

Blood Products Advisory Committee
March 16, 2001

Topic IV. Guidance on Malaria: Applicability to Plasma

Issue:

Is there a significant risk of malaria from transfusion of frozen plasma products collected from donors at risk for malaria?

Background:

Currently, the Code of Federal Regulations [640.3b6] prohibits the collection of whole blood and blood components from donors at risk for malaria. This is not true for Source Plasma for further manufacture, where malaria risk is excluded from donor criteria, however plasma derivatives are processed in a manner that eliminates parasites. Historical data suggest that the risk of transfusion-transmitted malaria from frozen plasma products is low, if it exists at all.

In a draft guidance document published on January 13, 2000, FDA proposed updated recommendations for deferral of donors with risk of malaria to be applicable to “donations containing intact red blood cells or platelets.” In preparing to issue its final guidance, FDA needs to clarify its policy on use of frozen plasma products when a donor has risk of malaria.

Issues for Discussion:

In a request for variance from the CFR, the FDA has been asked to review its current policy of requiring plasma donors to be deferred if they have traveled to a malarious area. The specific request asks that donors at risk for malaria be allowed to donate plasma products by a specific automated apheresis method using the Autopheresis C device. These products will be frozen and thawed prior to use for transfusion. These products include Fresh Frozen Plasma and Cyroprecipitate. It is also requested that use of apheresis plasma, relabeled as recovered plasma (for further manufacturing), also be permitted in the face of malaria risk. FDA therefore seeks to clarify whether it should permit exemptions to the regulations to permit collection of blood and components to make frozen plasma products despite malaria risk in the donor.

Currently, when a post donation information (PDI) report of malaria risk is received, the the FDA requires removal from inventory and distribution of any cellular components or fresh (never frozen) plasma products, consistent with guidance published in an FDA memorandum dated July 26, 1994. However, in its 1994 guidance, the Agency did not explicitly recommend the removal from inventory or distribution of frozen plasma products, and some centers have released these products for transfusion. Consistent with the CFR, a donor history positive for malaria risk would have precluded collection of

blood components. FDA therefore seeks to clarify whether it should continue its current policy that allows these products to remain in inventory and be released for transfusion.

Presentations:

The issue to be discussed is the malarial risk for frozen plasma products for transfusion, the laboratory and epidemiological evidence for and against that risk, and the practical effect of the FDA policy on product availability.

Questions for the Committee:

1. Are the available scientific data sufficient to conclude that it is safe to prepare frozen plasma products for use in transfusion despite a history of malaria risk in the donor
 - a) When the plasma is prepared by separation from whole blood?
 - b) When the plasma is prepared by automated apheresis (any method)?
 - c) When the plasma is prepared by apheresis using the Autopheresis C device?

2. Balancing the risks and the impacts on supply, should FDA continue its current policy to allow use of frozen plasma products for transfusion when the donor provides post-donation information positive for malaria risk?