Babesia and Blood Safety

American Red Cross, New England Region
Bryan Spencer, MPH
Manager of Blood Research / REDS-III Coordinator

ASM 46th Annual Region I Meeting
27 October, 2011
Randolph, MA
Emerging infectious disease agents and their potential threat to transfusion safety


BACKGROUND: Emerging infections have been identified as a continuing threat to human health. Many such infections are known to be transmissible by blood transfusion, while others have properties indicating this potential. There has been no comprehensive review of such infectious agents and their threat to transfusion recipient safety to date.

INTRODUCTION

The concept of emerging infectious disease (EID) has developed over the last 2 decades, as it became apparent that full control of infectious disease had not been achieved. From 1997 data, the World Health Organization (WHO) estimated that infectious diseases were responsible for about 33% of all deaths worldwide primarily in...
EID Agent Prioritization

**RED** = low to high scientific/epidemiologic evidence of blood safety risk combined with heightened public or regulatory concern

**ORANGE** = sufficient scientific/epidemiologic evidence of blood safety risk such that agent may become a future concern

**YELLOW** = absent to low scientific/epidemiologic evidence of blood safety risk but with public or regulatory concern
EID Agent Prioritization

**RED** =
- Dengue virus, *Babesia*, vCJD

**ORANGE** =
- *Plasmodium* spp., *Trypanosoma cruzi*, *Leishmania*, St. Louis encephalitis virus, Chikungunya virus

**YELLOW** =
- CWD prion, HHV-8, HIV variants, *Borrelia* (Lyme), Avian influenza virus (H5N1), Simian foamy virus, Parvovirus B19, HAV
How does risk from babesiosis compare to other transfusion risks in the United States?

<table>
<thead>
<tr>
<th>Agent</th>
<th>Population prevalence</th>
<th>Estimated Residual Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>0.45%</td>
<td>1:1.5M*</td>
</tr>
<tr>
<td>HBV</td>
<td>0.27%</td>
<td>1:300k</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1:1M (w/ NAT)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(BPAC, Apr 2009)</td>
</tr>
<tr>
<td>HCV</td>
<td>1.3%</td>
<td>1:1M</td>
</tr>
</tbody>
</table>

Annual transfusions: 15M RBC, 2M plt, 4.5M plasma

*yet, see MMWR v59,n41, (2010): TT HIV in 2008, 1st since 2002 (6 cases, 4 donors in 10 years)
How does risk from babesiosis compare to other transfusion risks in the United States?

<table>
<thead>
<tr>
<th>Agent</th>
<th>Population prevalence</th>
<th>Historical / recent risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chagas*</td>
<td>~ 100,000 prevalent infections 1:30,000 in blood donors</td>
<td>7 transfusion cases N. America 5 solid organ transplant cases</td>
</tr>
<tr>
<td>Malaria</td>
<td>Unknown</td>
<td>½ case TTM per year</td>
</tr>
<tr>
<td>Babesia</td>
<td>1-2% seroprevalence in “endemic” areas</td>
<td>162 cases over 30 years</td>
</tr>
</tbody>
</table>

Annual transfusions: 15M RBC, 2M plt, 4.5M plasma

*transmissibility recently established as ~ 1% in U.S.
**Babesia spp.**

- agents of human babesiosis:
  - *B. microti*: U.S.
  - *B. divergens*: Europe

- infects red blood cells

- transmitted by *Ixodes* ticks

- Infection often silent or associated with flu-like illness that is normally self-limited, but can be severe or fatal in:
  - elderly
  - infants
  - immunocompromised
  - asplenic

- Persistent parasitemia not uncommon
Life-Cycle: *Babesia* spp.
**Babesia in North America**

- Focal distribution of *B. microti*
- Sporadic distribution of other Babesia organisms
  - *B. duncani*, CA-1, MO-1, *B. divergens-like*)
- Expanding endemic range
- Limited seroprevalence studies in blood donors

![Map of Babesia distribution in North America](image)

- **Orange**: *B. microti*
- **Light Blue**: *Babesia spp.*
- **Purple**: *B. divergens-like*
B. microti: Survival In Blood Products

