



Current deferral policies to reduce the risk of transfusion-transmitted malaria and their impact on donor availability

FDA Workshop on Testing for Malarial Infections in Blood Donors

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Alan E. Williams

**Director, Division of Blood Applications
Office of Blood Research and Review, CBER**



Malaria Risk Deferral – Current Policy

- July 26, 1994 Guidance:
- *Recommendations for Deferral of Donors for Malaria risk*
- Deferral for 1 year:
 - Residents from non-endemic area who travel to endemic areas as defined by Malaria Branch, CDC.
- Deferral for 3 years:
 - If donor had malaria, defer for 3 years after becoming asymptomatic.
 - Immigrants, refugees, citizens or residents of malaria endemic countries defer for 3 years after departure (Note: Guidance does not define residence)
- Recommendations apply only to donations containing intact red cells.



Blood Products Advisory Committee

June 18, 1999

- Considered exemption for daylight travel, including travel to Mexico (cruises and resorts)
 - rural vs urban and dusk to dawn distinction would increase subjectivity of donor screening questionnaire
 - cannot rule out mosquito exposure during fringes of daylight hours

“ Do the Committee members support a change in the current blood donor policy to allow for travel endemic for malaria when travel exposure was limited to hours of bright daylight?”

Yes - 5; No - 9



June, 2000 Draft Guidance: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria

Proposed that July 26, 1994 recommendations be modified:

- Residence defined as 5 years in endemic country
- Specific donor travel questions provided (including capture questions and follow-up of travel history)
- Time-of-day and rural/urban exposures not distinguished
- Immigrants, refugees, citizens or residents of malaria endemic countries deferred for 3 years after last visit to endemic country.



Blood Products Advisory Committee

March 15, 2001

- Are the available data sufficient to conclude that it is safe to prepare frozen plasma products for transfusion despite a history of malaria risk in the donor
 - Plasma prepared by separation from whole blood 5 yes/ 10 no
 - by automated apheresis 9 yes/4 no
 - by Autopheresis C 10 yes/ 5 no
 -
 - Continue to allow use of FFP when donor PDI indicates a history of malaria risk 14 yes/1 no



Malaria Risk Deferral - Current Considerations

Propose that July 26, 1994 recommendations be modified:

- Countries defined as endemic for malaria may have malaria and non-malaria areas
- Residence defined as one continuous year in endemic country
- Travel exposure based on travel to endemic area
- Recommendation for specific donor travel questions removed
- Interorganizational TF Donor History Questionnaire accepted by FDA for donor screening
- Time-of-day and rural/urban exposures not distinguished
- Immigrants, refugees, citizens or residents of malaria endemic countries deferred for one year after last visit to endemic country (similar to residents of non-endemic countries)
- References <http://www.cdc.gov/travel/regionalmalaria/index.htm>



Malaria Risk Deferral - Current Considerations (cont.)

Revised recommendations will again be published as draft Guidance

Applies to:

- Cellular blood components for transfusion, immunization of Source Plasma donors, or manufacture of injectable products
- Plasma processed from Whole Blood or collected by apheresis and intended for transfusion or for the preparation of Cryoprecipitated AHF.

Does not apply to Source Plasma



Estimated Donor Loss Due to Malaria Deferral

- 1.2% loss of donors for potential malaria exposure (range 0.2 - 3.1%) (2006 ABC survey)
 - > 120,000 - potential donors/year known to be deferred; representing up to 180,000 donations (self-deferral higher)
 - Deferred donors are difficult to re-recruit (Vox Sang (87) 2004, (150-155).
 - Deferrals reflect increased travel to malaria-endemic countries not previously frequented (e.g. Vietnam)
 - Travel deferrals may impact repeat donors disproportionately - impact on donor base is cumulative
 - Travel deferrals may impact male donors age 25-39 disproportionately
 - (Transfusion (44) October, 2004



Screening Challenges

- Travel histories are difficult to obtain precisely
- Definition of residency has been vague
- Donor screening does not capture all exposure possibilities
(Is airport malaria a transfusion-transmitted malaria risk?
Transfusion 2001 (41); 301.)
- No test approved for re-entry of malaria-deferred donors in US
- Absence of up-to-date mapping utility for malaria risk areas
- Post-donation information (est 10,000/yr.) triggers costly operational measures including product retrieval and quarantine, consignee notifications, BDR submissions)
- Endemic areas are subject to change



CDC Recommendation for Malaria Chemoprophylaxis for Travelers to Great Exuma Island, Bahamas

- Eighteen cases of *P. falciparum* malaria identified June 8-19, 2006 (Four in travelers). No cases since June 19th.
- Previously, one case in past six years
- CDC recommends chloroquine prophylaxis for travelers (expected to be temporary)
- 12 month deferral for donor travel to Great Exuma, Bahamas after April 1, 2006 (AABB Latest News 6/19/2006)

