

# **FDA Workshop on Testing for Malarial Infections in Blood Donors**

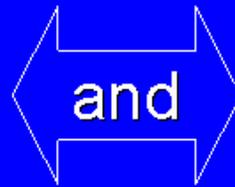
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# The Challenges for Blood and Blood Products

Enhance  
Product Safety,  
Purity and  
Potency



Avoid Product  
Shortages

# **FIVE LAYERS OF BLOOD SAFETY**

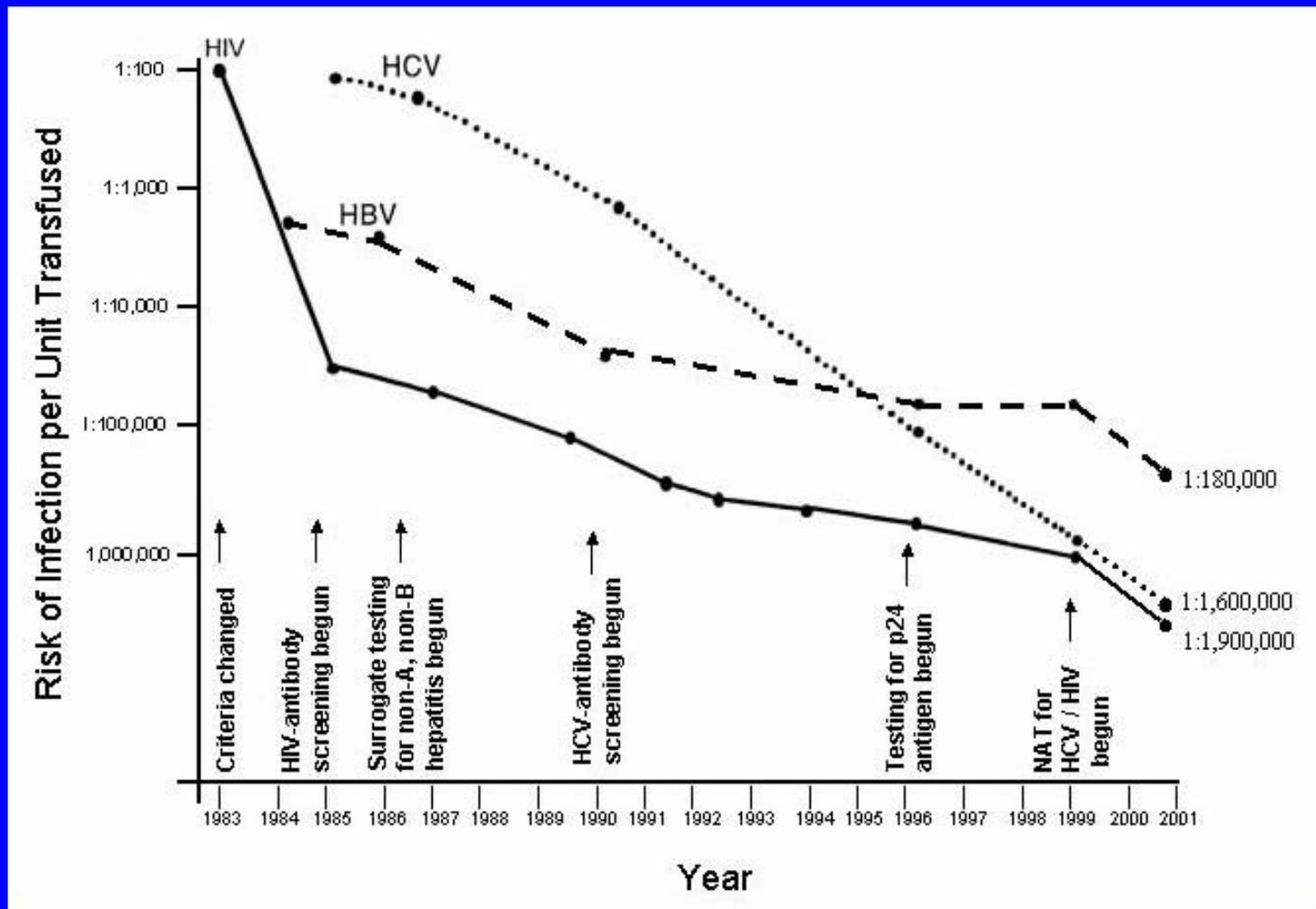
FDA's approach is to optimize each safety layer:

1. Donor screening and deferral based on geographic, behavioral and medical risk factors (donor education, self deferral, donor interview)
2. Laboratory testing and deferral (HIV-1, HIV-2, HBV, HCV, HTLV-I, HTLV-II, WNV, syphilis)
3. Deferral registries to prevent use of blood from deferred donors
4. Quarantine controls to prevent unit release pending verification of donor suitability
5. Investigation and correction of deviations

# Impact on the US Public Health: Blood Safety and Availability

- Millions of units are transfused annually
- Risk of transmission of infectious disease agents through transfusion has been significantly reduced with the introduction of tests

# New Test Implementation and Declining Risk of Viral Infections from Transfusion



# Evolution of Testing and Deferral

What happens when an emerging pathogen threatens the safety of the blood supply?

1. We introduce deferral criteria based on epidemiologically determined risk factors (medical, geographic or behavior-related exposures) as an initial safety measure
2. Where feasible, tests are developed, but deferral is maintained as an overlapping safeguard
3. Test sensitivity and specificity generally improve. However, risk-based deferrals are usually retained as an overlapping safeguard, especially when data are lacking on the relative safety contribution of risk-based vs. test-based deferrals

# Primary Goal of the Workshop

- To seek public input on scientific developments that might support:
  - donor testing for malarial infections as part of pre-donation testing,
  - or as follow-up testing to permit a reduced deferral period for donors deferred for risk of malaria.

