10-ID-27

Committee: Infectious Disease

Title: Public Health Reporting and National Surveillance for Babesiosis

I. Statement of the Problem:

The increasing incidence of reported cases of babesiosis, the identification of multiple *Babesia* agents, the geographic expansion of recognized areas where babesiosis is endemic, and the growing frequency of transfusion-associated cases suggest that the numbers of babesiosis cases in the United States will continue to increase. The purpose of this position statement is to add babesiosis to the CSTE Nationally Notifiable Condition List.

II. Background and Justification:

Background

Babesiosis is caused by intraerythrocytic parasites of the genus *Babesia*, which are transmitted in nature through bites of infected ticks. *Babesia* parasites are also transmissible by transfusion of blood components from asymptomatic, parasitemic donors; no licensed tests for screening U.S. blood donations for evidence of *Babesia* infection are currently available. In addition, sporadic cases of transplacental/perinatal transmission have been described.

Babesia microti is the most frequently identified agent of tick- and blood-borne cases of human babesiosis in the United States; to date, most U.S. reported cases have occurred in parts of the northeastern and north-central regions, but some transfusion-associated cases have occurred in other regions (1). Sporadic U.S. cases caused by other *Babesia* agents have been described, such as *B. duncani* (formerly the WA1 parasite) and related organisms (CA1-type parasites) in several western states as well as parasites characterized as "*B. divergens* like" (MO1 and others) in various states (1-3).

Babesia infection can range from subclinical to life-threatening. Symptoms, if any, usually develop within a few weeks or months after exposure but may first appear or recur many months later, particularly in persons who are or become immunosuppressed. Clinically manifest *Babesia* infection is characterized by the presence of hemolytic anemia and nonspecific influenza-like symptoms (e.g., fever, chills, body aches, weakness, fatigue) (2,3); diagnostic testing is required to distinguish babesiosis from other conditions. Risk factors for severe disease include asplenia, advanced age, and various causes of immune compromise (e.g., HIV, malignancy, immunosuppressive therapies), which also can mask or modulate the clinical manifestations (e.g., some immunosuppressed patients remain afebrile). Complications of severe babesiosis can include marked thrombocytopenia, disseminated intravascular coagulation, hemodynamic instability, acute respiratory distress, myocardial infarction, renal failure, hepatic dysfunction, altered mental status, and death. Reported case-fatality rates for

symptomatic *Babesia* infection have ranged from 5-9% and as high as 21% in immunocompromised patients (2).

In portions of the northeastern and north-central United States, *B. microti* circulates between *Ixodes scapularis* (blacklegged tick, sometimes called the deer tick) and animal reservoir hosts, primarily small mammals such as *Peromyscus leucopus* (white-footed mouse) (2,3). In these regions, this enzootic cycle is shared by the etiologic agents of Lyme disease (*Borrelia burgdorferi*) and human anaplasmosis (*Anaplasma phagocytophilum*). *B. microti* in humans can occur as a coinfection with *B. burgdorferi*, *A. phagocytophilum*, or both (4,5). From 1992 through 2006, the number of reported U.S. Lyme disease cases more than doubled, and the geographic range of reported Lyme disease cases expanded in portions of some northeastern and north-central states (5). From 2004 through 2008, the number of U.S. human anaplasmosis cases nearly doubled (6). Similarly, babesiosis appears to have increasing case numbers and an expanding endemic range in some areas (2), although the U.S. incidence and the full geographic extent of *B. microti* and novel *Babesia* agents are unknown. Distribution of novel *Babesia* agents is not limited to states in which they were initially identified (1), and the tick vectors and reservoir hosts for these novel agents also remain largely unknown (5).

