Enhancing US Blood Availability by Testing for *Plasmodium* spp. Infection

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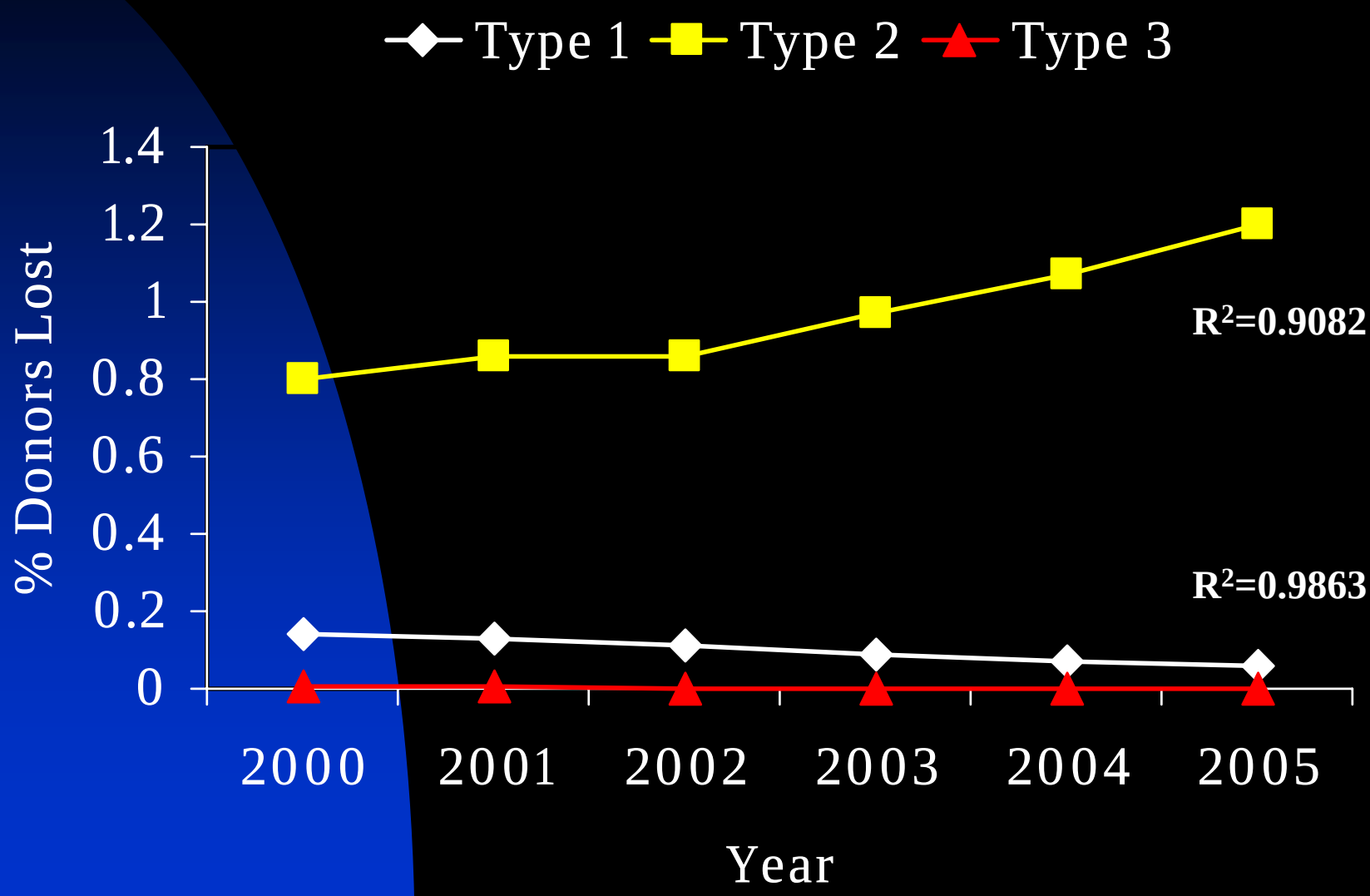
Malaria Deferrals: 2000-2005

