



AABB BABESIOSIS RISK-BASED DECISION-MAKING ASSESSMENT REPORT

About This Report

This report was submitted to the AABB Board of Directors in April 2017. As such, there are some statements in the document that were accurate at the time the report was written but are not today. This is a function of developments such as the availability of a licensed assay for *B. microti*, as well as the publication of new data. In the interest of ensuring full transparency and of presenting this report as it was submitted to the AABB Board of Directors, the content of the report has not been updated to reflect events that have taken place since April 2017.

Executive Summary

Recognizing the increasing threat of babesiosis to the US blood supply, the AABB Board of Directors tasked a specially formed working group to conduct a thorough assessment of the risk and benefits of babesia testing in the context of the US health-care sector. The resulting recommendations and best practice identification will be used to inform the Board and relevant committees on the formation of an AABB policy on screening for babesia by the blood sector. It is relevant to note that, at this time, there is no approved blood donation screening test for babesia.

The Ad Hoc Babesia Policy Working Group used the Alliance of Blood Operators risk-based decision-making (RBDM) framework to undertake the assessment. The group moved through each stage of the framework (RBDM Stages 1-6). Throughout this document, the pertinent stage is denoted, demonstrating where the particular step in the process resides within the framework, although there is no written report associated with stage 1, Preparation. The raw data collected as part of the activities comprising each stage are available upon request.

The following assessment question was used to guide the evaluation:

What policy should AABB advocate to achieve the following two goals?

- Mitigate transfusion-transmitted babesiosis (TTB) risk in the United States.
- Alleviate potential geographic disparity in safety risk and availability for babesia-related interventions in a sustainable manner and in the context of interventions that have been taken for other agents.

Additionally, the following four decision drivers were identified:

Patient safety:	A sustainable blood supply that adequately protects recipients in an affordable manner.
Economic factors affecting availability:	Appropriate allocation of finite resources within the health-care system (blood operators and hospitals).
Equity and sustainability:	Fairness and operational feasibility across the entire system (because of regional consequences and disparities).
Technology:	Availability of testing technologies that could affect the safety and availability of the blood supply.

Ten risk management options were identified within three broad categories:

Category 1: Mitigate transfusion risk

Option A	Universal donor screening
Option B	Regional donor screening: screen all units collected in babesia-endemic states
Option C	Regional and selective screening for selected at-risk recipients in babesia-endemic states
Option D	Regional donor screening based on hospital customer requests
Option E	Extended regional screening: all units collected in and transfused in babesia-endemic states, including imports

Category 2: Alleviate potential geographic disparity

Option F	Blood operators in babesia-endemic states absorb costs
Option G	Blood operators in babesia-endemic states pass through costs to hospitals
Option H	Spread costs of babesia screening across all suppliers/hospitals nationally
Option I	Reimbursement (federal, state, insurers) to blood operators or hospitals in babesia-endemic states to offset the costs

Category 3: Increase awareness to enhance protection and treatment

Option J	Education, awareness, surveillance, and hemovigilance
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As described in stage 5 below, these options were evaluated against the status quo, which was considered by the Working Group to be unacceptable. (See the Legal/Regulatory Assessment of stage 4 for additional details.)

Several detailed assessments were conducted relating to blood safety risk, health economics and fiscal impact, operational impact, ethical considerations and social concerns, and legal/regulatory risk. Two separate stakeholder engagement sessions were held to obtain feedback on the recommended approaches. After careful consideration of all the input, the Working Group made the following recommendations:

The Working Group recommends:

1. That risk management option B, “Regional donor screening: screen all units collected in babesia-endemic states” be the recommended approach to manage the risk of babesia to the blood supply. The reasons this option was selected include the following:

- It ensures screening for babesia is conducted where it is needed given the level of risk.
- It is an appropriate allocation of cost to risk.
- The level of risk outside the babesia-endemic states is low (1:10 million).

2. That nucleic acid testing (NAT) be the exclusive preferred platform for babesia screening. This recommendation is supported by the data presented on pages 12-13 of this report. Given the evolution of data to support a NAT-only approach, the Working Group encourages the Food and Drug Administration (FDA) to consider approval of this testing approach and encourages manufacturers to make available, as quickly as possible, a NAT-only approach for babesia.**
3. That the blood sector retains its current model for blood cost reimbursement and that the current practice as described in option G, “Blood operators in babesia-endemic states pass through costs to hospitals” be maintained, subject to the outcomes of Recommendation 4.
4. Recognizing the economic implications to blood operators posed by regional endemicity of emerging pathogens and testing approaches, and recognizing that these economic risks derive from the current reimbursement model for blood safety risk mitigation measures, it is recommended that AABB facilitate the future collection of data on adverse impacts experienced by babesia-endemic state blood operators related to implementation of option B, and ensuing threats to blood sector sustainability.

Potential tactics to achieve this objective include:

- a. Charging the AABB Transfusion Transmitted Diseases Committee to survey babesia-endemic state blood operators and hospitals 1 year after implementation to assess overall impact of the proposed approach.
 - b. Identifying a stakeholder interested in sponsoring and performing a study to evaluate whether implementation of option B will create a severe enough economic problem for blood operators in babesia-endemic states that it will be a threat to blood sector sustainability.
5. That a mechanism with evaluation time frames be put in place to periodically re-evaluate the spread of babesia to other states and regions of the country. In addition to the time frame for such re-evaluations, a standardized definition of “endemic” or “high risk” is required. The Working Group suggested that data collected by hemovigilance programs be collected and evaluated by the AABB Transfusion Transmitted Diseases Committee and the Centers for Disease Control and Prevention (CDC).
 6. Responding to the feedback from the stakeholder consultations about the need for public awareness of the risk of babesiosis, including that of blood recipients, and public education to prevent tick-borne diseases, it is recommended that AABB work with appropriate agencies such as the CDC and/or other public health agencies to increase awareness of babesia to enhance public protection and treatment (option J).

** Susan Galel abstained from participating in this recommendation, and the Chair noted the stated conflict of interest.

Summary of Risk: Babesiosis threat to the US blood supply

Babesiosis is an infection caused by a parasite (*Babesia microti*) transmitted by ticks. It is considered a significant infectious disease threat to transfusion recipients in the United States; as documented through FDA fatality reports, it is the single agent responsible for the highest number of transfusion-related fatalities associated with an infectious disease.¹ It was responsible for four of 15 deaths (27%) due to an infectious agent in blood-transfusion recipients that were reported to the FDA from 2010 through 2014.^{1,2} A review by Fang and McCullough reports that complicated or severe outcomes of transfusion-transmitted babesia have occurred in patients with a variety of underlying diagnoses and highlights the difficulty of identifying “at-risk” recipient populations.³ The epidemiology, probability of infection, and clinical severity have also been described in [AABB Association Bulletin #14-05](#).

