U.S. FOOD & DRUG ADMINISTRATION

125th Blood Products Advisory Committee

Proposed Strategies to Reduce the Risk of Transfusion-Transmitted Malaria by Testing Donations from Donors at Risk of Malaria Exposure for the Presence of *Plasmodia* spp. Nucleic Acid

May 9, 2024

INTRODUCTION AND CHARGE TO THE COMMITTEE

Anne Eder, MD PhD

Director, Office of Blood Research and Review (OBRR),

Center for Biologics Evaluation and Research (CBER)

May 9, 2024

Agenda – Morning

9:50 a.m. (15 min.)	Opening Remarks and Charge to the Committee	**Anne Eder, M.D., Ph.D** FDA, CBER
10:05 am (25 min.) Q&A (10 min)	Public Health and Clinical Malaria in the U.S.	**Seymour Williams, M.D., M.P.H.** CDC
10:40 a.m.	**BREAK (10 min.)**	
10:50 a.m. (25 min.) Q&A (10 min.)	Transfusion-Transmitted Malaria in the United States	**Sanjai Kumar, Ph.D.** FDA, CBER
11:25 a.m. (25 min.) Q&A (10 min.)	Molecular Testing for Detection of Asymptomatic Plasmodium Infections	**Susan Galel, M.D.** Roche Diagnostics Solutions
12:00 p.m. (25 min.) Q&A (10 min.)	FDA's Policy Considerations for Testing Blood Donations for Malaria Infection	**Jennifer Scharpf, M.P.H.** FDA, CBER
12:35 p.m.	**LUNCH BREAK (25 min.)**	

1:00 p.m. – Open Public Hearing, Committee Discussion

Adjourn, 3:10 p.m.

Overview
Transfusion-transmitted Malaria

1. Malaria in the U.S. and public health considerations in the general population and among blood donors
2. Transfusion-transmitted malaria (TTM) cases and the scientific basis of the current deferral policy and proposed selective testing approaches
3. Licensed blood donor screening test for malaria
4. Regulatory basis of proposed recommendations to reduce the risk of TTM by selective testing

Current Approach to RTTIs with Selective Testing

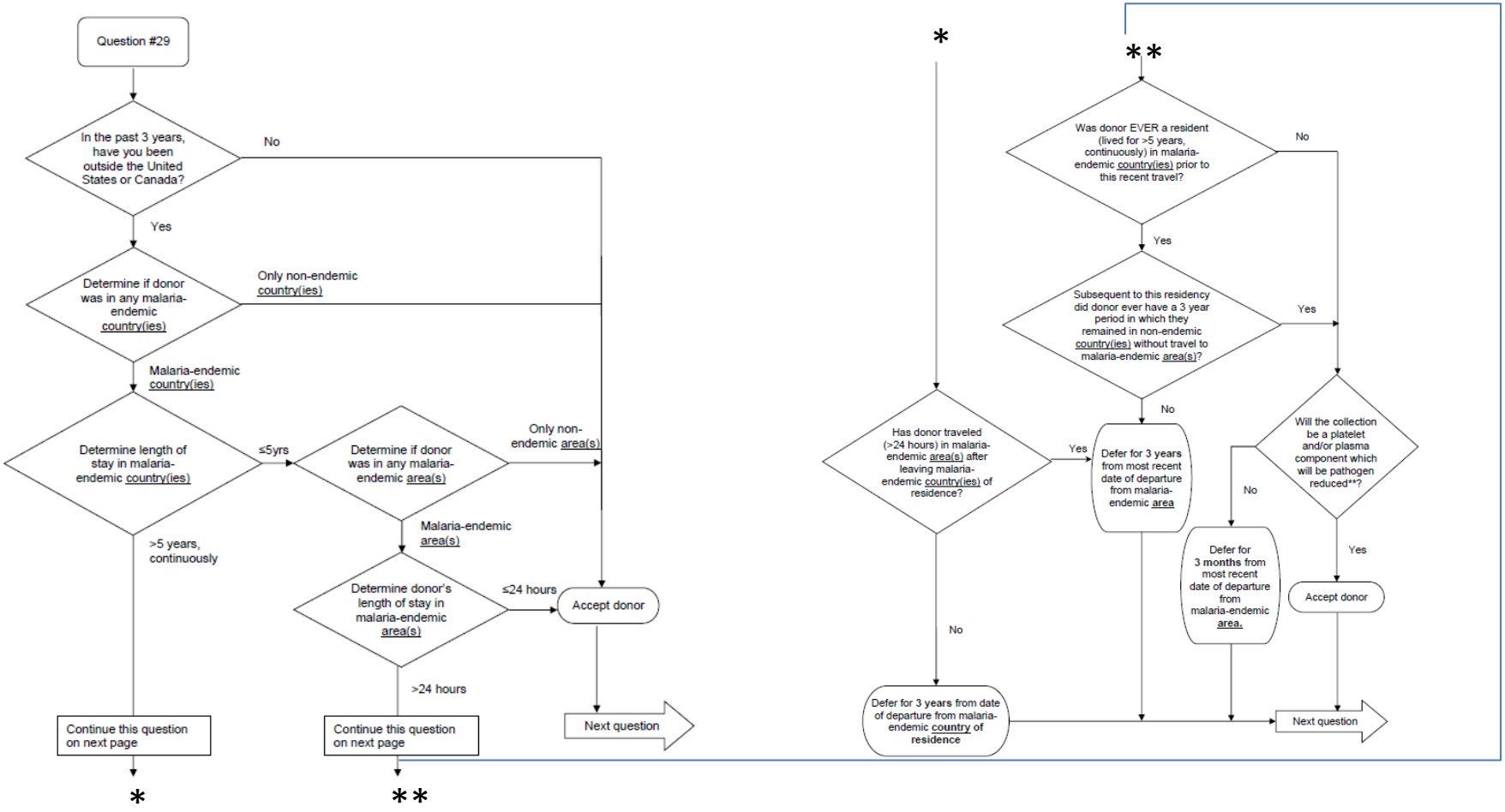
Agent	Measures to Reduce Risk of Transfusion Transmission	TTI risk to patients
T. cruzi (Chagas disease)	One-time testing of all donors	Before testing: • ~7 reported cases over ~20 years in US After testing: • no reported cases
Babesia spp. (Babesiosis)	Selective testing in 14 risk states and D.C.	Before testing: • more than about 20 cases each year After testing: • 0 cases, in 14 risk states, DC • ~2 cases/yr, states that do not test;