Transfusion-associated babesiosis is not restricted to regions where tick-borne babesiosis is endemic. Because of donor travel to and from regions where babesiosis is endemic and the importation of blood products, blood-borne transmission in the United States has been reported outside of regions where babesiosis is known to be endemic (1). Transfusion-associated babesiosis can also occur during any season, including winter months, due to protracted, asymptomatic parasitemia in donors (8). The blood components associated with blood-borne transmission have included red blood cells (RBCs) and platelet concentrates (because of residual RBCs/parasites) (9,10). Since 1979, at least 70 cases of transfusion-associated babesiosis have been documented in the United States, including 9 deaths reported from 1997-2007 (11). Transfusion-associated babesiosis, which has been documented for *B. microti* and *B. duncani*, is likely underdetected and underreported (9,11).

Tick-borne and transfusion-associated babesiosis can be severe or fatal. In particular, the risk factors for severe babesiosis (e.g., advanced age, immunosuppression) are common characteristics of transfusion recipients; these patients are especially vulnerable to serious complications of *Babesia* infection.

Justification

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support "automated case reporting from electronic health records or other clinical care information systems." The purpose of this position statement is to add babesiosis to the CSTE Nationally Notifiable Condition List and to provide a standardized case classification definition for babesiosis. Currently, individual states' case classification

criteria for babesiosis are variable and do not provide mechanisms for monitoring transfusion-associated babesiosis.

Babesiosis meets the following criteria for a nationally and **standard** notifiable condition, as specified in CSTE position statements 08-EC-02 and 10-SI-02:

- CDC requests **standard** notification of babesiosis to federal authorities
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

In 2009, reporting of babesiosis was explicitly requested in the reporting rules of 17 states or territorial jurisdictions and implicitly requested in 16 additional jurisdictions. Of note, during the period 2004 through 2009, 17 states or jurisdictions reported babesiosis cases to CDC using the National Notifiable Diseases Surveillance System (NNDSS), including 4 states in which babesiosis was implicitly reportable. Babesiosis can occur in states in which it is not known to be endemic. Like other tick-borne diseases (e.g., Lyme disease), patients infected during travel to regions where it is endemic may become ill after they return to their state of residence. Transfusion patients in these states can also acquire *Babesia* parasites in contaminated blood components imported from regions where babesiosis is endemic or donated by travelers to endemic regions.

Transfusion-transmitted babesiosis is the most frequently reported parasitic disease associated with transfusions in the United States (10). In 2009, the American Association of Blood Banks categorized babesiosis in the highest priority risk level for blood safety (12). Blood donors with subclinical infections (which may persist for many months, even more than 1 year) are not identified and deferred by existing donor screening mechanisms; no tests for screening U.S. blood donations for evidence of Babesia infection have been licensed, and donor deferral based on potential tick exposure is neither sensitive nor specific for distinguishing Babesia-infected donors from uninfected donors (1,9). Therefore, preventing transfusion transmission of *Babesia* currently depends largely on halting further transmission potential after an index case of transfusion transmission is identified. If *Babesia* infection is identified in a transfusion recipient, a prompt investigation is crucial to identify a donor with evidence of *Babesia* infection and defer this person from further blood donations. Testing of other patients who received blood components from this donor can be useful to identify additional Babesia-infected persons, some of whom may benefit from antimicrobial treatment. Multiagency collaboration among public health authorities at local, state, and federal levels with blood centers and medical providers is critical to investigate and document potential cases of transfusion-associated babesiosis.

A standardized case classification definition for babesiosis will enable the collection of national surveillance data and enhance the ability of public health authorities to detect, monitor, and prevent babesiosis. Inclusion of transfusion-associated cases and positive donors and co-recipients, even if asymptomatic, will specifically facilitate national surveillance for transfusion-associated babesiosis. We request that babesiosis be added to the CSTE Nationally Notifiable Conditions list.

III. Statement of the desired action(s) to be taken:

- 1. Babesiosis should be added to the Nationally Notifiable Conditions List as a routinely notifiable condition.
- 2. CSTE requests that CDC adopt this standardized case classification definition for babesiosis to facilitate timely, complete, and standard local and national reporting of this condition and that these criteria be adopted by each state in which babesiosis is a recognized public health priority.