- survives in red cells maintained at 4°C
  - 21 days experimentally
  - 42 days in association with a transfusion case
  - *survives indefinitely in cryopreserved red cells*
- parasite killed in frozen plasma
- contaminating red cells pose potential issues for platelet apheresis & fresh plasma products
Recent Increases in TTB Cases

• Increase in TTB reports NYC: 7 cases reported, Sept 2008 to Feb 2009, compared to 1-2 a year historically

• Increase in TTB reports Rhode Island (Asad, et al. AABB 2008)

• Increase in TTB identified by American Red Cross Hemovigilance Program (Tonnetti L et al Transfusion; Dec,2009)

• Increase in Fatality Reports from FDA (Gubernot, et al. CID 2009:48:25-30)
Health Advisory #5:
Increase in Transfusion-associated Babesiosis in NYC

- Seven cases of transfusion-associated babesiosis have been identified among New York City (NYC) residents since September 2008; this is a notable increase over baseline as previously an average of one to two transfusion-associated cases were reported annually;
- The NYC Health Department is asking providers to consider babesiosis in the differential diagnosis of patients with fever and/or hemolytic anemia who have a history of transfusion or organ transplant within the preceding 3 months;
- Suspected cases should be tested for babesiosis (see below for details), and laboratory positive cases should be reported to the NYC Health Department as well as the New York State Department of Health (NYSDOH) Blood and Tissue Resources Program (see contact information below).

Please distribute to staff in the Departments of Internal Medicine, Pediatrics, Family Medicine, Infection Control, Infectious Disease, Emergency Medicine, Critical Care, Hematology/Oncology, Pharmacy, Blood Bank and Laboratory Medicine.

February 23, 2009
Transfusion-Transmitted Babesiosis in Rhode Island (1999-2007)
Asad et al AABB Abstract 2008

• 21 cases identified from 17 implicated units
  – 15 cases 2004-2007 (1 per 9300 RBC transfusions)
• Age range: premature to 88 years (median 57)
• Incubation period: 24 – 84 days (median 39)
• All some degree of being immunocompromised or asplenic
• 1 death (5%)
Babesia Infection through Blood Transfusions:
Reports Received by the US Food
and Drug Administration, 1997–2007


Office of Blood Research and Review, Center for Biologics Evaluation and Research, US Food and Drug Administration, Office of Biostatistics and Epidemiology and US Public Health Service, and Office of Compliance and Biologic Quality, Rockville, Maryland
Fatalities Reported to the FDA
Following Blood Collection and Transfusion
Annual Summary FY 2008

Table 4: Microbial Infection by Implicated Organism, FY2005 through FY2008

<table>
<thead>
<tr>
<th>Organism</th>
<th>FY05</th>
<th>FY05</th>
<th>FY06</th>
<th>FY06</th>
<th>FY07</th>
<th>FY07</th>
<th>FY08</th>
<th>FY08</th>
<th>Total</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babesia*</td>
<td>0</td>
<td>0%</td>
<td>2</td>
<td>29%</td>
<td>3</td>
<td>50%</td>
<td>5*</td>
<td>63%</td>
<td>10</td>
<td>36%</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>3</td>
<td>37%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>17%</td>
<td>1</td>
<td>13%</td>
<td>5</td>
<td>18%</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>0</td>
<td>0%</td>
<td>3</td>
<td>43%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>3</td>
<td>11%</td>
</tr>
<tr>
<td>Serratia marcescens</td>
<td>2</td>
<td>24%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>2</td>
<td>7%</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>1</td>
<td>13%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>13%</td>
<td>2</td>
<td>7%</td>
</tr>
<tr>
<td>Staphylococcus lugdunensis</td>
<td>1</td>
<td>13%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Eubacterium limosum</td>
<td>1</td>
<td>13%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Morganella morganii</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>14%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Yersinia enterocolitica</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>14%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Group C Streptococcus</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>17%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Klebsiella oxytoca</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>17%</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>100%</td>
<td>7</td>
<td>100%</td>
<td>6</td>
<td>100%</td>
<td>7</td>
<td>100%</td>
<td>28</td>
<td>100%</td>
</tr>
</tbody>
</table>