The risk of TTB to the blood supply has been assessed by several expert working groups that generated a variety of risk management responses, as summarized below:

1. In September, 2014 the AABB Transfusion Transmitted Diseases Committee recommended that “transfusion transmission of *B. microti* requires an intervention, and that donor testing is appropriate.” The Committee further indicated that regional testing was endorsed for all components collected or transfused in babesia-endemic states.
2. In April 2015, a subgroup of the AABB Transfusion Transmitted Diseases Committee, the Babesia Working Group, was charged with “developing medical, scientific and epidemiological and logistical recommendations regarding the prevention of TTB infection.” Their report recommended the following:
 - a. Blood donation screening for *B. microti* in babesia-endemic states using a regional model.
 - b. Regional is defined as testing all donations in states with significantly elevated prevalence of *B. microti* infection. At the time of the report, this included nine babesia-endemic states: Connecticut, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Rhode Island, and Wisconsin. Future expansion of states included in the regional definition is to be based on a detailed review of the evolving epidemiology of *B. microti* infection in collaboration with public health authorities.
 - c. Reduction of testing in a babesia-endemic state requires justification by providing a review of contemporary epidemiologic data in collaboration with public health authorities.
 - d. All TTB cases should be reported to state public health authorities.
3. In May 2015, the Blood Products Advisory Committee (BPAC) of the FDA voted in favor of antibody screening for *B. microti* in all 50 US states and NAT-only screening in high-risk states.

There is no licensed blood donation screening test for *B. microti*, although some blood operators have begun screening using tests in an investigational new drug (IND) protocol. In anticipation of expected FDA action regarding test licensure and recommendations and or/requirements for donor screening, the AABB Board of Directors established the Ad Hoc Babesia Policy Working Group to:

- Conduct a thorough assessment of the risk and benefits of babesia testing using risk-based decision-making tools and resources within the context of the US health-care sector.
- Develop a white paper and other resources to inform the Board, BBTS Standards Program Unit, and other committees to address recommendations and/or requirements for babesia testing.
- Identify best practices for managing blood donor testing.

The Working Group used the guidance and tools provided by the Risk-Based Decision-Making Framework for Blood Safety, which can be found on the Alliance of Blood Operators website at: <https://allianceofbloodoperators.org/abo-resources/risk-based-decision-making/rbdtm-framework.aspx>.

A fundamental goal of the RBDM Framework is to assess the proportional allocation of finite resources to mitigate the most serious risks, recognizing that the elimination of all risk is not possible. A necessary step in the process is analyzing both qualitative and quantitative factors, including the economic impact of options under consideration. Although the Working Group recognizes that AABB, as a voluntary, member-based association needs to base standards-related decisions on safety and availability, economic factors (ie, those that affect availability, overall, macro-level cost and cost utility) are considered and discussed in this report.

Characterizing the Risk

Between 1979 and 2009, 162 TTB cases were reported in the United States, of which 159 were due to *B. microti*.⁴ The majority were associated with contaminated red cells and four were due to contaminated platelets; 77% of cases were reported between 2000 and 2009, and 87% were reported in seven US babesia-endemic states (New Jersey, New York, Rhode Island, Connecticut, Massachusetts, Minnesota, and Wisconsin). Since then, the geographic range of the parasite has been expanding and at least two additional states, Maine and New Hampshire, have been categorized “babesia-endemic.”⁵ For purposes of this report, “babesia-endemic regions” are defined as the states of New Jersey, New York, Rhode Island, Connecticut, Massachusetts, Minnesota, Wisconsin, Maine, and New Hampshire. Data are lacking regarding the prevalence of babesia in other contiguous states and the potential need to expand the definition of “endemic” or “high risk.”

In 2011, the CDC made babesiosis nationally notifiable by health departments in states where babesiosis is a reportable communicable disease. Just over 1000 cases are reported to the CDC each year. The outstanding disparity related to risk for TTB is geographic. Risk for donor exposure and infection is primarily based on residence in a babesia-endemic state, although travel to a babesia-endemic area also contributes to donor risk. The risk for infection in recipients of blood products is also geographic, with the highest risk to recipients who live in babesia-endemic states and primarily receive blood products from regional donors, although the wide distribution of blood products leads to some risk among recipients outside babesia-endemic states receiving blood collected in those areas. Thus, the bulk of risk to the supply and recipients exists in relatively defined regions of vector and organism prevalence.

The uneven geographic distribution of risk between blood operators in babesia-endemic states vs non-babesia-endemic states is a significant issue in terms of the cost to protect against babesiosis. If a supplier in a babesia-endemic state loses contracts due to economics of testing (ie, must pass on the additional costs of testing to hospitals) there may be increased risk of lack of availability of blood components supplied by operators in that state if the financial viability of some operators is challenged by the expense of testing.

Formulating the Problem and the Risk Management Options

(RBDM Stage 2)

Decision Drivers

The predominance of *B. microti* risk in specific states adds a level of complexity to the RBDM assessment that goes beyond blood safety. As noted in the previous section, the regional nature of the risk introduces operational and financial considerations for blood operators and hospitals in babesia-endemic states. In considering these factors, the Working Group identified the following four decision drivers:

Patient safety:	A sustainable blood supply that adequately protects recipients in an affordable manner.
Economic factors affecting availability:	Appropriate allocation of finite resources within the health-care system (blood operators and hospitals).
Equity and sustainability:	Fairness and operational feasibility across the entire system (because of regional consequences and disparities).
Technology:	Availability of testing technologies that could affect the safety and availability of the blood supply.

Risk Assessment Question

To guide the RBDM assessment, the following question was developed:

What policy should AABB advocate to achieve the following two goals?

- Mitigate TTB risk in the United States.
- Alleviate potential geographic disparity in safety risk and availability for babesia-related interventions in a sustainable manner and in the context of interventions that have been taken for other agents.

Risk Management Options

Ten risk management options were identified within three broad categories:

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Communicating and Consulting on the Risk (RBDM Stage 3)

In addition to the informal consultation that took place with community and public health representatives on ethical and social issues, a formal stakeholder consultation event was held on February 23, 2017, with Harvard University's Community of Ethics Committee (CEC). This committee is a volunteer group of individuals with diverse and mostly nonmedical backgrounds. They are of varying ages (including recent undergraduate and graduate students), work in diverse environments (a high school teacher, an artist, a radiologist, a rabbi, an imam, a phone company employee), but share an interest in bioethical issues.

Dr. DeMaria provided an overview of AABB and of babesiosis. He explained that: ticks are highly adaptive; there has been a double-digit increase of cases (50 to >500) in Massachusetts alone in recent years; most infected individuals are asymptomatic; and although treatable, it can be life-threatening, especially for immune-compromised individuals. The estimated risk of babesia is thought to be in 1 in 18,000 donors in Massachusetts. The geographic nature of babesia and the mitigation options identified by the Working Group also were explained. A series of questions were posed and factual points were clarified. The questions can be found in Appendix I.

