and product management

Based on published data and the data presented today, we believe that it is time to give serious consideration to different approaches for preventing transfusion-transmitted malaria. We have heard data showing that the risk of malaria transmission from casual travelers is minimal and that Mexico in particular offers the lowest risk. We believe that these data support the elimination of the deferral period for travel to malarial endemic areas of Mexico popular among travelers and perhaps other selected countries. Any incrementally small increase in transfusion-transmitted malaria risk could be offset by strengthening deferral policies that are applied to those donors who are the source of almost all transfusion-transmitted malaria cases; e.g., consideration could be given to permanently deferring donors with a history of malaria (absent proof of curative therapy) and/or lengthening the deferral period for former residents of high-endemicity malarious areas.

In conclusion, we believe that it is time for a full consideration of creative new approaches to the mitigation of transfusion-transmitted malaria that reflect its current epidemiology and transfusion-transmission risk in the US. The motivation for this change is multifactorial. It includes an analysis of existing differential risks, the extremely low specificity of deferrals for specific geographic areas with a very low risk of malaria and the urgent need to simplify the existing deferral policies. Our interim suggestions should serve as the basis for a broader discussion.