*Four Babesia microti and one probable Babesia MO-1 species
ASSOCIATION BULLETIN
#09-06

Date: August 5, 2009
To: AABB Members
From: Jay E. Menitove, MD – President
       Karen Shoos Lipton, JD – Chief Executive Officer
Re: Transfusion-Transmitted Babesia

This bulletin was developed by the AABB Transfusion-Transmitted Diseases Babesia Work Group to provide: 1) information about the potential for transfusion-transmitted Babesia (TTB), 2) educational materials for clinicians about the epidemiology of Babesia, along with descriptions of the signs, symptoms, diagnosis, and treatment of babesiosis, 3) information on the processes that have been used by blood centers in endemic areas for investigating TTB cases, and 4) a summary of the development of interventions to reduce transfusion transmission of Babesia. The experience of blood centers operating in endemic areas gives insight into management of patients, donors, and blood components in the event of known or suspected cases of TTB.
Transfusion-Associated Babesiosis in the United States: A Description of Cases

Barbara L. Herwaldt, MD, MPH; Jeanne V. Linden, MD, MPH; Elizabeth Bosserman, MPH; Carolyn Young, MD; Danuta Olsowska, MD; and Martanna Wilson, MS

Herwaldt et al., Ann Intern Med 2011;155:509-519
162 Cases

- 162 cases in 30 years (1979 – 2009)
  - 159 cases attributed to *B. microti*
  - 3 cases attributed to *B. duncani*
- Median patient age - 65 years
- Primarily associated with red cells (4 platelets)
- Fatalities (n=12) increasingly reported
- Likely undercounts cases
  - Lack of physician recognition
  - Case selection criteria
- 87% of cases in 7 endemic states
TTB Cases on the Rise

Herwaldt et al., Ann Intern Med 2011;155:509-519
Year-Round Risk of TTB?

Herwaldt et al., Ann Intern Med 2011;155:509-519
Diagnosis of Babesiosis

• No licensed diagnostic test in U.S.
  – Direct testing
    ▪ peripheral blood smear
    ▪ PCR
    ▪ hamster inoculation
  – Indirect testing
    ▪ IFA
    ▪ Automated immunoassays under development
What information is available about the distribution of *B. microti* transmission?

• Only made nationally notifiable disease this year (Jan 2011)

• Previously notifiable in states considered endemic

• Sporadic reports in literature associated with unusual clinical reports or appearance in new locations. Few representative, population-based studies.
Passive surveillance -- CT

Figure 1: Babesiosis Cases, Connecticut 1991-2002

Source: Connecticut Epidemiologist, 2003

Figure 2: Babesiosis Rates* (Cases) by County, Connecticut, 2002

* per 100,000 population
Babesiosis Reported to the Massachusetts Department of Public Health, 2000-2008

Source: Al DeMaria, State Epidemiologist, MA
Babesiosis in New York State

New York State Council on Human Blood and Transfusion Services

BABESIOSIS,

HUMAN EHRLICHIOSIS AND

HUMAN ANAPLASMOSIS:

POTENTIAL TRANSFUSION COMPLICATIONS

Second Edition 2008
Babesiosis in New York State


-2000: 3 cases transfusion babesiosis reported, high seroprevalence eastern Long Island (Transfusion, Mar 2000)

-human cases and infected ticks in Lower Hudson Valley (Emerging Infect Dis, 2005; 11(3): 476-8)

-doubling of incidence 2002 (93) to 2007 (205), 80% Suffolk, Dutchess, Westchester (Wadsworth)
Beginning in January 2011 . . .

CSTE List of Nationally Notifiable Conditions
June 2010

This list indicates the nationally notifiable conditions for which health departments provide information to CDC. It specifies the manner and time frame in which the health department notifies CDC. Local requirements for reporting to public health by healthcare providers, laboratorians and others generally include these conditions but may require reporting of additional diseases, syndromes or findings and may specify different time frames. For information on local reporting requirements, contact the city, county or state health department.