IV. Goals of Surveillance:

To provide information on the temporal, geographic, and demographic occurrence of babesiosis, including transfusion-associated babesiosis, to facilitate its prevention and control.

V. Methods for Surveillance:

Surveillance for babesiosis should use the following recommended sources of data and the extent of coverage listed in Table V.

Table V. Recommended sources of data for case identification and extent of coverage for ascertaining cases of babesiosis.

	Coverage			
Source of data for case ascertainment	Population-wide	Sentinel sites		
clinician reporting	Х			
laboratory reporting	Х			
reporting by other entities (e.g., hospitals, veterinarians, pharmacies)	Х			
death certificates	Х			
hospital discharge or outpatient records	Х			
extracts from electronic medical records	Х			
telephone survey				
school-based survey				
other				

VI. Criteria for case identification

A: Narrative: A description of suggested criteria that may be for case ascertainment of a specific condition.

Report any infection or illness to public health authorities that meets any of the following criteria:

- 1. A person who meets at least one of the following:
 - Identification of intraerythrocytic *Babesia* organisms by light microscopy in a Giemsa, Wright, or Wright-Giemsa–stained blood smear
 - Detection of *Babesia microti* DNA in a whole blood specimen by polymerase chain reaction (PCR)
 - Detection of *Babesia* spp. genomic sequences in a whole blood specimen by nucleic acid amplification
 - Isolation of *Babesia* organisms from a whole blood specimen by animal inoculation
 - Elevated *Babesia microti*, *Babesia divergens*, or *Babesia duncani* Indirect Fluorescent Antibody (IFA) total immunoglobulin (Ig) or IgG antibody titer
 - Demonstration of a *Babesia microti* Immunoblot IgG positive result
- 2. A person whose healthcare record contains a diagnosis of babesiosis
- 3. A person whose death certificate lists babesiosis as a cause of death or a significant condition contributing to death

Other recommended reporting procedures

- All cases of babesiosis should be reported.
- Reporting should be on-going and routine.
- Frequency of reporting should follow the state health department's routine schedule.

B. Table of criteria to determine whether a case should be reported to public health authorities:

Table VI-B. Table of criteria to determine whether a case should be reported to public health authorities. Requirements for reporting are established under State and Territorial laws and/or regulations and may differ from jurisdiction to jurisdiction. These criteria are suggested as a standard approach to identifying cases of this condition for purposes of reporting, but reporting should follow State and Territorial law/regulation if any conflicts occur between these criteria and those laws/regulations.

Criterion	Reporting
Clinical Presentation	
Healthcare record contains a diagnosis of babesiosis	S
Death certificate lists babesiosis as a cause of death or a significant condition contributing to death	S
Laboratory findings	
Identification of intraerythrocytic <i>Babesia</i> organisms by light microscopy in a Giemsa, Wright, or Wright-Giemsa–stained blood smear	S
Detection of <i>Babesia microti</i> DNA in a whole blood specimen by polymerase chain reaction (PCR)	S
Detection of <i>Babesia</i> spp. genomic sequences in a whole blood specimen by nucleic acid amplification	S

Criterion	Reporting
Isolation of <i>Babesia</i> organisms from a whole blood specimen by animal inoculation	S
Elevated <i>Babesia microti</i> , <i>Babesia divergens</i> , or <i>Babesia duncani</i> Indirect Fluorescent Antibody (IFA) total immunoglobulin (Ig) or IgG antibody titer	S
Demonstration of a <i>Babesia microti</i> Immunoblot IgG positive result	S

Notes:

S = This criterion alone is Sufficient to identify a case for reporting.

C. Disease-specific data elements:

Disease-specific data elements to be included in the initial report are listed below.