# Background

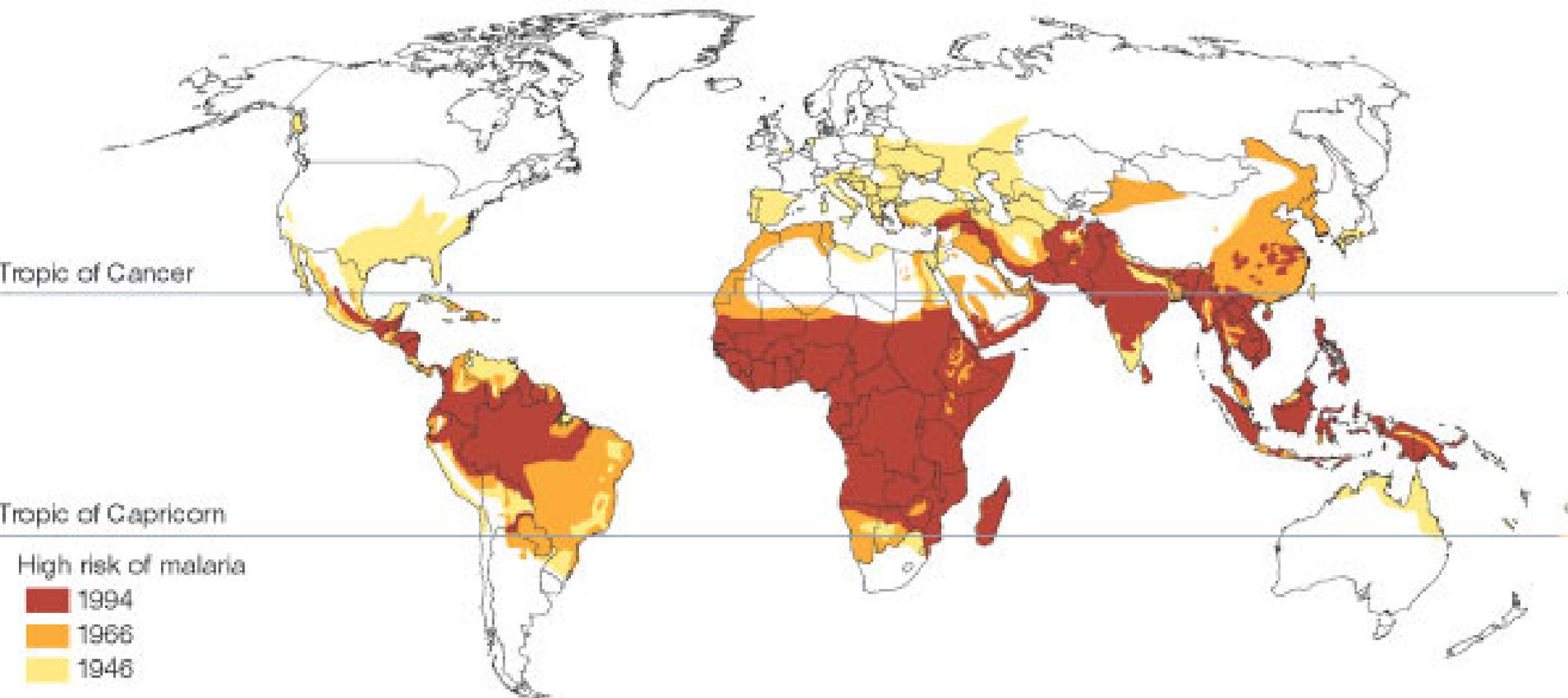
- Transfusion-transmitted malaria (TTM) is a public health concern in the U.S. and around the world.
- All four species of human Plasmodium (*Plasmodium falciparum*, *P. vivax*, *P. malariae*, and *P. ovale*) have caused TTM in the U.S.

# Background

- No approved laboratory test to screen donors for malarial infections.
- Blood safety from TTM is maintained through:
  - deferral policies based on a history of malarial infection,
  - and travel or residence in malaria endemic countries or regions.

## Risk of TTM in the US

- Each year more than 27 million Americans visit endemic areas
- Several millions of immigrants from endemic countries
- 1500 clinical cases and sporadic local transmission



# Malaria and its Impact on the US Blood Supply

- Incidents of TTM in US are all time low; down from 3 cases per year to 0.6 case per year
- Significant donor loss from deferral based prevention policy (~ 150,000 donors/yr)
- Availability of a blood screening test for malaria will minimize the unnecessary donor loss

# Biology of malaria parasites that influence its transmission through blood

- Infectious unit of blood form parasites is very low
  - 1 parasite in case of murine *P. berghei* malaria
  - 10 parasites in infected RBC in case of human *P. vivax* malaria
- Under refrigeration condition parasites are known to survive up to 20 days

# FDA Guidelines for Donor Deferral Based on 1994 Memorandum

- Three-year deferral:
  - History of clinical malaria
  - Prior residents of endemic country
- One-year deferral:
  - Visit to a malaria endemic area by residents of nonendemic countries

Identification of malaria endemic area as provided by CDC:

[www.cdc.gov/travel/regionalmalaria/index.htm](http://www.cdc.gov/travel/regionalmalaria/index.htm)

# Topics for Discussion

- What are the desirable characteristics of laboratory tests to detect malaria infections in blood donors?
- What are the risks and benefits of donor screening for malaria infections in lieu of risk-based deferrals?

# Topics for Discussion

- What are the prospects for the use of DNA-based methods as blood screening tests in the US?
- What are the prospects for the use of a malaria antibody test in the US?
  - To screen blood donors
  - To reenter deferred blood donors