After the presentation of the issues, discussion, and information gathering, the CEC began a consensus development process with discussion framed to the questions posed. The committee agreed unanimously that screening should be conducted because the risk is not trivial. The CEC thought that there would be public buy-in in the babesia-endemic areas while outside those areas there would not be much awareness. The consensus clearly leaned toward universal national screening as most defensible, even though the group understood the differential geographic risk, the cost, and the potential impact on the viability of the blood collection and distribution system.

The CEC looked at the cost from the standpoint of \$10-20 per donor amounting to \$140,000,000 to \$280,000,000 (assuming approximately 14,000,000 collections) not being a lot of money compared to the overall cost of health care or even in consideration of an award(s) resulting from a law suit over TTB. The cost argument did not resonate: safety and equity were more important. The committee also felt that concern over the potential geographic spread of risk would support national testing. It would be hard to explain to someone that they got TTB from unscreened blood. Justice argues for national screening. The public relies on confidence that all is being done to ensure safe blood, and not screening would result in loss of trust. The use of autologous donation for surgery was cited as evidence of public concern over blood safety. However, CEC members were interested in getting more information about potential negative impacts of screening and about how a screened product for special use (cytomegalovirus model) might work.

The CEC thought that AABB should do all it can to educate the public about prevention of tick-borne disease. The group inquired whether there are transfusion advocacy organizations that could also participate in public education (one member cited a relative with aplastic anemia).

WORKING GROUP OBSERVATIONS AND COMMENTARY ON THE STAKEHOLDER CONSULTATION

The feedback from this stakeholder consultation mirrored that of the first consultation on ethical issues (page 17), in that there was no awareness of the risk associated with blood transfusions. However, when stakeholders became aware, there was an elevated level of concern. Given that both consultations were held with groups in babesia-endemic areas, it is not surprising that screening of all blood in the region was seen as imperative.

Outside the babesia-endemic region, the initial reaction of the stakeholders was that all blood nationally should also be screened, although stakeholders did acknowledge that it would be helpful to have a deeper understanding of the consequences of such a move and what alternative approaches there could be. Both groups expressed the importance of increased public awareness of the risk and public education to prevent tick-borne disease.

Assessing the Risk and the Risk Management Options (RBDM Stage 4)

To help inform decisions on the risk management options, the following assessments were conducted:

- Blood safety risk
- Economic impact
- Operational risk for blood operators and for hospitals
- Reimbursement equity impact
- Legal/regulatory risk
- Ethical considerations and social concerns

Blood Safety Risk Assessment

The Working Group's consideration of the blood safety risk relied significantly on the most current assessment of the risk of *B. microti* to the blood supply conducted by the American Red Cross.² The study used data collected during screening, donor follow-up, and investigations of cases of TTB. The objectives of the study were to assess the "natural history of infection in blood donors and the effect of screening on blood safety." The following key findings were reported:

- The study identified 335 (0.38%) confirmed-positive donation samples from 89,153 screened donations from June 2012 through September 2014 using a combination of antibody and NAT assays [specifically, an automated immunofluorescence assay (AFIA) and polymerase chain reaction (PCR) as the NAT assay]. An additional 367 (0.28%) confirmed-positive donation samples from 131,326 screened donations were identified between October 1, 2014 and August 31, 2016. Twenty percent of identified samples were PCR positive and 1 in 10,000 of the total donations screened were from donors in the antibody-negative window period. PCR-positive units were infectious in hamsters (54% of challenged animals became infected).
- Infected donors were from eight states: Connecticut, Massachusetts, New Hampshire, New Jersey, Maine, Minnesota, New York, and California. The last had one travel-associated case linked to a donor infected in Rhode Island.
- The study identified 62 probable cases of TTB in which a *B. microti* positive donor was identified in the period from January 1, 2010 through August 31, 2016; 29 of these occurred during the study period. When compared to screened blood in 10 highly babesia-endemic counties during the study period, in which no cases of TTB occurred, unscreened blood resulted in 14 TTB cases ($p=0.05$; odds ratio = 8.6), or a residual risk of 1 in 18,000 unscreened donations.
- The estimated TTB risk in nine babesia-endemic states (seven previously identified plus New Hampshire and Maine), is 1 case in 101,000 donations.
- The incidence of TTB outside these states (attributable to travel) is 1 case in 10 million donations.
- Most asymptomatic donors who are deferred from donating retain PCR-positive status for less than 1 year, whereas antibody reactivity may be retained for several years.

Table 1 provides detail on the number of suspected TTB cases investigated by the American Red Cross between January 2010 through August 2016. The data in Table 1 also identify cases in states such as Pennsylvania that were previously considered to be at low risk for babesiosis. This indicates that, while geographic areas affected by *B. microti* are still restricted, they are expanding and require periodic re-evaluation of "endemic" status.

Table 1: Number of suspected TTB cases investigated by American Red Cross between January 2010 – August 2016²

Year	2010	2011	2012	2013	2014	2015	2016	Totals
Cases opened	11	22	17	11	18	24	14	117
# Involved donors	115	163	153	69	114	163	141	918
# Positive donors	4	11	11	8	12	12	4	62
# Negative donors	55	114	120	52	79	120	53	593
# Pending /untested donors	56	38	22	9	23	31	84	263
Positive donor residence (County, State)	Stamford, CT Cape May, NJ New London, CT Plymouth, MA	Hunterdon, NJ Washington, MN Fulton, GA* Elk, PA Albany, NY Middlesex, CT Philadelphia, PA Barron, WI Polk, WI Atlantic, NJ Hampden, MA	Hampshire, MA Worcester, MA Bucks, PA Tolland, CT Fairfield, CT Dukes, MA Norfolk, MA Dakota, MN Cumberland, NJ Plymouth, MA Alameda, CA*	New London, CT Mercer, NJ Rockingham, NH Stratford, NH Middlesex, MA Merrimack, NH New Haven, CT Barnstable, MA	Litchfield, CT Middlesex, NJ York, ME Plymouth, MA Plymouth, MA Sagadahoc, ME Monmouth, NJ Hartford, CT Cumberland, ME Litchfield, CT Schenectady, NY Windham, CT	Atlantic, NJ New Haven, CT Fairfield, CT New London, CT Middlesex, CT Hartford, CT Fairfield, CT Hillsborough, NH Bristol, MA Middlesex, MA Bucks, PA Middlesex, MA	Hampden, MA Prince Georges, MD Bucks, PA Barnstable, MA	

* Indicates travel-associated TTB cases in which a donor traveled to a babesia-endemic area, returned home, and donated an infectious unit.

This study confirms that the risk of *B. microti* to the blood system remains predominantly in the regionally babesia-endemic states (1:101,000 risk) but is expanding to additional states.

It also concludes that blood donation screening for antibodies to and DNA from *B. microti* was associated with a decrease in the risk of transfusion-transmitted babesiosis. Table 2 provides data on the performance of the testing methods.

