

Date: July 26, 1994

From: Director, Center for Biologics Evaluation and Research

Subject: Recommendations for Deferral of Donors for Malaria Risk

To: All Registered Blood Establishments

Transmission of malaria remains a rare, but medically serious risk of transfusion. Since 1958, blood establishments have deferred donors based on exposure history and previous illness to minimize this risk. The current standards accepted by the Food and Drug Administration (FDA), in use since 1974, are listed in FDA's inspection guidelines, Instruction Booklet for Blood Bank Inspection Checklist and Report, Form FDA-2609, May 1991.

Surveillance studies conducted by the Centers for Disease Control and Prevention (CDC) since 1974 indicate no change in the frequency of transfusion-transmitted malaria, estimated at 0.25 cases per million blood units collected, compared with the experience under previous donor deferral practices (1). Nevertheless, recently obtained scientific data have led some researchers and the American Association of Blood Banks to reexamine the current standards (2,3) and propose revised standards for donors at risk for malaria.

FDA's Blood Products Advisory Committee discussed the issue of revising donor deferral standards for malaria at the June 29, 1993, meeting. Consistent with the Committee's opinion, FDA's recommendations for deferring blood donors at increased risk for malaria follow:

1. Permanent residents of nonendemic countries who travel to an area considered endemic for malaria by the Malaria Branch, CDC, U.S. Department of Health and Human Services, should not be accepted as donors of whole blood and blood components prior to 1 year after departure from the endemic area. After 1 year after departure, such otherwise suitable prospective donors may be accepted provided that they have been free of unexplained symptoms suggestive of malaria and regardless of whether or not they have received antimalarial chemoprophylaxis.
2. Prospective donors who have had malaria should be deferred for 3 years after becoming asymptomatic.

3. Immigrants, refugees, citizens, or residents of endemic countries should not be accepted as donors of whole blood or blood components prior to 3 years after departure from the area. After the three year period, otherwise suitable prospective donors may be accepted if they have remained free of unexplained symptoms suggestive of malaria.

These recommendations apply only to donations containing intact red blood cells. Donations used for preparing plasma, plasma components or derivatives devoid of intact red blood cells are excluded.

Because there are no approved tests to screen donated blood for malaria, careful questioning is essential for identifying prospective donors at risk for transmitting malaria. Blood establishment personnel should carefully elicit the necessary information regarding travel and disease history in order to defer those at risk. When more than one deferral period applies to a donor, the longest period of deferral should go into effect.

Blood establishments should promptly implement these recommendations for all new donors.

Questions about these recommendations may be directed to the Division of Transfusion Transmitted Diseases, Telefax number (301) 594-6989.

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References:

1. Guerrero I, Weniger B, Schultz M. Transfusion malaria in the United States, 1972-1981. Ann Intern Med 1983;99:221-226.
2. Sazama K. Prevention of transfusion-transmitted malaria: Is it time to revisit the standards? Transfusion 1991;31:786-788.
3. Nahlen B, Lobel H, Cannon S, Campbell C. Reassessment of

blood donor selection criteria for United States
travelers to malarious areas. Transfusion 1991;31:798-
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