Deferral	n	%*	Lost Donations**
Type 1	25,303	0.1	42,797
Type 2	241,503	0.96	412,520
Type 3	494	0.002	834
Totals	267,300	1.07	456,151

* total donations = 25,036,751

** lost donations = n x donation rate (~ 1.7)

Donors Lost to Malaria Deferrals



Travelers' Health

Outbreak Notice

Malaria, Great Exuma, Bahamas: Recommendations for Travelers

This information is current as of today, June 29, 2006, 02:39:54 PM

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CDC

“Malaria” Deferred Donor Study

- are deferred donors infected?
  - type of deferral associated with infection?
- effectiveness of EIA assay?
  - specificity/sensitivity
- usefulness of PCR/RT-PCR follow-up?
- interventions?
  - testing alone
  - testing of subset:
    - at donation or months later
  - permanent deferral for subset
  - status quo

Study Approach

- serologic testing of donors by Newmarket EIA
  - ~3,000 non-deferred donors from GC&P
    - determine EIA background
  - “malaria” deferred donors from GC&P and PJ
- supplemental testing of seropositives
  - IFA by CDC
  - PCR and RT-PCR
  - ability to identify species
- risk factor questionnaire
  - malaria deferred donors
  - positive, non-deferred donors

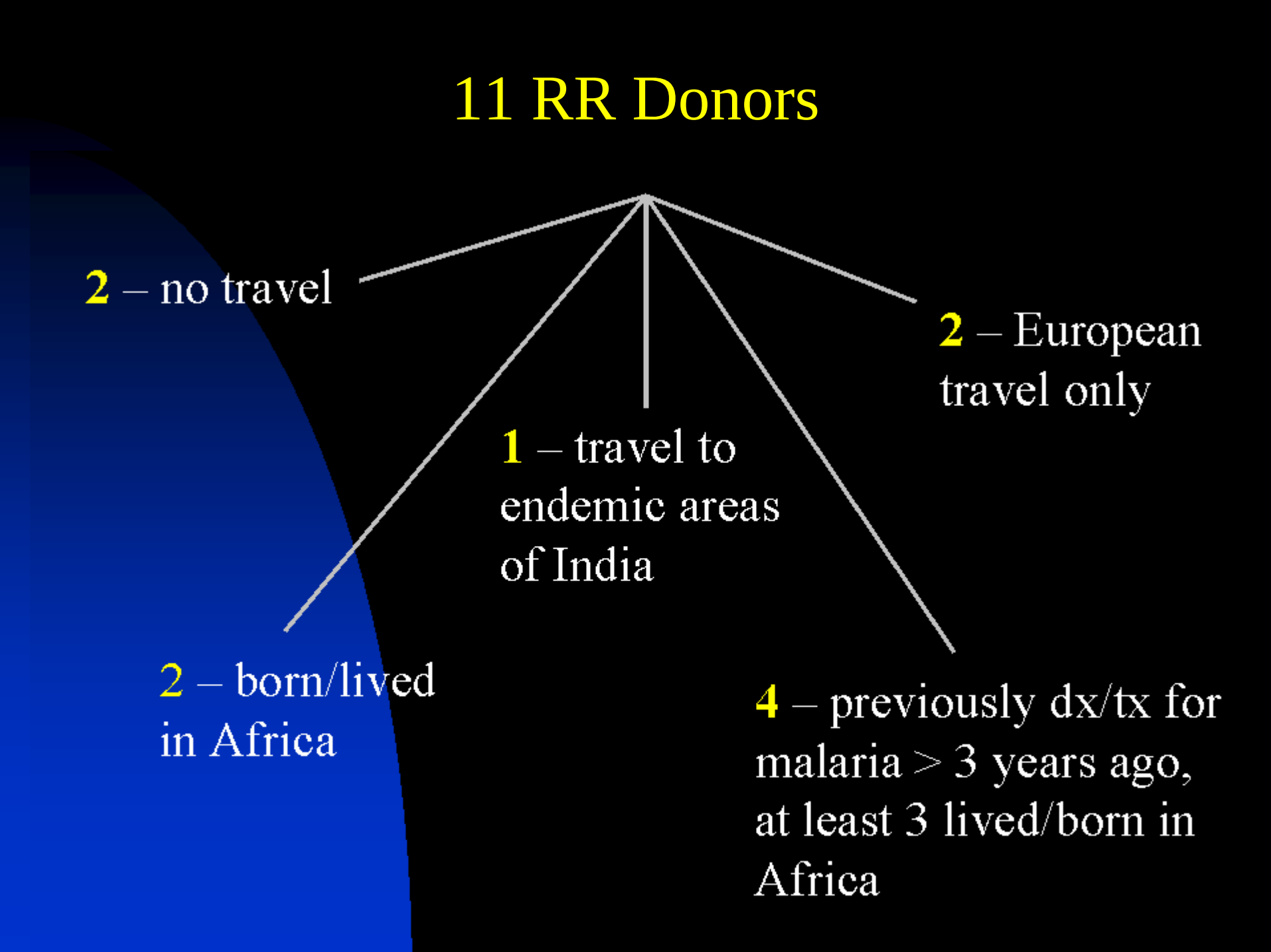
Challenges

- obtaining sufficient numbers of deferred donors
  - specific type of deferred donors
- EIA:
  - biased towards only two species, albeit most important
- PCR/RT-PCR:
  - parasitemia may have cleared
  - sampling/concentration issues
- accuracy of questionnaire

EIA Testing of Non-Deferred Donors

n	3,229
IR	21 (0.65%)
RR	11 (0.34%)

11 RR Donors


2 – no travel
1 – travel to endemic areas of India
2 – European travel only
2 – born/lived in Africa
4 – previously dx/tx for malaria > 3 years ago, at least 3 lived/born in Africa