Clinical information

Clinical signs and symptoms of babesiosis (see clinical description in VII-A) Complications of infection Immune suppression due to medical condition or therapy Asplenia, including date of splenectomy Blood transfusion in past year Blood donation in past year Organ transplantation in past year Organ donation in past year Hospitalized and total days hospitalized Death and date of death

Epidemiologic Risk Factors

County and state where infection was presumably contracted Known tick exposure Transfusion recipient of a donor known to have molecular, parasitologic, or serologic evidence of *Babesia* infection

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

Clinical presentation

Babesiosis is a parasitic disease caused by intraerythrocytic protozoa of the *Babesia* genus (*Babesia microti* and other species). *Babesia* are transmitted in nature through the bites of infected ticks but can also be acquired through contaminated blood components from asymptomatic parasitemic donors or, more rarely, transplacentally. *Babesia* infection can range from subclinical to life-threatening. Clinical manifestations, if any, can include hemolytic anemia and nonspecific influenza-like signs and symptoms (e.g., fever, chills, sweats, headache, myalgia, arthralgia, malaise, fatigue, generalized

weakness). Splenomegaly, hepatomegaly, or jaundice may be evident. In addition to signs of hemolytic anemia, laboratory findings may include thrombocytopenia, proteinuria, hemoglobinuria, and elevated levels of liver enzymes, blood urea nitrogen, and creatinine. Risk factors for severe babesiosis include asplenia, advanced age, and other causes of impaired immune function (e.g., HIV, malignancy, corticosteroid therapy). Some immunosuppressive therapies or conditions may mask or modulate the clinical manifestations (e.g., the patient may be afebrile). Severe cases can be associated with marked thrombocytopenia, disseminated intravascular coagulation, hemodynamic instability, acute respiratory distress, myocardial infarction, renal failure, hepatic compromise, altered mental status, and death.

Clinical evidence

For the purposes of surveillance:

- <u>Objective</u>: one or more of the following: fever, anemia, or thrombocytopenia.
- <u>Subjective</u>: one or more of the following: chills, sweats, headache, myalgia, or arthralgia.

Epidemiologic evidence for transfusion transmission

For the purposes of surveillance, epidemiologic linkage between a transfusion recipient and a blood donor is demonstrated if all of the following criteria are met:

- (a) In the transfusion recipient:
 - i. Received one or more red blood cell (RBC) or platelet transfusions within one year before the collection date of a specimen with laboratory evidence of *Babesia* infection; **and**
 - ii. At least one of these transfused blood components was donated by the donor described below; **and**
 - iii. Transfusion-associated infection is considered at least as plausible as tickborne transmission; **and**
- (b) In the blood donor:
 - i. Donated at least one of the RBC or platelet components that was transfused into the above recipient; **and**
 - ii. The plausibility that this blood component was the source of infection in the recipient is considered equal to or greater than that of blood from other involved donors. (More than one plausible donor may be linked to the same recipient.)

Laboratory criteria for diagnosis

For the purposes of surveillance:

Laboratory confirmatory:

- Identification of intraerythrocytic *Babesia* organisms by light microscopy in a Giemsa, Wright, or Wright-Giemsa–stained blood smear; **or**
- Detection of *Babesia microti* DNA in a whole blood specimen by polymerase chain reaction (PCR); **or**
- Detection of *Babesia* spp. genomic sequences in a whole blood specimen by nucleic acid amplification; **or**
- Isolation of *Babesia* organisms from a whole blood specimen by animal inoculation.

Laboratory supportive:

- Demonstration of a *Babesia microti* Indirect Fluorescent Antibody (IFA) total immunoglobulin (Ig) or IgG antibody titer of greater than or equal to (≥) 1:256 (or ≥1:64 in epidemiologically linked blood donors or recipients); **or**
- Demonstration of a Babesia microti Immunoblot IgG positive result; or
- Demonstration of a *Babesia divergens* IFA total Ig or IgG antibody titer of greater than or equal to (≥) 1:256; or
- Demonstration of a *Babesia duncani* IFA total Ig or IgG antibody titer of greater than or equal to (\geq) 1:512.