STANDARD - Notification by electronic transmission
Submit within the next normal reporting cycle (i.e., within 7 days for NNDS5 conditions)

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>CASES REQUIRING NOTIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaplasmosis</td>
<td>Confirmed and probable cases</td>
</tr>
<tr>
<td>Arboviral disease (Calif. serogroup, EEE, Powassan, SLE, WN, WEE)</td>
<td>Confirmed and probable cases</td>
</tr>
<tr>
<td>Babesiosis</td>
<td>Confirmed and probable cases</td>
</tr>
<tr>
<td>Botulism</td>
<td>Confirmed and probable cases</td>
</tr>
<tr>
<td>Infant, sporadic cases</td>
<td>All cases prior to classification</td>
</tr>
<tr>
<td>Wound, sporadic cases</td>
<td>All cases prior to classification</td>
</tr>
<tr>
<td>Ehrlichiosis</td>
<td>Confirmed and probable cases</td>
</tr>
<tr>
<td>Cases not temporally/spatially clustered</td>
<td>Confirmed cases²</td>
</tr>
<tr>
<td>Cancer</td>
<td>Confirmed cases</td>
</tr>
<tr>
<td>Chlamydia trachomatis infection</td>
<td>Confirmed cases</td>
</tr>
</tbody>
</table>
**Notifiable Diseases and Mortality Tables**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Current week</th>
<th>Cum 2011</th>
<th>5-year weekly average</th>
<th>Total cases reported for previous years</th>
<th>States reporting cases during current week (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Arboviral diseases:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>California serogroup virus disease</td>
<td>—</td>
<td>88</td>
<td>2</td>
<td>75 55 62 55 67</td>
<td></td>
</tr>
<tr>
<td>Eastern equine encephalitis virus disease</td>
<td>—</td>
<td>3</td>
<td>0</td>
<td>10 4 4 4 8</td>
<td></td>
</tr>
<tr>
<td>Powassan virus disease</td>
<td>—</td>
<td>12</td>
<td>—</td>
<td>8 6 2 7 1</td>
<td></td>
</tr>
<tr>
<td>St. Louis encephalitis virus disease</td>
<td>—</td>
<td>2</td>
<td>0</td>
<td>10 12 13 9 10</td>
<td></td>
</tr>
<tr>
<td>Western equine encephalitis virus disease</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Babesiosis</td>
<td>25</td>
<td>559</td>
<td>1</td>
<td>NN NN NN NN NY (25)</td>
<td></td>
</tr>
</tbody>
</table>
Blood center sources of information on babesiosis

1) Question on health history for presenting donors: low yield
   ▪ “Have you ever had babesiosis?”

2) Post-donation information (PDI): very low yield
   ▪ from donor callback

3) Ongoing research program (also PDI):
   ▪ CT, then MA Cape /offshore islands, then coastal NH, ME

4) Investigation of suspected transfusion-transmitted infection (TTI) cases reported to blood center

5) “Lookback” investigations triggered by any of the foregoing – no longer standard practice
Question from donor health history

1) In **New England Region** (MA, NH, VT, ME), over 10-year period, 48 donors with deferral for “yes” to question on babesiosis.
   • >4mm donations and 500k deferrals
   • rate of 1:83,000 donations and 1:10,400 deferrals

2) In **Connecticut Region**, over same period, 77 donors w/ same deferral:
   • >1.6mm donations and 233k deferrals
   • rate of 1:21,200 donations and 1:3,000 deferrals
PDI from donor callbacks

New England Region:

- Donor callbacks: 6 cases 2005; 1 each 2007 & 2008
**Babesia Natural History Study**

co-operative agreement, Red Cross with CDC
Several years’ study in CT
enrolling *B. microti* seropositive donors
tested every 30 - 60 days
- serology
- blood smear
- PCR
- hamster inoculation
Relationship between serology and parasitemia
## Babesia research program in CT Red Cross

