Frequently Asked Questions and Answers for the Babesiosis Case Notification Message Mapping Guide (MMG)

OVERVIEW

The babesiosis Health Level 7 (HL7) case notification message has two components, (i) the Generic Version 2 (GenV2) data elements, which are part of all case notification messages, and (ii) the data elements specific to babesiosis. The babesiosis message mapping guide (MMG) describes the content (e.g., data elements and valid values) and message mapping specifications to send babesiosis HL7 case notifications to CDC. This frequently asked questions (FAQ) document will provide technical guidance and additional instructions for the submission of cases.

In preparation to onboard for babesiosis HL7 reporting, please review the guidance within the CDC NNDSS (National Notifiable Diseases Surveillance System) Technical Resource Center (<u>https://www.cdc.gov/nndss/trc/index.html</u>) on the implementation of MMGs and preparations for onboarding. Below are the high-level steps jurisdictions should take prior to initiating the onboarding process:

- ✓ Perform the gap analysis.
- ✓ Complete the implementation spreadsheet and test case scenario worksheet.
- ✓ Prepare the test case scenario messages.
- ✓ Submit year-to-date (YTD) records in the legacy format (case report form or flat file) to the CDC babesiosis program prior to the onboarding kickoff call.

Onboarding for babesiosis HL7 case notification implementation is a collaborative process among the jurisdiction, CDC babesiosis program in the Division of Parasitic Diseases and Malaria Center for Global Health (DPDM-CGH) program, and the NNDSS Onboarding Specialists. If you have any onboarding or technical questions or would like to request technical assistance, please email <u>edx@cdc.gov</u> with the subject "Technical Assistance." The CDC babesiosis program (<u>qek6@cdc.gov</u>) can answer any programmatic and surveillance questions about the MMG.

FREQUENTLY ASKED QUESTIONS

Question 1: Which GenV2 data elements are especially important for babesiosis surveillance?

Answer 1: The priority 1 data elements in GenV2 are of particular importance to national babesiosis surveillance. The CDC babesiosis program's prioritization for all babesiosis data elements can be found within the babesiosis MMG (<u>https://ndc.services.cdc.gov/mmgpage/babesiosis-message-mapping-guide/</u>).

DATA ELEMENT SPECIFIC FAQS

Question 2: What is the process that CDC will take to validate messages during onboarding?

Answer 2: The CDC babesiosis program will compare the submitted limited production messages and legacy case data to validate for total counts, completeness, and accuracy of data elements. CDC will validate year-to-date cases for total counts and completeness of data elements. If 10/18/2021 v1

changes or updates were made to the case after the submission date, please inform CDC of data field changes. Additionally, review of the test case scenario messages will ensure that the repeating blocks and the new and updated data elements are properly received.

Question 3: What is the onboarding and validation process for jurisdictions with few to no cases in the last Morbidity and Mortality Weekly Report (MMWR) year?

Answer 3: The CDC babesiosis program and CDC NNDSS Onboarding Specialist recommend that the jurisdiction take full advantage of the test case scenarios by transmitting multiple fully populated messages. In addition, we will request that the jurisdiction send its most recent cases, if within the past 2 years. After the jurisdiction is moved into production and cases occur, the jurisdiction should email edx@cdc.gov with the Subject "First Case of [Condition]" and copy the babesiosis program to ensure that the data transmitted correctly.

Question 4: "State Case Identifier" (INV173), Local Record ID (OBR-3)," and "Local Subject ID" (PID-3) are all included on the GenV2 MMG. Which data element takes priority?

Answer 4: The "Local Subject ID" (PID-3) and "Local Record ID" (OBR-3) are required data elements and must be submitted in the HL7 messages. It is the jurisdiction's choice to send or not to send the "State Case Identifier" (INV173) in the babesiosis message. Jurisdictions should notify the program if the "Local Subject ID" (PID-3) is not a person-level identifier.

Question 5: Are there any new or updated data elements compared to the paper case reporting system? Also, are there any new/updated value sets?

Answer 5: There are no new data elements. However, compared to the case report form, several data elements have been updated to capture multiple instances of the data elements in the form of a repeating block. The below list describes the new repeating blocks in the babesiosis MMG, which permit you to submit more than one set of information.

