

# Plamapheresis from donors deferred for Malarial travel

Variance request from Memorial  
Blood Centers of Minnesota  
(MBCM)

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# Current Malarial Deferral Criteria

- Residents of areas not endemic for Malaria are deferred for 12 months if they visit a Malarial area (except Korea-2 year deferral)
- Individuals from endemic areas, or individuals who have had malaria are deferred 3 years.
- MBCM variance request applies only to travelers, not those who have had malaria.

# Genesis of Variance Request

- MBCM has a high rate of donor deferral for Malarial travel (0.78 % of donors, 5.5% of all donor deferrals).
- Donors deferred even once for any extended period are less likely to return to donate.
- To retain donors, MBCM is requesting variances to allow plasma to be collected by automated plasmapheresis devices to make Plasma components.

# Manufacture of FFP from Plasmapheresis

- MBCM currently has two Baxter Autopheresis C devices. These produce relatively cell (both red and white) free components. (AABB 2000 SP 240)
- Plasma is rapidly frozen in a blast freezer (-80°C). It then remains at <-18 °C awaiting completion of donor testing (1-3 days). Cryoprecipitate and Plasma, Cryo reduced involve an additional thaw-freeze cycle.

# What does the Code of Federal Regulations (CFR) allow?

- 21CFR 640.63 c(9) allows drawing donor with risk of Malaria for Source Plasma.
  - Suitability of any donor “Freedom from any disease, other than malaria, transmissible by blood transfusion...”

# What does the CFR preclude?

- 21CFR 640.32 (b) specifically precludes this malarial exemption for Plasma donors.
  - Plasmapheresis donors shall meet the criteria for donor suitability prescribe in 640.63, excluding the phrase “other than malaria” in paragraph © (9) of that section.
- 21 CFR 640.51 (b) similarly precludes this same malarial exemption for donors of plasma made into Cryoprecipitate.

# Science I

- “Plasma which has been frozen or fractionated has never been known to transmit Malaria.” Mollison p.779 9th ed.
- A prospective trial using fresh & frozen plasma from donors with active malaria (*P. malariae* or *falciparum*) showed no transmission in 20 episodes of frozen plasma transfusion. *Am J. Med Sci* (1943) 206:141

## Science II

- A review article by L. Wells and F. Ala in Lancet (June 8, 1985) states that transmission may occur following “cryoprecipitates”. No further reference or data is provided within the text.
- Dr. Chiang Syin, CBER contacted Dr. Ala who observed a single case in Iran (1970) using “homemade cryo” with visible RBC.

# Post-donation Information Recalls

- The office of compliance at CBER receives ~9,000 PDI notifications annually from blood centers.
- The single largest category (1497 or 16.6% in 1999) results from donor travel to malarial endemic area.
- Following such a PDI only CELLULAR products from prior donations are recalled.

# PDI- Recalls for Malarial Travel

- CBER has never historically required recall of FFP or other frozen components from prior donations due to malarial travel.
  - Why not? Presumably because it is well known that FFP and its derivatives don't transmit Malaria!
  - Hence, about 1500 units of plasma from donors who later report malarial travel are NOT recalled each year.

# PDI-Large Scale Data

- Hence, assuming that only about 1/3 of plasma is transfused (MBCM data...as opposed to further manufacture), one may estimate that about 15,000 experiments have been done, without known Malarial transmission in any US case ( $\sim 1,500$  recalls/yr x 1/3 Plasma transfused x 30 years experience).

# Summary of Variance Request

- MBCM requests variances to allow drawing of donors, by automated plasmapheresis devices for the purpose of making Plasma components.
- Current restrictions are inconsistent with decades of CBER policy not requiring recall of frozen plasma components

# Summary of Variance Request

- Overwhelming historical data compliment the prospective data for safety of this practice.
- A single anecdote using admittedly outmoded manufacturing methods, should not preclude allowing this variance.

# MBCM Variance

- Furthermore, I suggest that FDA consider adopting a policy similar to the AABB that granted variances be published, so that other centers learn from their colleagues and not have to “reinvent the wheel”.
- I thank the committee for their time and patience in hearing this request.