<table>
<thead>
<tr>
<th>Year</th>
<th>Donors Tested</th>
<th>IFA Positive (%)</th>
<th>Parasitemia Testing*</th>
<th>Parasitemic (%)</th>
<th>Lookbacks Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>3669</td>
<td>30 (0.8%)</td>
<td>19</td>
<td>10 (53%)</td>
<td>5/17</td>
</tr>
<tr>
<td>2000</td>
<td>2681</td>
<td>28 (1.0%)</td>
<td>18</td>
<td>10 (56%)</td>
<td>3/13</td>
</tr>
<tr>
<td>2001</td>
<td>2162</td>
<td>30 (1.4%)</td>
<td>25</td>
<td>3 (12%)</td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>2230</td>
<td>18 (0.8%)</td>
<td>14</td>
<td>3 (21%)</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>1989</td>
<td>34 (1.7%)</td>
<td>20</td>
<td>2 (10%)</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>2864</td>
<td>43 (1.5%)</td>
<td>33</td>
<td>6 (18%)</td>
<td>0/21</td>
</tr>
<tr>
<td>2005</td>
<td>1841</td>
<td>25 (1.4%)</td>
<td>10</td>
<td>0 (0%)</td>
<td>0/12</td>
</tr>
<tr>
<td>2006</td>
<td>3254</td>
<td>30 (0.9%)</td>
<td>19</td>
<td>2 (11%)</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>5263</td>
<td>42 (0.8%)</td>
<td>22</td>
<td>1 (4.6%)</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>5295</td>
<td>32 (0.6%)</td>
<td>22</td>
<td>0 (NA)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>31248</td>
<td>312 (1.0%)</td>
<td>202</td>
<td>37 (18%)</td>
<td>8/63</td>
</tr>
</tbody>
</table>
### Active vs. passive surveillance: seroprevalence by CT county per 10,000 donations vs. CT-DPH case reports

<table>
<thead>
<tr>
<th>County</th>
<th>Seroprevalence in donors, 2007 - 2008</th>
<th>Reported case rates per 10k population, 2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hartford</td>
<td>39</td>
<td>0.06</td>
</tr>
<tr>
<td>New Haven</td>
<td>43</td>
<td>0.02</td>
</tr>
<tr>
<td>Fairfield</td>
<td>49</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>New London</strong></td>
<td><strong>198</strong></td>
<td><strong>1.5</strong></td>
</tr>
<tr>
<td>Middlesex</td>
<td>242</td>
<td>0.2</td>
</tr>
<tr>
<td>Windham</td>
<td>51</td>
<td>0.4</td>
</tr>
<tr>
<td>Tolland</td>
<td>82</td>
<td>0.2</td>
</tr>
<tr>
<td>Litchfield</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td><strong>Statewide</strong></td>
<td><strong>70</strong></td>
<td><strong>0.15</strong></td>
</tr>
</tbody>
</table>
Expanded Geographic Range

- poster presentation (SP404) by Johnson et al. AABB 2011
- tested blood donors from Maine, Massachusetts’ North Shore and New Hampshire
  - 3789 donations tested by IFA over 3 years
  - 9 (0.2%) positive
    - 3 of 1420 (0.2%) – ME
    - 2 of 985 (0.2%) – MA
    - 4 of 1425 (0.3%) – NH
- 3 suspected peridomestic exposures (ME & NH)
Expanded Geographic Range

- oral presentation (S58-030F) by Tonnetti et al.
  AABB 2011
- tested blood donors from Minnesota and Wisconsin
  - 2008 donations tested by IFA
    - 40 (2.0%) positive
      - 2 of 19 (10.5%) – WI
      - 38 of 1989 (1.9%) – MN
  - positive donors: evidence of tick exposure and outdoor activities
3 donor patterns for infection / clearance

- transient elevation of IFA titer with/without parasitemia
  - clearance of measurable parasitemia
  - serologic status returns to baseline

- long-term elevation of IFA titer
  - with/without parasitemia

- infection/clearance/re-infection (intermittent parasitemia)
  - residence in endemic area
  - no knowledge of tick re-exposure

- All donors seropositive deferred indefinitely
Lookback investigations of *Babesia microti*-seropositive blood donors: seven-year experience in a *Babesia*-endemic area

*Stephanie T. Johnson, Ritchard G. Cable, and David A. Leiby*
## Investigations and Components

