KNOWLEDGE INFUSION:
FOCUS ON RISK-BASED DECISION-MAKING

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Risk-Based Decision-Making Analysis of Babesia Microti
Risk to the Canadian Blood Supply

Prepared by Canadian Blood Services Knowledge Mobilization Team
with special thanks to Margaret Fearon

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CENTRE FOR INNOVATION PRESENTS

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Presentation Objective:

✔ Learn how Canadian Blood Services uses the Risk-Based Decision-Making Framework, developed by the Alliance of Blood Operators, to make informed decisions on strategies to deal with emerging and current risks to the blood supply.
Risk-Based Decision-Making Analysis of Babesia Microti Risk to the Canadian Blood Supply

Knowledge Infusion: Focus on Risk-Based Decision-Making Case Studies
Dr. Margaret Fearon
February 27, 2017

The ABO Risk-Based Decision Making Framework for Blood Safety

https://riskframework.allianceofbloodoperators.org/log-in/
Policy foundations

- Risk management principles
- Risk communication and stakeholder participation
- Assessment principles
- Risk tolerability

An emerging risk

Babesia microti (B. microti)

- An infection caused by a parasite transmitted by ticks.
- Endemic in parts of the United States with 96% of reported cases in Northeast and Midwest States.
- For some people (immunosuppressed, the elderly, and asplenics, symptoms can lead to severe complications that include death.

It can be transmitted by blood transfusion and is increasingly recognized as posing a risk to the US blood supply.
Babesia microti – reported Cases of Transfusion Transmission

**UNITED STATES**

160 transfusion transmissions\(^1\)

12 deaths

**CANADA**

1 transfusion transmission (1998)\(^2\)

0 deaths

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\(^2\)Kain KC, Jassoum SB, Fong IW, Hannach B. Transfusion-transmitted Babesiosis in Ontario: First reported case in Canada. CMAJ 2001;164:1721-3

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**Evidence suggests B. microti is emerging as an endemic infection in Canada**

- It is well established in the U.S. states bordering Canada.
- It has been identified (0.02 – 1.7% of ticks tested) in tick populations in Manitoba, Ontario, Quebec and New Brunswick, by passive and active surveillance.
- Incidence of Lyme disease, a reasonable surrogate for B. microti, appears to be slowly increasing.
- First confirmed human case of endemically acquired B. microti reported in Manitoba in 2013.
Results of Active Tick Surveillance 2008-2012

Ogden N. et al
Environmental Risk from Lyme Disease in central and eastern Canada: a summary of recent surveillance information.
CCDR 2014;40:58-67

<table>
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<tr>
<th>Canada Communicable Disease Report</th>
<th>Relevé des maladies transmissibles au Canada</th>
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</table>

**CASE REPORT**

The first case of locally acquired tick-borne Babesia microti infection in Canada

**Abstract**

A case of locally acquired Babesia microti infection is described in a child living in central Canada. The patient was diagnosed with babesiosis on August 2, 2015, following a tick bite in May 2015. The child had no history of travel outside of North America. The diagnosis was made through the detection of Babesia microti DNA in peripheral blood samples. The patient was treated with doxycycline and recovered completely. This case highlights the need for continued surveillance and public health measures to prevent the spread of tick-borne diseases in this region.

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**Results of Active Tick Surveillance 2008-2012**

Ogden N. et al. 2014 CCDR 40: 73-75

*Environmental Risk from Lyme Disease in central and eastern Canada: a summary of recent surveillance information.*

**Abstract**

A summary of recent surveillance information on tick-borne diseases in central and eastern Canada. The surveillance data highlights the importance of tick-borne diseases in the region and the need for continued monitoring to understand the epidemiology and risk factors associated with these diseases.
Positive ticks and rodents with proportion of CBS donations by census divisions in Manitoba*

*Map courtesy of Robbin Lindsay, National Microbiology Laboratory, Public Health Agency of Canada

What level of risk does Babesia microti pose to the blood supply in Canada?

- 2013 study conducted by Canadian Blood Services and Héma Quebec revealed:
  - Seroprevalence testing of 13,993 blood donors in affected regions indicated no positive donors

  **Conclusion:** Current risk to blood supply is very low.
Assessment team

Dr. Margaret Fearon, Director, Medical Microbiology
Dr. Sheila O’Brien, Associate Director, Epidemiology & Surveillance
Judie Leach Bennett, Director, Centre for Innovation
Sheila Ward, Partner, Industry Knowledge Integration
Stephanie Kelly, Senior Manager, Stakeholder Relations

Assessment question

What are the current and future risks of babesia microti to Canadian blood donors and transfusion recipients and what are the options to address the risks to the Canadian blood supply?