Repeating Blocks	
Block Name	Element Names
Physician Name/ Number	Physician Name (52526-1),
	Physician Phone (68340-9)
Date of Previous Illness	Date of Previous Illness (82758-4)
Clinical Manifestation	Clinical Manifestation (INV929),
	Clinical Manifestation Indicator (INV930)
Blood Transfusion	Blood Transfusion Date (14687-8)
Blood Donation	Blood Donation Date (82756-8)
Tick Bite	Tick Bite Location (82755-0),
	Tick Bite Date (45347-2)
Travel History	International Destination(s) of Recent Travel (82764-2),
	Travel State (82754-3),
	Travel County (82753-5),
	Date of Arrival to Travel Destination (TRAVEL06),
	Date of Departure from Travel Destination (TRAVEL07)
Industry and Occupation	Current Occupation (85658-3),

	Current Occupation Standardized (85659-1),
	Current Industry (85078-4),
	Current Industry Standardized (85657-5)
Interpretive Laboratory	Test Type (INV290),
	Test Result (INV291),
	Organism Name (LAB278),
	Test Result Quantitative (LAB628),
	Specimen Collection Date/Time (68963-8),
	Parasitemia Level Percentage for Babesiosis (82748-5)

SPECIAL CASE SCENARIO FAQS

Question 6: How should jurisdictions notify CDC of a possible congenital babesiosis case?

Answer 6: The CDC babesiosis program requests that the jurisdiction provide pertinent information regarding the potential congenital case: "Mother Babesiosis While Pregnant (82751-9)," "Mother Confirmed Positive Prior To Delivery (MTH162)," "Mother Confirmed Positive After Delivery (82750-1)," "Mother Confirmed Positive Date (82749-3)." If your jurisdiction does not include these data elements in their HL7 message, provide this information via the comment field "Comment (77999-1)" or secure methods to the CDC babesiosis program along with the mother's case ID (value for OBR-3 "Local Record ID") if available. If using the Comment field is a challenge for a jurisdiction, please contact the babesiosis program. Additionally, include this information in the implementation spreadsheet. Please report any possible congenital cases to CDC as quickly as possible so that prompt follow-up can occur.

Question 7: How should jurisdictions notify CDC of a possible babesiosis-related fatality case?

Answer 7: The CDC babesiosis program requests that the jurisdiction include: "Subject Died (INV145)," "Deceased Date (INV146)." The comment field "Comment (77999-1)" can be used to include any pertinent death data such as cause of death information if available. If the jurisdiction does not include these data elements in the HL7 message, send information using secure methods. Please report any fatal case to CDC as quickly as possible so that prompt follow-up can occur.

Question 8: How should jurisdictions notify CDC of possible blood transfusion-transmitted babesiosis cases?

Answer 8: The CDC babesiosis program requests that the jurisdiction provide the following critical data elements: "Blood Transfusion (82312-0)"; "Transfusion Associated (418912005)"; "Blood Transfusion Date (14687-8)"; "Blood Donor (105470007)"; "Blood Donor Implicated During Investigation (82761-8)"; "Blood Donation Date (82756-8)." If your jurisdiction does not include these data elements in the HL7 message, provide this information via secure methods to the CDC babesiosis program. Please report any possible transfusion-transmitted babesiosis case to CDC as quickly as possible so that prompt follow-up can occur. If investigation assistance is required, contact the CDC babesiosis program.

Question 9: How should jurisdictions notify CDC of a babesiosis culture test result?

Answer 9: For babesiosis, Lab Test Type (INV290) does not include culture as a value; please use LAB608 (other test type) if reporting a culture.

Question 10: How should a babesiosis case be reported by a low-incidence/non-endemic state?

Answer 10: The CDC babesiosis program requests that the jurisdiction provides travel history: "Travel (420008001)," "Travel State (82754-3)," and "Travel County (82753-5)" and date "Date of Arrival to Travel Destination (TRAVEL06)" in order to assess endemicity. If the patient's state of residence does not have known endemic babesiosis, assess the subject's travel to known endemic states (Connecticut, Massachusetts, Minnesota, New Jersey, New York, Rhode Island, and Wisconsin). If travel to an endemic area is not indicated, consider the case locally acquired.