Case Classification

Confirmed case:

A case that has confirmatory laboratory results and meets at least one of the objective or subjective clinical evidence criteria, regardless of the mode of transmission (can include clinically manifest cases in transfusion recipients or blood donors).

Probable case:

(a) a case that has supportive laboratory results and meets at least one of the objective clinical evidence criteria (subjective criteria alone are not sufficient); **or**

(b) a case that is in a blood donor or recipient epidemiologically linked to a confirmed or probable babesiosis case (as defined above) **and**:

- i. has confirmatory laboratory evidence but does <u>not</u> meet any objective or subjective clinical evidence criteria; **or**
- ii. has supportive laboratory evidence and may or may not meet any subjective clinical evidence criteria but does <u>not</u> meet any objective clinical evidence criteria.

Suspect case:

A case that has confirmatory or supportive laboratory results, but insufficient clinical or epidemiologic information is available for case classification (e.g., only a laboratory report was provided).

Comment

The validity of the diagnosis of babesiosis is highly dependent on the laboratory that performs the testing. For example, differentiation between *Plasmodium* and *Babesia* organisms on peripheral blood smears can be difficult. Confirmation of the diagnosis of babesiosis by a reference laboratory is strongly encouraged, especially for patients without residence in or travel to areas known to be endemic for babesiosis.

A positive *Babesia* IFA result for immunoglobulin M (IgM) is insufficient for diagnosis and case classification of babesiosis in the absence of a positive IFA result for IgG (or total Ig). If the IgM result is positive but the IgG result is negative, a follow-up blood specimen drawn at least one week after the first should be tested. If the IgG result remains negative in the second specimen, the IgM result likely was a false positive.

When interpreting IFA IgG or total Ig results, it is helpful to consider factors that may influence the relative magnitude of *Babesia* titers (e.g., timing of specimen collection relative to exposure or illness onset, the patient's immune status, the presence of clinically manifest versus asymptomatic infection). In immunocompetent persons, active or recent *Babesia* infections that are symptomatic are generally associated with relatively high titers (although antibody levels may be below the detection threshold early in the course of infection); titers can then persist at lower levels for more than a year. In persons who are immunosuppressed or who have asymptomatic *Babesia* infections, active infections can be associated with lower titers.

Babesia microti is the most frequently identified agent of human babesiosis in the United States; most reported tick-borne cases have been acquired in parts of northeastern and north-central regions. Sporadic U.S. cases caused by other *Babesia* agents include *B. duncani* (formerly the WA1 parasite) and related organisms (CA1-type parasites) in several western states as well as parasites characterized as "*B. divergens* like" (MO1 and others) in various states. Serologic and molecular tests available for *B. microti* infection do not typically detect these other *Babesia* agents.

Blood-borne transmission of *Babesia* is not restricted by geographic region or season. The epidemiologic linkage criteria for transfusion transmission that are described here provide a low threshold for asymptomatic donor or recipient cases to be considered probable cases for surveillance purposes and are not intended to be regulatory criteria. Transfusion investigations entail laboratory testing for evidence of *Babesia* infection in recipients and donors as well as epidemiologic assessments of the plausibilities of bloodand tick-borne transmission.

B. Classification Tables:

Table VII-B. Criteria for classifying a case of babesiosis.

	Case Definition				
Criterion	Confirmed	Probable		Suspect	
Clinical Evidence					
fever	0	0	A	A	