### TABLE 1. Annual LB investigations: results for donor and recipient testing

<table>
<thead>
<tr>
<th>Year</th>
<th>IFA positive/tested (%)</th>
<th>PCR positive/tested (%)</th>
<th>Number of associated donations*</th>
<th>Number of cellular components subject to LB†</th>
<th>Number positive/tested LB recipients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>30/3,656 (0.8)</td>
<td>10/19 (52.6)</td>
<td>145</td>
<td>194</td>
<td>2/8 (25.0)</td>
</tr>
<tr>
<td>2000</td>
<td>28/2,682 (1.0)</td>
<td>10/18 (55.6)</td>
<td>81</td>
<td>103</td>
<td>3/7 (42.9)</td>
</tr>
<tr>
<td>2001</td>
<td>30/2,162 (1.4)</td>
<td>2/25 (8.0)</td>
<td>32</td>
<td>50</td>
<td>1/4 (25.0)</td>
</tr>
<tr>
<td>2002</td>
<td>18/2,230 (0.8)</td>
<td>2/14 (14.3)</td>
<td>38</td>
<td>58</td>
<td>2/8 (25.0)</td>
</tr>
<tr>
<td>2003</td>
<td>34/1,988 (1.7)</td>
<td>1/20 (5.0)</td>
<td>51</td>
<td>84</td>
<td>0/6 (0.0)</td>
</tr>
<tr>
<td>2004</td>
<td>43/2,864 (1.5)</td>
<td>1/33 (3.0)</td>
<td>83</td>
<td>113</td>
<td>0/17 (0.0)</td>
</tr>
<tr>
<td>2005</td>
<td>25/1,840 (1.4)</td>
<td>0/10 (0.0)</td>
<td>44</td>
<td>54</td>
<td>0/13 (0.0)</td>
</tr>
<tr>
<td>Totals</td>
<td>208/17,422 (1.2)</td>
<td>26/139 (18.7)</td>
<td>474</td>
<td>656</td>
<td>8/63 (12.7)</td>
</tr>
</tbody>
</table>

* Index donations (1999-2000 only), donations in the previous 12 months, and subsequent donations.
† Includes RBCs, whole blood-derived PLTs, and whole blood.

### TABLE 3. Transfused component type for *Babesia* tested recipients

<table>
<thead>
<tr>
<th>Transfused component</th>
<th><em>Babesia</em>-positive recipients</th>
<th><em>Babesia</em>-negative recipients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index donation RBCs</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Index donation PLTs</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Previous donation RBCs</td>
<td>4*</td>
<td>36</td>
</tr>
<tr>
<td>Previous donation PLTs</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>55</td>
</tr>
</tbody>
</table>

* All received components from donation immediately preceding the index donation.
Risk Mitigation for *Babesia* Transmission

Donor Questions
- History of babesiosis – most donors unaware of history
- History of tick bite – predictive value limited to none
- Travel deferral (!?) – possible but logistically challenging, low specificity

Geographic Deferral (seasonal or otherwise) – practice used in some areas but of unproven effect

Donor Testing
- Serology vs. NAT – serology good to determine exposure, NAT is good tool but might miss low level parasitemia
There is no test . . .

- . . . no FDA licensed tests for blood screening
- tests are under development (from AABB 2011)
  - PCR: S59-030F Bloch et al.
    SP428 Thorp & Tonnetti
  - ELISA: SP419 Erwin et al.
  - AFIA/NAT: SP427 Devine et al.
- Rhode Island Blood Center currently testing at-risk recipients under IND
- pathogen reduction
  - feasibility demonstrated using amotosalen and riboflavin
    - targeting whole blood: S60-030F Tonnetti et al.
- FDA/NIH actively supporting test development
Cautionary lesson from Chagas testing

Chagas RIPA-Positives through 10/25/11
Implementation Questions

- serology and/or NAT?
- universal vs. regional screening?
  - 7 vs 20 states?
- selective “CMV” model?
- role for pathogen reduction?
- specter of differential pricing?
- financial issues
  - different models by state/region
  - undue burden on state/region
- blood importation?
- donor re-entry?
Summary – *Babesia* risk

- Donor exposure to *B. microti* is many times higher than passive surveillance data suggest

- *Babesia* spp. pose a significant blood safety risk

- Known geographic range continues to expand, and blood products travel, so risk in areas not known to be endemic might have greater than appreciated risk from both locally-collected and imported blood

- Licensed diagnostic test not available, and is sorely needed