BABESIOSIS CASE DEFINITIONS

Case Definition (https://ndc.services.cdc.gov/case-definitions/babesiosis-2011/)

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 not 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 not meet any objective clinical evidence criteria.

Suspect case:

a) 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).

Clinical Evidence

- <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

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 tick-borne 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

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
 (≥) 1:512.

INSTRUCTIONS FOR COMPLETING SELECT BABESIOSIS MMG DATA ELEMENTS

To assist with mapping data elements to the case report form (CRF), please refer to the annotated babesiosis CRF available in the artifacts section here: <u>https://ndc.services.cdc.gov/mmgpage/babesiosis-message-mapping-guide/</u>. Please refer to the guidance below for specific elements on the CRF. Please note that select variables are not included on the CRF but are included in the MMG.

Section 1: Demographic and Clinical Data

- a) Enter the case state of residence, county of residence, and zip code (*Subject Address County, DEM165; Subject Address State N/A: DEM162; Subject Address ZIP Code N/A: DEM163*); if more than one residence is reported, provide the more frequent residence.
- b) Age at time of illness onset and age unit, (e.g., years, months, weeks, or days). For subjects aged >24 months, it is preferable for age to be calculated in years. Please provide the subject's date of birth, if allowed by local confidentiality regulations. (*Birth Date N/A: DEM115; Age at Case Investigation 77998-3; Age Unit at Case Investigation N/A: OBX-6*)

Section 2: Clinical Manifestations

- a) Indicate whether the subject experienced any of the following signs or symptoms: fever, anemia, thrombocytopenia, headache, chills, sweats, myalgia, arthralgia, other. See case definitions for acceptable data types. Please provide "Yes," "No," or "Unknown" for each of the clinical manifestations. (*Clinical Manifestation INV929; Clinical Manifestation Indicator INV930*)
- b) If the subject dies, indicate the date of death. Also indicate any available cause of death information in the comments section. If the subject death data are received after initial case submission, update and resubmit the case data.

(Subject Died 77978-5; Deceased Date N/A: PID-29)

Section 3: Epidemiologic Factors

- a) Eight weeks before symptom onset or diagnosis, indicate the following (note multiple instances of each data element can be reported in the repeating block)
 - a. Travel Information (specific location, and travel dates). (Travel 420008001; International Destination(s) of Recent Travel 82764-2; Travel State 82754-3; Travel County 82753-5; Date of Arrival to Travel Destination TRAVEL06; Date of Departure from Travel Destination TRAVEL07)
 - b. The type of outdoor activity and date Engage In Outdoor Activities (82762-6); Outdoor Activities (82763-4); Wooded or Brushy Areas (272500005)
 - c. Documented tick bite and location *Tick Bite (95898004); Tick Bite Location (82755-0)*

Section 4: Laboratory Testing for Babesia

Enter the type of test, result, species, percentage parasitemia (for blood smear tests), laboratory name and contact phone number for each test reported on the subject. Include specimen collection date and laboratory result report date and the reporting laboratory name and phone number.

a) The percentage parasitemia (*Parasitemia Level Percentage for Babesiosis, 82748-5*) is the number of infected erythrocytes expressed as a percentage of the total erythrocytes. For blood smear tests, enter the highest percentage parasitemia observed for this illness as numeric value. (Do not include the '%').

REFERENCES

NNDSS Technical Resource Center - HL7 Message Mapping Guides & Standards: <u>https://www.cdc.gov/nndss/trc/mmg/index.html</u>

Babesiosis MMG and artifacts: <u>https://ndc.services.cdc.gov/mmgpage/babesiosis-message-mapping-guide/</u>

NNDSS eSHARE training webinars: <u>https://www.cdc.gov/nndss/trc/onboarding/eshare.html</u>

Babesiosis case report form (CRF): https://www.cdc.gov/parasites/babesiosis/resources/50.153.pdf

Babesiosis case definition: <u>https://ndc.services.cdc.gov/case-definitions/babesiosis-2011/</u>