	Case Definition				
Criterion	Confirmed	onfirmed Probable Su			Suspect
anemia	0	0	Α	Α	
thrombocytopenia	0	0	Α	Α	
chills	0		Α		
sweats	0		А		
headache	0		А		
myalgia	0		А		
arthralgia	0		Α		
Laboratory Evidence					
Laboratory confirmatory: Identification of intraerythrocytic <i>Babesia</i> organisms by light microscopy in a Giemsa, Wright, or Wright- Giemsa–stained blood smear	Ο		0		0
Detection of <i>Babesia microti</i> DNA in a whole blood specimen by polymerase chain reaction (PCR)	0		0		0
Detection of <i>Babesia</i> spp. genomic sequences in a whole blood specimen by nucleic acid amplification	0		0		0
Isolation of <i>Babesia</i> organisms from a whole blood specimen by animal inoculation.	0		0		0
Laboratory supportive: Demonstration of a <i>Babesia microti</i> Indirect Fluorescent Antibody (IFA) total immunoglobulin (Ig) or IgG antibody titer of greater than or equal to (\geq) 1:256 (or \geq 1:64 in epidemiologically linked blood donors or recipients)		0		0	Ο
Demonstration of a <i>Babesia microti</i> Immunoblot IgG positive result		0		0	0
Demonstration of a <i>Babesia divergens</i> IFA total Ig or IgG antibody titer of greater than or equal to (\ge) 1:256		0		0	0
Demonstration of a <i>Babesia duncani</i> IFA total Ig or IgG antibody titer of greater than or equal to (\ge) 1:512		0		0	0
Epidemiological Evidence					
Involved transfusion recipient: Received one or more red blood cell (RBC) or platelet transfusions within one year before the detection of laboratory evidence of <i>Babesia</i> infection.			N	N	
Involved transfusion recipient: At least one of these transfused blood components was donated by the donor described below.			N	N	
Involved transfusion recipient: Transfusion-associated infection is considered as or			Ν	Ν	

	Case Definition			
Criterion	Confirmed	Probable		Suspect
more plausible than tick-borne transmission.				
Involved blood donor(s): Donated at least one of the RBC or platelet components that was transfused into the above recipient.		N	N	
Involved blood donor(s): The plausibility that this blood component was the source of infection in the transfusion recipient is considered equal to or greater than that of blood from other involved donors. (More than one plausible donor may be linked to the same recipient.)		N	N	

Notes:

N = All "N" criteria in the same column are Necessary to identify a case for reporting. A = This criterion must be absent (i.e., NOT present) for the case to meet the reporting criteria.

O = At least one of these "O" (Optional) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to identify a case for reporting. (These optional criteria are alternatives, which means that a single column will have a either no O criteria or multiple O criteria; no column should have only one O.)

VIII. Period of Surveillance:

Surveillance should be ongoing.

IX. Data sharing/release and Print criteria:

- Notification to CDC of confirmed and probable cases of babesiosis is recommended.
- Data reported through NNDSS will be summarized weekly in the *MMWR* Tables and yearly in the Summary of Notifiable Diseases. Data reviewed over multiple years may be presented, if of public health importance.
- Summary de-identified case data will be published in the annual *MMWR* Surveillance Summary reports for all confirmed and probable cases. Cases will be verified at the state before notification. Some personal identifying and state information (e.g. FIPS code, age, sex, date of report, and date of diagnosis) will be necessary to differentiate cases. Confidentiality and security precautions will be maintained for all potential identifiers.
- In addition to these reports, information may be distributed to states and territories depending on the current epidemiologic situation. Unusual situations may increase the need for communication. For example, results of ad-hoc analyses may be made available to health departments involved in investigations.
- Cumulative and aggregate case data will be monitored by CDC subject matter experts and epidemiologists to facilitate detection of changing trends in cases. Cumulative data may be compared with reports received by CDC's Division of

Parasitic Diseases and Malaria (DPDM) through additional mechanisms, including telephone inquiries and reports from other groups internal to CDC, to evaluate the completeness of notification. Data reviewed over multiple years may be presented if they are of public health importance.

• In circumstances where there is a potential for an international health impact, aggregate data from these notifications may be shared with international partners (e.g., PHAC, ECDC, WHO, PAHO), with all necessary precautions taken to protect patient confidentiality. Only case count data, as reported in *MMWR*, will be released to other agencies or parties. It is the policy of CDC to refer outside agencies or parties to state health departments for more detailed information on cases.

X. References:

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