What are reasonable short and long term risk reduction strategies, including surveillance and triggers for future action?
Risk scenarios

Scenario 1 - Current state: 
The risk of babesia is low. The risk is being managed through public health and tick surveillance coupled with periodic blood donor seroprevalence studies.

Scenario 2 - Potential future state: 
The risk of babesiosis to the blood supply escalates and requires a more substantial mitigation response, over and above the ongoing prevalence surveillance.

Risk Management Options

<table>
<thead>
<tr>
<th>Scenario 1</th>
<th>Low risk: manage through public health and tick surveillance coupled with periodic blood donor seroprevalence studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option A</td>
<td>When risk is low, maintain surveillance (i.e. monitor public health surveillance for disease such as Lyme disease, ticks and human cases, in Canada and U.S.) and undertake enhanced surveillance in the form of a blood donor seroprevalence study every 3-5 years. Timing of the study will be guided by data emerging from ongoing surveillance such as increased babesiosis in U.S. states or human cases in Canada.</td>
</tr>
</tbody>
</table>
## Risk Management Options

<table>
<thead>
<tr>
<th>Scenario 2</th>
<th>Risk escalates: requires a more substantial mitigation response, over and above the ongoing prevalence surveillance.</th>
</tr>
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<tbody>
<tr>
<td>Option B</td>
<td>If risk increases based on information from Options A, stop collecting blood from the risk area.</td>
</tr>
<tr>
<td>Option C</td>
<td>If risk increases based on information from A, undertake selective testing for babesiosis of a) donors living in high risk areas and b) travellers to US or Canadian risk areas.</td>
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<tr>
<td>Option D</td>
<td>Maintain a small inventory of babesia tested units for selected patients, e.g. neonates.</td>
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<tr>
<td>Option E</td>
<td>Implement universal testing for babesiosis.</td>
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<tr>
<td>Option F</td>
<td>Implement pathogen reduction technology.</td>
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</tbody>
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## Participation Strategy

Feedback from stakeholder consultation with National Liaison Committee, March 2016:
- Vector-borne threats becoming more common
- Good test run for this and future disease threats
- Response must be appropriate to threat level posed
- Regular communication with stakeholders will reduce fear around emerging threats
- Requires consistent funding and routine collection of surveillance data; support for investment for a proactive response
- Obtain donor consent for future tests to enable research and quick response

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Canadian Blood Services

IT'S IN YOU TO GIVE
What the analysis revealed - Scenario 1:

- Risk to blood supply from babesia is very low; zero antibody positives amongst ~14,000 donors.
- Monitoring for increase in babesia should continue, including blood donor seroprevalence monitoring.
- Donor travel to endemic areas of the U.S. is currently the key risk factor for Canadian blood supply.
- Trigger to reassess risk level will be observed increase in level of babesia in general or donor population.

What the analysis revealed - Scenario 2:

- Reasonable to assume experience in U.S. will be similar in Canada (transfusion transmissions, fatalities).
- There is no licensed universal test for babesia in Canada or the U.S.
- There is no pathogen reduction technology available to treat all fresh blood components.
- Donor travel questions, to prompt deferral, have not been very effective due to complexity/depth of questioning required.
Mitigation option for Scenario 1

When the risk of B. microti is low, the risk mitigation provided by a Option A is considered tolerable:

- ongoing passive and active tick monitoring,
- blood donor seroprevalence studies every 3-5 years
- revisit the 3-5 year study timetable depending on developments with the tick data.

Mitigation option for Scenario 2

The risk mitigation provided by Option C is the proposed option:

*Introduce selective testing of donors living in high risk areas and travelers to the U.S. or Canadian risk areas.*

- A reliable investigational test is available.
- Focus on regional risk balances effective mitigation against cost.
- More manageable operationally than ceasing collections in certain areas.
- Distributes a small risk across all inventory (i.e. that an infected donor may donate outside a high risk area).
Decision

- EMT endorsed the recommendation of the assessment team
- They directed that a donor seroprevalence study should be conducted no later than 2018 to
  - Reassess the level of risk
  - Serve as a basis for developing a trigger to escalate migration efforts in accordance with Scenario 2
- EMT requested some knowledge mobilization about the application of the RBDM framework at CBS. Please follow the link below for more information on this case study. [https://blood.ca/en/blog/2016-12/making-decisions-right-way-global-endeavour-part-1](https://blood.ca/en/blog/2016-12/making-decisions-right-way-global-endeavour-part-1)