Table 2. Number of donations screened and confirmed positive for DNA from and antibodies to *Babesia microti* as used to calculate positive predictive value of an investigational screening protocol.²

Screening Result	No. Confirmed/ No. Tested [*]	Confirmation Method	Positive Predictive Value
PCR Pos/AFIA Neg (titer <64)	9/9	Quantitative PCR; Ab seroconversion [†] (AFIA, IgM/IgG WB)	100%
PCR Pos/AFIA Pos	67/67‡	IgM/IgG WB; quantitative PCR	100%
PCR Neg/AFIA Pos (titer ≥512)	68/68	IgM/IgG WB; Ab pos on index plasma	100%
PCR Neg/AFIA Pos (titer <512)	191/192	IgM/IgG WB; Ab pos on index plasma	99.5%
Overall	335/336		99.7%

*Positive predictive value calculation excludes one donation that tested AFIA inconclusive due to nonspecific fluorescence on index and on repeated follow-up samples from the donor.

†Eight donors seroconverted on follow-up. One donor did not seroconvert; PCR-reactivity on index was confirmed by detectable parasite load in the original screened sample and PCR-reactivity on an independent red cell sample from the index donation. The index screening result was therefore considered confirmed-positive.

‡Includes 14 ePCR-positive units.

Ab = antibody; AFIA = arrayed fluorescence immunoassay; PCR = polymerase chain reaction; Pos = positive; Neg = negative; WB, western blot; and ePCR, enhanced sensitivity PCR.

For full text of the article that details the blood safety risk assessment utilized, see Appendix II. Additionally, for the supplemental material used as input into the study, see Appendix III.

Economic Impact Assessment

The assessment team noted that since 2014, three studies have been conducted on the cost effectiveness of *B. microti* screening. The results of the studies were highly variable with cost-effectiveness thresholds ranging from \$54,000-\$83,000 per quality-adjusted life-year (QALY)⁶ to between \$5.2 million/QALY⁷ and \$8.8 million/QALY.⁸ Rather than undertake another cost-effectiveness study, the team determined that an alternate approach would be to conduct an analysis of the number of infectious units that would be removed from the system through various testing methods and the cost of prevention.

Leveraging the work of Bish et al,⁶ the assessment team calculated the number of units that would be removed annually by using four testing strategies, the number of units that would be wasted per year, the total annual cost, and the cost to prevent one infection. The results are presented in Table 3.

“Scenario 1” is described by Bish as a “donor only” scenario where the transmission probability from infected blood depends only on the donor’s stage of infection.

Table 3: Babesia Cost Analysis Per Year

Screening Strategy	Testing Method	# Units Removed (True Pos; Moritz et al ²)* Infectious* (range indicates variable PCR reactivity)	# Units Removed (Waste) [†]	Total # Lost Units (A)	Cost (\$)/Lost Units @ \$220/RBC collected (NBCUS, ⁹ AABB ¹⁰) (A)	All Costs (Testing, Processing, TTB Treatment)/RBC (Bish et al Table 4 ⁶) (B)	Total Cost (\$) (B)	Annual Total Costs (A+B)	Cost to prevent 1 infection
Universal - 11 million RBC units collected (NBCUS, AABB 2015) ⁹ ; No change in prevalence vs 13 states+DC [‡]	Both (Ab+PCR)	1654 201	2191	3845	845,900	27.39	301,290,000	302,135,900	1,503,164
	Ab-Imugen (97.31%)	1610 188	2191	3801	836,220	16.15	177,650,000	178,486,220	949,395
	Ab-Immunetics [§] (97.31% adjusted to 91% sensitivity)	1465 171	34,100 (a) 7700 (b) (uses 2 values for specificity) §	(a) 35,565 (b) 9165	(a) 7,824,300 (b) 2,016,300	16.15	177,650,000	(a) 185,474,300 (b) 179,666,300	(a) 1,084,645 (b) 1,050,680
	PCR (22.68%)	375 (377) 191 (198)	0	375 (377)	82,500 (83,317)	14.95	164,450,000	164,532,500 (164,533,317)	861,427 (830,976)
Regional - 4 million units (13 states+DC) likely FDA model; adds 10% yield to 2-million unit model	Both (Ab+PCR)	1654 201	797	2451	539,220	27.39	109,560,000	110,099,220	547,757
	Ab-Imugen (97.31%)	1610 188	797	2407	529,540	16.15	64,600,000	65,129,540	346,434
	PCR (22.68%)	375 (377) 191 (198)	0	375 (377)	82,500 (83,317)	14.95	59,800,000	59,882,500 (59,883,317)	313,521 (302,441)
Regional – 2 million units (7 states; Bish et al; Table 6) ⁶ ; base case*	Both (Ab+PCR)	1504 (2 million × 0.376%/5)* 183	398	1902	418,440	27.39	54,780,000	55,198,440	301,631
	Ab-Imugen (97.31%)	1464* 171	398	1862	409,640	16.15	32,300,000	32,709,640	191,284
	PCR (22.68%)	341 (343)* 174 (180)	0	341 (343)	82,500 (83,317)	14.95	29,900,000	29,982,500 (29,983,317)	172,313 (166,574)

Risk Model; 20% screen negative inventory [◇]	Both (Ab+PCR)	331 40	610	941	207,020	20.46	16,368,000	16,575,020	414,376
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*0.376% confirmed positive by antibody (Ab)+ DNA by PCR; 97.31% Ab positive (regardless of PCR positivity) and 22.68% PCR positive (regardless of Ab positivity).² The total is divided by 5 to compensate for state-wide estimates vs those in only highly babesia-endemic areas⁶ (1:100,000/1:18,000).

The percent and number of infectious units are based on hamster infectivity data² using the number of reactivities by category (Figure 1) × hamster infectivity of each group are listed below. Note that PCR refers to the technology used in Moritz et al² (DNA as the target):

#PCR + only:	9	30%	2.7
#Ab+, PCR +	67	54%	36.2
#Ab+	259	0.8% (2 of 259)	2

Therefore, overall infectivity for all measures is $2.7 + 36.2 + 2 = 40.9/335 = 12.2\%$

The number of infections prevented in 2 million would be $1504 \times 0.122 = 183$

For antibody testing alone the numbers are $36.2 + 2 = 38.2/326 = 11.7\%$

The number of infectious units per 2 million would be $1464 \times 0.117 = 171$

For PCR testing alone, the overall infectivity is $2.7 + 36.2 = 38.9/76 = 51.1\%$

The number of infectious units per 2 million would be $341 \times 0.511 = 174$ (assuming that the 2 infectious Ab+ only samples would not have been detected by PCR screening)

IF those infectious samples ARE detected by DNA screening (Moritz et al² and ARC internal data):

Overall infectivity by PCR alone: $2.7 + 36.2 + 2 = 40.9/78 = 52.4\%$

The number of infectious units per 2 million would be $343 (341+2) \times 0.524 = 180$

† 19.92 lost units per 100,000 for Ab and Ab/PCR, 0 for PCR, 76.27 for the risk model (Bish et al⁶ Table 5 scenario 1).