Supplemental Testing

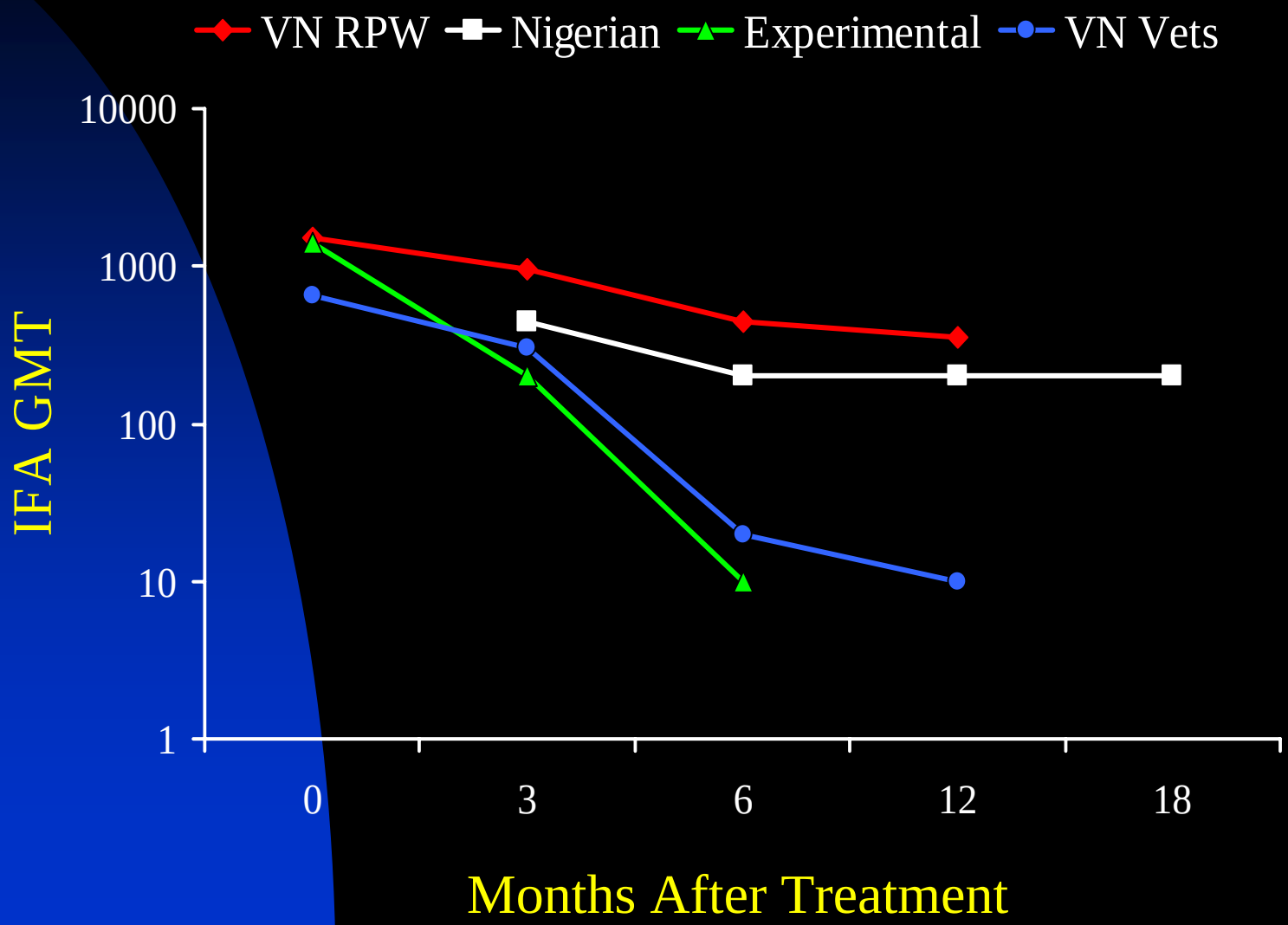
EIA Reactivity	n	IFA + 1:64	IFA + 1:16	PCR +
Negative	10	1*	2	0
RR	11	2	8	0

* positive for *P. ovale*

Implications

- significant number of donors with past malaria exposure
- not captured by travel history
- long term antibody titers

Plasmodium spp. Antibody Persistence



CDC

Implications

- significant number of donors with past malaria exposure
- not captured by travel history
- long term antibody titers
  - semi-immune?
  - relationship to transfusion-transmission
- infectious status unclear
- caveat: few transmission cases

Approaches for Enhancing Availability

- "had malaria"
  - primary core of blood safety issue
  - permanent deferral
    - easy to manage
    - done in many countries
    - precedent with babesiosis
  - test
    - defer those with persistent titers for defined period
    - accept those with baseline titers

Approaches for Enhancing Availability

- "residence"
  - secondary core of blood safety issue
    - relationship to "had malaria" group
  - limited deferral
    - difficult to manage
    - questions have specificity/sensitivity issues
  - test
    - those with measurable titers entered in "had malaria" group
    - accept those with baseline titers

Approaches for Enhancing Availability

- "travel"
  - core of blood availability issue
  - limited deferral
    - questions have specificity/sensitivity issues
    - "Princess and the Pea" phenomena
  - test
    - those with measurable titers entered in "had malaria" group
    - accept those with baseline titers

Conclusions

- unique opportunity to address “malaria” issues
  - realign the blood availability/safety dynamic
- foster additional research:
  - immigration and donor demographic issues
  - retention and re-entry of deferred donors
  - rate of infectivity in “travel” deferred donors
  - significance of long-term Ab titers
  - declining rate of transfusion-transmission
- stimulate test development

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