TTM: Current DHQ Deferrals or PRT

Donor History Table Summary of Recommendations		Donor Deferral	Pathogen Reduction Plasma or Platelets
Travel to a malaria endemic area	Resident of a non-endemic country	**3 months**	**Yes**
	Resident of a malaria-endemic country, if spent 3 or more consecutive years in non-endemic country	**3 months**	**Yes**
	Resident of a malaria-endemic country, if spent less than 3 consecutive years in non-endemic country	3 years	No
Resident of a malaria-endemic country		3 years	No
Diagnosis of malaria		3 years	No

Current DHQ

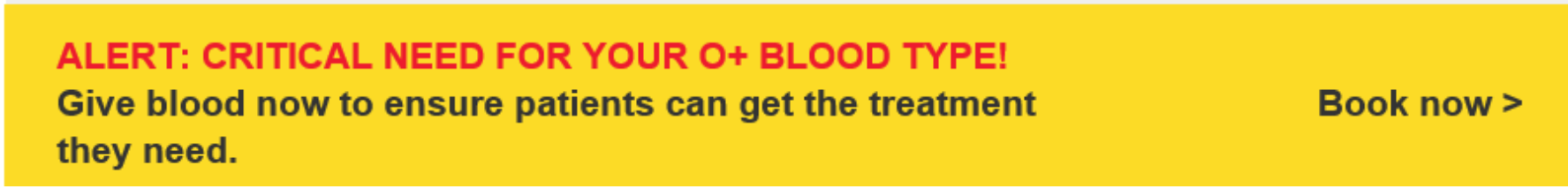
Question: 29. In the past 3 years, have you been outside the United States or Canada?



Risk to Patients - TTM

- About 1 TTM case reported every 2 years
- All cases implicated donors who were prior residents of malaria-endemic countries
- Almost all cases were *P. falciparum*
  - TTM has a higher fatality rate in transfusion recipients compared to mosquito-borne transmission in general population
- Limitations of current DHQ-based deferrals reflect chronic, prolonged, asymptomatic parasitemia in prior residents of malaria endemic countries (~60% TTM cases) or staff errors in evaluating donor history of prior residence in malaria endemic country (~40%)

Risk to Patients - Availability



- DHQ travel question defers a significant number of donors
  - Estimated 50,000 to 160,000 donors each year
- Urgent appeals for blood donation and reported shortages, especially of group O RBC units
- Advisory Committee of Blood and Tissue Safety and Availability recommended, and HHS invested in, the Giving=Living public awareness campaign in 2021 to increase donor recruitment and increase diversity in the donor base
- DHQ residency question defers a significant number of donors likely to have rare blood types that patients need
  - Malaria deferrals limit the availability of diverse blood types

Proposed Recommendations

- CBER is recommending selective testing to reduce the risk of TTM
- One-time testing could be part of a selective testing strategy to adequately reduce the risk of TTM
- Selective testing strategies of donors who report risk of malaria (i.e., former residents, prior malaria diagnosis, travelers) based on the DHQ has some advantages and limitations
- Time-limited testing in regions with mosquito-borne malaria transmission

Charges to the Committee

1. Please comment on FDA's proposed selective testing strategies for testing blood donations from donors at risk for malaria using an FDA-licensed NAT

   1A. Selective testing based on DHQ for prior residents, history of malaria, and travelers

   --OR--

   1B. One-time testing of all donors combined with selective testing based on DHQ for all travelers and history of malaria

Charges to the Committee

2. Please comment on FDA's proposal that blood establishments should implement time-limited NAT screening of all donations collected in area(s) of the U.S. when a single case of local mosquito-borne malaria is reported by public health authorities.

Agenda – Morning

9:50 a.m. (15 min.)	Opening Remarks and Charge to the Committee	**Anne Eder, M.D., Ph.D** FDA, CBER
10:05 am (25 min.) Q&A (10 min)	Public Health and Clinical Malaria in the U.S.	**Seymour Williams, M.D., M.P.H.** CDC
10:40 a.m.	**BREAK (10 min.)**	
10:50 a.m. (25 min.) Q&A (10 min.)	Transfusion-Transmitted Malaria in the United States	**Sanjai Kumar, Ph.D.** FDA, CBER
11:25 a.m. (25 min.) Q&A (10 min.)	Molecular Testing for Detection of Asymptomatic Plasmodium Infections	**Susan Galel, M.D.** Roche Diagnostics Solutions
12:00 p.m. (25 min.) Q&A (10 min.)	FDA's Policy Considerations for Testing Blood Donations for Malaria Infection	**Jennifer Scharpf, M.P.H.** FDA, CBER
12:35 p.m.	**LUNCH BREAK (25 min.)**	

1:00 p.m. – Open Public Hearing, Committee Discussion

Adjourn, 3:10 p.m.


FDA
U.S. FOOD & DRUG
ADMINISTRATION