‡ Specificity using current cutoff and screening in a non-babesiosis-endemic state = 99.69% (a) (6 true pos, 26 false pos of 8363 screened, or 8331/8357=99.69%; Table 1; Levin et al¹⁰); although 99.93% was recalculated (b). Both figures are used (reactive rates of 0.31% or 0.07%). Sensitivity for the test = 91%.

§ Risk from outside a babesiosis-endemic state is 1 per 10 million (Moritz et al²); thus, negligible yield from 11 million screened units.

◇ 20% of 13 states+DC (800,000 units screened of 4 million) (Bish et al⁶).

Conclusions

PCR testing, or other comparable or more sensitive NAT methodologies, is the most cost-effective strategy, results in no wasted units, and captures nearly the same number of potentially infectious units as antibody + PCR (calculations should be identical assuming each infectious unit contained DNA detected by PCR; differences between antibody + PCR and PCR only, assuming all units are infectious, are due to rounding).

In one proposed model using 13 states plus the District of Columbia and 2 million donations screened annually, approximately 200 confirmed-positive donations considered infectious are interdicted annually, fewer with only antibody screening, at costs ranging from ~\$550,000 for both antibody + PCR to ~\$310,000-\$350,000 with either PCR only or antibody only. These data are based on investigational

screening using the Imugen protocol. Relative differences in investigational antibody testing performance are shown in the universal testing model in table 3 above.

Operational Risk Assessment

The operational risk assessment was conducted to better understand the operational impact of options A through E on both blood operators and hospitals. Subject matter experts representing both groups identified and assessed the operational risks for these options. They provided background details for each risk and identified current controls—the strategies, processes, and procedures that are already in place and available to manage the risks. They also assessed both the likelihood and the impact of each risk occurring. Finally, they identified potential mitigations. A complete list of operational risks and a heat map are appended to this report as Appendix IV.

The most significant risks for blood operators (rated High) related to the cost and complexity of introducing a new testing platform (all options) and the risk that testing manufacturers may not pursue test approval if testing for babesia is limited (option C).

For hospitals, the highest rated risks were associated with cost of testing that would be added to the product price (all options), having dual inventories of tested and untested product (depending on labeling requirements) and/or availability of enough product from states outside of the area of concern on hand (options B, C, D, and E), and difficulty associated with identifying “at-risk” patients (option C).

Across all options, the risks associated with cost and availability of safe product were repeatedly raised as serious concerns.

Reimbursement Equity Assessment

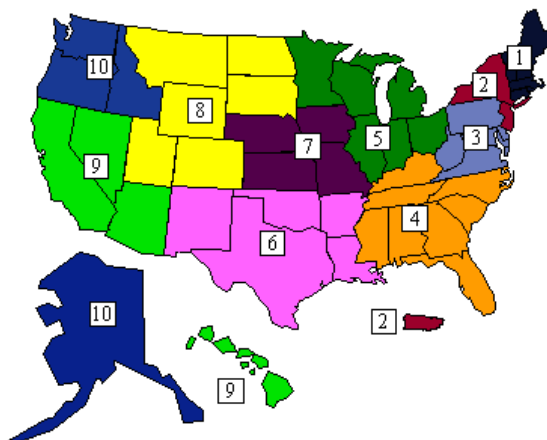
Although cost of testing was identified as one of the highest risk factors for both hospitals and blood operators, the risks associated with ability to absorb the cost by either group were not rated as high. The only risk that was rated as a significant factor under the reimbursement category was the ability to leverage or develop a mechanism to equitably distribute cost across the health-care sector. The free market economy was assessed as an adequate mechanism to manage the economic disparity faced by babesia-endemic states.

There is benefit from maintaining blood collections throughout the country to respond to adverse events, such as new regional epidemics or other disasters, that could affect blood collections. Hence, a minor shift of blood collections from one region of the country to another likely would not be a significant problem. A larger shift is more likely to be a problem.

Currently, some blood is shipped across regions for financial reasons. Some hospitals have standing orders for some of their blood supplies from distant blood providers who provide less expensive blood. In general, these supplies have not provided all of the blood for a hospital.

Geographic pricing differentials currently exist. The 2011 National Blood Collection and Utilization Survey Report found that the prices of Red Blood Cell (RBC) units already vary among different regions of the country as shown in the table below.⁹

USPHS Region	RBCs Avg (\$)
1	254.76
2	237.36
3	225.07
4	213.49
5	212.30
6	222.36
7	209.03
8	253.26
9	246.80
10	230.68



In 2011, the average RBC price ranged from \$209.03 in region 7 to \$254.76 in region 1. Of note, region 1, the most expensive region, is New England and includes several states where babesia is endemic. This is relevant if the listed prices accurately reflect the costs of RBC units in different regions of the country because these regional differences in costs have not, up until now, significantly affected blood collections in the more expensive areas of the country.

However, while anticipated costs of babesia testing are not precisely known, it is estimated to be in the \$10 - \$20 per unit range. Basic economic theory states that there is some point at which there is price sensitivity. Furthermore, blood pricing is already in a range where there is some price sensitivity, because some blood is being shipped across regions for financial reasons. So, raising the cost of blood in a region like New England could result in shifting collections toward some non-babesia-endemic and less expensive parts of the country. Significant studies would need to be conducted to accurately assess the magnitude of the anticipated shift in blood collections.

Legal/Regulatory Assessment

Legal risks to AABB with regard to recommendations developed through the Babesia RBDM process are substantially similar to those in AABB's standard-setting activities; there exists a potential litigation risk for negligent or anticompetitive standards setting (ie, AABB's determination as to when there is adequate scientific evidence to take action). AABB mitigates these risks in numerous ways, including:

1. Engaging subject matter experts (both volunteers and staff members) who possess significant expertise to keep abreast of developments in the transfusion medicine and cellular therapy fields. Actions have included: convening Babesia Work Groups, issuing association bulletins, making public statements/participating in meetings with FDA, as well as a number of TTD projects, and this RBDM exercise.
2. Monitoring, advocating, and communicating to stakeholders about guidance, regulations, and other government actions helps members make informed decisions, especially when standards have not yet been set.
3. Following a well-developed process to help ensure science-based development of standards by subject matter and quality experts including public comment period; comprehensive internal technical/legal/regulatory reviews; periodic evaluation of review process; robust conflicts of interest policy in place with staff, chair, and committee training.

4. Maintaining professional liability insurance (shifts financial risk) that is reviewed and renewed annually.

Regarding risks related to the specific mitigation strategies under consideration, a potential legal risk to AABB lies with the “status quo” option in view of the fact that AABB has gone on record with a recommendation to BPAC for regional screening. The various testing options would not pose substantially different risks to AABB as long as the organization’s recommendations are evidence-based, which can include availability and risk/benefit considerations. Given that AABB is a professional standard-setting organization, it should avoid recommendations related to distribution of costs. However, AABB can advocate for reimbursement from third-party payers for blood costs, including the cost of testing.

With regard to regulatory considerations, it is anticipated that FDA will issue a guidance at some point in the future and, when final, this would likely constitute a minimum standard of practice. It is expected that the guidance will be issued initially as a draft, which would provide AABB the opportunity to comment on factors that may pose operational, medical, ethical, or other risks.

Ethical Considerations and Social Concerns

To conduct an exploration of the ethical and social issues related to screening donors for babesiosis and reimbursement methods, within the context of risk management options F to I, the following sources of stakeholder input were obtained:

1. Review of published articles on ethics and transfusion, as well as cost-effectiveness analyses of strategies for reducing risk for TTB.
2. Community groups in New York that were audiences at several “tick talks” given by public health officials around the state. These groups were primarily Medical Reserve Corps volunteers and public health professionals, but included community members attending public forums sponsored by local municipalities.
3. Public health graduate students in classes on infectious disease epidemiology and risk communication.
4. A focus group of microbiology laboratory directors from Massachusetts and Connecticut.
5. The Executive Director of the Center for Bioethics at Harvard Medical School.

The literature dedicated to general ethical principles and transfusion safety would basically allow defensible grounds for the various scenarios of screening and reimbursement under consideration, except for taking no action. Feasibility and unintended consequence concerns are ascribed to some scenarios, particularly as related to apportionment of cost and dual inventory.

Although the community groups were generally cognizant of babesiosis because of living in a babesia-endemic region, they were almost totally unaware of the threat to the blood supply. This is consistent with evidence that this issue has not come to general attention. However, once apprised of this, consensus was evident about the need to do something about the threat, although there was no sense of urgency. Most attendees who were queried about potential publicity agreed that a high-profile case of TTB would trigger significant public concern. Several people who had personal histories of babesiosis (not transfusion transmitted), expressed a concern about their future need for blood and a desire to

receive screened blood. The general public consulted was unaware of how blood products were priced and reimbursed.

The public health students mirrored the community groups in both a very low awareness of the risk for TTB and of the economics of blood product production and distribution. The students particularly felt that there would be outrage if they, or someone they knew or knew of, suffered major complications from TTB and it was discovered that there was a test that could have screened the blood and that test was not used.

The laboratory directors' primary focus was on logistics and cost. They initially saw the issue in terms of cost-benefit and were concerned whether the incidence of transfusion transmission and its consequences justified the cost of testing. As laboratorians, they were somewhat focused on the performance parameters of the screening tests. After discussion, they reached a conclusion that testing should be done and should be adequately compensated, but did not have a clear idea about how it should be funded. It made sense to them to test donors originating from babesia-endemic states because that was where the risk was, and then to monitor the situation over time for evidence of geographic spread and unexpected cases outside the babesia-endemic region. They tended to think that the costs should be shared among all who avail themselves of the resource, but could not define how such a system of apportionment would occur.

The ethicist had reviewed a sampling of the literature and other information sent to her before the consultation. During the consultation, the ethicist communicated the following conclusions:

- There is an ethical imperative to make the blood supply safer in respect to the risk for babesiosis, and that this ethical imperative is even more relevant for babesia than for Zika virus.
- It is entirely reasonable to screen donors residing in babesia-endemic states, but continue monitoring for expansion of areas at risk and for cases of transmission that occurred despite the screening program.
- It is reasonable to use only screened blood in the babesia-endemic state, regardless of where collected, as a way of dealing with the cost differential of products, but such a measure would not be required on ethical grounds.
- Screened product availability by request (or mixed availability) does not meet the standard of fairness unless the blood product recipient is informed of risk and availability of screened vs unscreened blood, understands the difference, and is involved in the decision of which product to use — “blood should be safe for everyone.”

In summary, a very low level of public awareness of TTB was confirmed, even in a highly babesia-endemic region. When apprised of risk, most people believed that if there is a way to screen blood, it should be done; there is a general sense that it would be unethical not to do so.

There is little to no concern about cost-effectiveness except among the health professionals, and none of the people had any idea how blood is paid for. The professional ethicist agreed with the laboratorians that, for any regional screening approach, there should be ongoing monitoring for changes in epidemiology and exposure risk. The ethicist also raised issues of fairness and equity in access and cost.

Managing the Risk: Risk Management Options Evaluation (RBDM Stage 5)

Evaluation of the blood safety risk management options:

Informed by all of the completed risk assessments, blood safety risk management options A through E were evaluated in terms of their strengths and weaknesses and the level of residual risk across the dimensions of safety, economic impact, ethical and social concerns, and legal and regulatory requirements.

The options were assessed against the status quo, which is defined as:

- There is a donor health questionnaire that is used by blood operators.
- The majority of the blood supply from babesia-endemic states is not tested for babesia because there is no licensed test.
- Some blood operators are providing units that have been screened under IND testing.
- There is no AABB requirement for testing.

Although the status quo does not add cost to the health-care system, a safety risk has been identified; consequently, maintaining the status quo is considered as not recommended, as explained more fully above in the “Legal/Regulatory Assessment” section of stage 4, Assessing the Risk and the Risk Management Options.

Option A: Universal donor screening nationwide

This option provides the advantages of uniform safety across the country and equally distributes the cost of testing nationally. It also addresses the risk of geographic expansion of babesia as well as several operational concerns that were raised such as dual inventories, labeling issues, and distribution across babesia-endemic borders. However, this is the most expensive option and assessed to have low cost utility. It was seen as not scientifically justified because there is extremely low risk in most parts of the country and, on a national basis, does not proportionally distribute resources to the risk level presented by babesia. It fails to move beyond a “precaution at any cost” paradigm.

Option B: Regional donor screening: screen all units collected in babesia-endemic states

This option was seen as proportional allocation of cost to risk, as it addresses the safety issue where the risk is highest. However, it does not address the cost disparity between babesia-endemic states and the rest of the country and also could adversely affect availability in babesia-endemic states if the financial viability of some operators is challenged by the expense of testing. It was acknowledged that it is difficult to determine what is a “babesia-endemic state,” as there is no national mechanism to assess the spread of disease and not all states require reporting of babesiosis. This gap results in residual risk from donors infected in a babesia-endemic area and donating elsewhere. This option also introduces the issue for hospitals possibly having to manage dual inventories of tested and untested blood, depending on labeling requirements.

Option C: Regional and selective screening for selected at-risk recipients in babesia-endemic states

Although this option lowers the cost of testing because it would result in fewer units tested, the biggest drawback is that it is not possible to identify all patients at risk for severe disease. Available data on at-risk recipient populations and potential clinical outcomes are insufficient. Concern was expressed with

“under selecting” at-risk patients to receive screened units and related ethical implications. The operational issues noted in option B also apply to this option.

Option D: Regional donor screening based on hospital customer requests

This is another lower cost option because volume of tested product produced is based on hospital demand; it also recognizes the autonomy of clinical decision makers and end users. The cost of each test may be higher because there will not be economies of scale in testing. Although the usual operational issues were raised, this option generated significant legal and ethical concerns. Because a safety risk has been identified and an investigational test is available, even if a hospital does not order a babesia screened unit, there may be a duty-of-care expectation on both the hospital and the blood operator to provide a screened unit. This references back to the ethical assessment where it was noted that “if there is a test, it should be applied.” There may also be a legal risk for similar reasons.

Option E: Extended regional screening: all units collected in and transfused in babesia-endemic states, including imports

This option is more cost effective than universal testing. It normalizes inventory and cost within babesia-endemic states, reduces the safety risk, and helps preserve regional blood centers’ collections (because hospitals will not order “cheaper” blood from outside the region as they may for options C and D). It was also seen as marginally a safer option compared to option B because it could contribute to safety by catching “bellwether” cases in importing jurisdictions, given that the endemicity of babesia is a moving target.

However, it was seen as presenting a barrier to availability because operators that provide blood to the babesia-endemic states may decide not to continue to do so if their costs are increased, resulting in potential lack of product availability in an emergency or in times of high utilization. There was also a concern that requiring testing of imports could create a barrier to importing blood components that are medically needed by particular patients in babesia-endemic states. For example, blood operators outside the babesia-endemic region are likely to perform babesia testing on only a subset of their units, ie, those that are intended for potential export. If a patient in an endemic region needs a blood component with a particular antigen profile, units with these requirements may be available outside the babesia-endemic area but not tested for babesia. Thus, a requirement that all imported blood should be screened for babesia may create barriers to supporting patients in babesia-endemic states without measurably improving the babesia-related safety of the blood for these patients. This option was considered to be an economic disincentive to import/export to the babesia-endemic region and seen as not proportionally allocating cost to risk.

Finally, this option was assessed as increasing risk to AABB, whose mandate is to focus on availability and safety of blood products, and not on blood operator economics.

Evaluation of Options A through E (Category 1: Mitigate transfusion risk)

Before commencing the option evaluation process, the Working Group reflected once again on the feedback received from the two stakeholder consultations:

- There was no awareness of the risk associated with blood transfusions.
- When made aware, stakeholders had an elevated level of concern.
- Screening of all blood in the babesia-endemic region was considered imperative.
- For areas beyond the babesia-endemic region, stakeholders believed all blood nationally should be screened.
- Stakeholders acknowledged it would be helpful to have a deeper understanding of the consequences of universal screening and what alternative approaches there could be.
- Stakeholders expressed the importance of increased public awareness of the risk and public education to prevent tick-borne disease.

Table 4: Risk Management Option Scoring

Risk Scale Low – 1; Medium – 2; High – 3	RISK MANAGEMENT OPTIONS				
RISKS	Option A	Option B	Option C	Option D	Option E
Safety/Supply risk	1	1	2.5	2.5	1
Infrastructure and financial resources required	3	1.5	1.5	1.5	2
Other concerns (ethics, trust, stakeholder tolerability)	2	2	2.5	2.5	2
Total	6	4.5	6.5	6.5	5

The assessment team determined that option A afforded disproportionate allocation of cost to the level of risk in non-babesia-endemic states. At a national cost of \$202 million dollars annually (11 million units × \$20) to avoid a 1 in 10 million risk of acquiring babesia, this option was assessed as intolerable.

Options C and D were rejected due to the safety implications for babesia-endemic area patients given the level of risk from babesia in those areas (1:101,000 overall and 1:18,000 in certain counties). A second, but equally important, consideration was the ethical implication of patient access to screened units; this is particularly relevant given the comments received during the ethical/social concerns stakeholder consultations. Finally, erosion of confidence and trust in the blood system was seen as a high risk with these options.

Options B and E were ranked equally in terms of safety and stakeholder tolerability, but there were differing points of view regarding babesia-endemic state blood sector sustainability given the inequity of the financial burden on operators within babesia-endemic states.

To assist in the further evaluation of the two options, a “pros and cons” exercise was conducted to generate a comparator table.

Table 5: Pros and Cons of the Risk Management Options B and E

Option	Pros	Cons
<p>Option B: Regional donor screening: screen all units collected in babesia-endemic states</p>	<ul style="list-style-type: none"> Substantially lowers patient risk as the risk of babesia in endemic states is high: 1:101,000. It is even higher in some babesia-endemic counties: 1:18,000 Increased cost utility due to closer proportionality between the mitigation measure and the risk magnitude and patient outcomes achieved Although there is little or no awareness among the general public about the risk of babesia, there is an ethical imperative placed on blood operators and hospitals to protect the public once a risk is identified 	<ul style="list-style-type: none"> New testing systems and new vendors; more operationally complex than if test were being implemented on an existing platform Will require ongoing monitoring, leading to changes in definition of “endemic,” which can confound risk and cost utility assessments Significant safety, feasibility, and economic implications associated with “imposing” definitions of babesia-endemic regions Blood collectors in babesia-endemic states will be subjected to higher operational costs; hospital collectors and smaller operators may not be able to afford the additional cost and may stop collecting Blood operators will pass costs on to hospital customers; hospitals may buy more of their blood from operators in non-babesia-endemic regions to save money Does not address cost disparity faced by collectors in babesia-endemic states vs those in non-babesia-endemic states Potential public confidence issue if testing is not universal
<p>Option E: Extended regional screening: all units collected in and transfused in babesia-endemic states (including imports)</p>	<ul style="list-style-type: none"> Meets the safety risk issues discussed in option B Because the endemicity of babesia is a moving target, this option may contribute to safety by catching “bellwether” cases in exporting jurisdictions, thus providing marginally greater safety than option B More cost effective than universal testing Addresses potential competitive disadvantage imposed on blood operators in babesia-endemic states 	<ul style="list-style-type: none"> New testing systems and new vendors; more operationally complex than if tests were being implemented on an existing platform Ethical disconnect: if the unit is transfused in non-babesia-endemic region, no requirement for testing; but if the same unit were transfused in a babesia-endemic region, testing would be required; two standards for the same unit of blood Economic disincentive to export to babesia-endemic states; may result in supply availability issues Risk management measure is overbroad and therefore not commensurate with risk magnitude and patient outcomes achieved Potential public confidence issue if testing is not universal

After careful deliberation, the group agreed that option B was the recommended option. However, the potential economic consequences for babesia-endemic state blood collectors as well as impact on blood supply availability were seen as important issues that could not be properly assessed before implementation of the option. It was suggested that an implementation monitoring regimen is required. Such a mechanism could introduce monitoring requirements and triggers not only for the extension of “endemic” or “high risk” definitions, but also monitoring of the business and supply risks that may arise as babesia-endemic state testing is introduced. It was suggested that AABB could take a lead role in providing guidance in this regard.

Evaluation of Options F through J (Category 2: Alleviate potential geographic disparity and Category 3: Increase awareness to enhance protection and treatment)

In arriving at the decision that the optimal blood safety risk mitigation was option B, “Regional donor screening,” the assessment team acknowledged that there were several risks that could especially affect the blood sector in babesia-endemic states. It is estimated that 70% of blood collected in the United States is collected at a loss. Adding a significant per unit testing cost between \$10 and \$20 may be beyond the capacity of smaller operators to continue operating. In some cases, this may result in consolidation with larger operators or, in the case of hospital collectors, it may cause them to withdraw from collecting. The potential risk would be a reduction in availability of supply in the babesia-endemic region. Although the expectation would be for product to be supplied by non-babesia-endemic suppliers, emerging issues such as deficient iron levels in young donors may result in little to no excess product for export to babesia-endemic states.

In assessing the options in Category 2, the assessment team determined that option F, “Blood operators in babesia-endemic states absorb costs,” was not a realistic option for the reasons cited above. The team decided that, for the immediate term, option G, “Blood operators in babesia-endemic states pass through costs to hospitals” was the only reasonable option as it reflects the current financial model within the blood sector. However, it does nothing to mitigate the risks noted in the previous paragraph.

It was noted that fiscal relief to blood collectors in babesia-endemic states as proposed in risk management option H, “Spread costs of babesia screening across all suppliers/hospitals nationally,” and option I, “Reimbursement (federal, state, insurers) to blood operators or hospitals in babesia-endemic states to offset the costs,” is a model that is not typical in the United States and advocating for implementation of such a model would take time and effort. Nevertheless, there was some support for financial remuneration in the RAND report¹²; this may be an area for further consideration by the AABB Board of Directors.

Finally, the assessment team recommended AABB support option J, “Education, awareness, surveillance, and hemovigilance.” The stakeholder consultation clearly showed little to no awareness of the risk of babesia to the general public and how to prevent it. Early identification by physicians not only improves treatment outcomes but also provides important information about the spread of babesia to other parts of the country. A national organization such as AABB could have important influence in ensuring a robust reporting system in the United States.

Recommendations

The Babesia Policy Working Group recommends:

1. That risk management option B, “Regional donor screening: screen all units collected in babesia-endemic states,” be the recommended approach to manage the risk of babesia to the blood supply. The reasons this option was selected are:
 - It ensures screening for babesia is conducted where it is needed given the level of risk.
 - It is an appropriate allocation of cost to risk.
 - The level of risk outside the babesia-endemic states is low (1:10 million).
2. That a NAT-only approach is the preferred platform for babesia screening.** This recommendation is supported by the data presented on pages 12-13 of this report. Given the evolution of data to support a NAT-only approach, the Working Group encourages the FDA to consider approval of this testing approach and encourages manufacturers to make available, as quickly as possible, a NAT-only approach for babesia.
3. That the blood sector retains its current model for blood cost reimbursement and that the current practice as described in option G, “Blood operators in babesia-endemic states pass through costs to hospitals,” be maintained, subject to the outcomes of Recommendation 4.
4. Recognizing the economic implications to blood operators posed by regional endemicity of emerging pathogens and testing approaches, and recognizing that these economic risks derive from the current reimbursement model for blood safety risk mitigation measures, it is recommended that AABB facilitate the future collection of data on adverse impacts experienced by babesia-endemic state blood operators related to implementation of option B, and ensuing threats to blood sector sustainability.

Potential tactics to achieve this objective include:

- a. Charging the AABB Transfusion Transmitted Diseases Committee to survey babesia-endemic state blood operators and hospitals 1 year after implementation to assess overall impact of the proposed approach.
 - b. Identifying a stakeholder interested in sponsoring and performing a study to evaluate whether implementation of option B will create a severe enough economic problem for blood operators in babesia-endemic states that it will be a threat to blood sector sustainability.
5. That a mechanism with evaluation time frames be put in place to periodically re-evaluate the spread of babesia to other states and regions of the country. In addition to the time frame for such re-evaluations, a standardized definition of “endemic” or “high risk” is required. The Working Group suggested that data collected by hemovigilance programs be collected and evaluated by the AABB Transfusion Transmitted Diseases Committee and the CDC.

6. Responding to the feedback from the stakeholder consultations about the need for public awareness of the risk of babesia, including that of blood recipients, and public education to prevent tick-borne diseases, it is recommended that AABB work with appropriate agencies such as the CDC and/or other public health agencies to increase awareness of babesia to enhance public protection and treatment (option J).

** Susan Galel abstained from participating in this recommendation, and the Chair noted the stated conflict of interest.

Ad Hoc Babesia Policy Working Group

***If there are, in fact, two separate groups, then more clarity is needed in the report, as Working Group is the predominant name for the whole crew. "Teams" seems to be used for subgroups within.

The personnel assembled for this risk analysis included various types of relevant subject-matter expertise.

Member	Title and Affiliation	Subject-Matter Expertise
Zbigniew M. Szczepiorkowski, MD, PhD, FACP	Associate Professor of Pathology and of Medicine, Dartmouth-Hitchcock Medical Center	Transfusion medicine specialist; director of a blood donor program in a babesia-endemic area
Susan L. Stramer, PhD	Vice President, Scientific Affairs, American Red Cross and Chair of AABB TTD Committee,	Testing risk mitigation efforts for babesia; principal investigator (PI) of largest IND study and author of relevant publications
Steven R. Sloan, MD, PhD	Blood Bank Medical Director, Boston Children's Hospital	Transfusion medicine specialist; director of donor program and patient program in babesia-endemic area; site PI on Imugen study to test donor units for babesia
Susan A. Galel, MD	Senior Director of Medical Affairs, Blood Screening at Roche Molecular Systems Associate Professor Emeritus, Stanford University	Transfusion-transmitted infectious diseases
Alfred DeMaria Jr, MD	State Epidemiologist, Massachusetts Department of Public Health	Public health, infectious diseases, epidemiology
Jeanne V. Linden, MD, MPH	Director, Blood and Tissue Resources, New York State Department of Health	Transfusion risks and public health
Dan Waxman, MD	Chief Medical Officer, Indiana Blood Center	Transfusion medicine specialist and Chief Medical Officer of a regional blood center with a donor testing lab
Diane F. Killion, JD	General Counsel, AABB	Law, risk management
Arnold McKinnon, BA	Advocacy Specialist, AABB	Advocacy
Judie Leach Bennett, LL.B, LL.M.	Director, Centre for Innovation, Canadian Blood Services	Risk, risk-based decision-making, law
Sheila Ward, BA	Partner, Industry Knowledge Integration, Canadian Blood Services	Risk, risk-based decision-making, RBDM facilitator

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