

#### 13-ID-08

Committee: Infectious Disease

Title: Public Health Reporting and National Notification for Malaria

# I. Statement of the Problem:

Malaria is one of the nationally notifiable conditions for which CSTE has a standardized reporting definition that was last updated in 2009 (CSTE position statement 09-ID-47). To improve the completeness and accuracy of the data reported, there is a need to make some minor revisions to that case definition.

# II. Background and Justification:

# Background

Malaria is a mosquito-borne disease caused by a parasite; intraerythrocytic protozoa of the genus Plasmodium (e.g., *P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae* among other species). The first two species cause the most infections worldwide. *P. falciparum* is the agent that most commonly causes severe and potentially fatal malaria. There were an estimated 219 million clinical cases and 660,000 deaths in 2010, mostly in children under 5 years of age living in sub-Saharan Africa. *P. vivax* and *P. ovale* may have dormant liver stage parasites, which can reactivate and cause malaria several months or years after the infecting mosquito bite. *P. malariae* can result in long-lasting infections and if untreated can persist asymptomatically in the human host for years, even a lifetime. About 1600 cases of malaria are reported each year in the United States, most of which are imported, i.e., acquired in malaria-endemic countries.

The first symptoms of malaria (most often fever, chills, sweats, headaches, muscle pains, nausea and vomiting) are often not specific and are also found in other diseases (such as influenza and other common viral infections). Likewise, the physical findings are often not specific (elevated temperature, perspiration, tiredness). In severe malaria (caused by *P. falciparum*), clinical findings (confusion, coma, neurologic focal signs, severe anemia, respiratory difficulties) are more striking and may increase the suspicion index for malaria.

#### Justification

Malaria meets the following criteria for a nationally and **standard** notifiable condition, as specified in CSTE position statement 08-EC-02:

- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring standard reporting of malaria to public health authorities
- CDC requests standard notification of malaria to federal authorities
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

Between 2006 and 2010 (the last 5 years for which malaria surveillance data has been published), 23% of the malaria cases reported in the United States did not identify the parasite species. A nationwide survey of laboratories in the United States and its nine dependent territories was conducted in 2010 to determine factors that may contribute to shortcomings in the diagnosis of malaria. This survey explored the availability of malaria diagnostic tests, techniques used, and reporting practices. Although malaria diagnostic testing services were available to a majority of U.S. laboratories surveyed, very few were in complete compliance with all of the CLSI guidelines for analysis and reporting of results, and most respondents reported very few cases of malaria annually. Laboratories' difficulty in adhering to the rigorous



CLSI guidelines and their personnel's lack of practice and proficiency may account for delays and errors in diagnosis.

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

1. Utilize standard sources (e.g. reporting\*) for case ascertainment for malaria. Surveillance for malaria should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases
of malaria.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	Х	
Laboratory reporting	Х	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	X	
Death certificates	Х	
Hospital discharge or outpatient records	Х	
Extracts from electronic medical records	Х	
Telephone survey		
School-based survey		
Other		

2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for malaria and <u>keep</u> this condition on the *Nationally Notifiable Condition List.* 

2a. Immediately notifiable, extremely urgent (within 4 hours)

<sup>2</sup> 2b. Immediately notifiable, urgent (within 24 hours)

2c. Routinely notifiable

CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications\*\* to CDC.

CSTE further recommends that CDC collaborates with CSTE to develop a data dictionary and a Message Mapping Guide to receive these data through states' routine electronic data transmission mechanisms.

3. CDC should publish data on malaria as appropriate in *MMWR* and other venues (see Section IX).

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined above.

Terminology:

\* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health



\*\*Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

The malaria case definition will be revised to include reporting requirements for malaria species, and quantification of the parasitemia. These elements will improve the completeness and accuracy of malaria surveillance. Species confirmation by molecular tests such as PCR will also be encouraged.

#### IV. Goals of Surveillance:

To provide information on the temporal, geographic, and demographic occurrence of malaria to facilitate its prevention and control.

# V. Methods for Surveillance: Surveillance for malaria should use the recommended sources of data and the extent of coverage listed in Table III.

Surveillance for malaria should use the sources of data and the extent of coverage listed in table III above.

#### VI. Criteria for case identification:

Reporting refers to the process of healthcare providers or institutions (e.g., clinicians, clinical laboratories, hospitals) submitting basic information to governmental public health agencies about cases of illness that meet certain reporting requirements or criteria. The purpose of this section is to provide those criteria to determine whether a specific illness should be reported.

#### A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

Report any person (symptomatic or asymptomatic) with laboratory confirmed malaria diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country based on the following criteria:

1. Any person with demonstration of *Plasmodium* species in blood film

- 2. Any person with demonstration of *Plasmodium* species by molecular testing (e.g. PCR)
- 3. Any person with demonstration of unspeciated malaria parasites in blood film\*
- 4. Any person with demonstration of *Plasmodium* species by rapid diagnostic antigen testing

Other recommended reporting procedures:

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

\*Efforts should be made to determine a species for all cases of malaria either by expert microscopists or by molecular methods such as PCR.

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



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**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	
Laboratory Evidence	
Demonstration of <i>Plasmodium</i> species in blood film	S
Demonstration of <i>Plasmodium</i> species by molecular testing (e.g. PCR)	S
Demonstration of unspeciated malaria parasite in blood film*	S
Detection of <i>Plasmodium</i> species by rapid diagnostic antigen testing	S

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

\*Efforts should be made to determine a species for all cases of malaria either by expert microscopists or by molecular methods such as PCR.

# C. Disease-specific data elements

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

Clinically compatible symptoms AND

Positive tests result

- Demonstration of *Plasmodium* sp. in blood films OR
- Demonstration of *Plasmodium sp.* by molecular testing (e.g. PCR)

Disease-specific data elements to be included in the follow-up report to CDC are listed below.

What was the species of malaria?

Was the diagnosis PCR-confirmed?

Was patient admitted to hospital?

- Hospital name
- Hospital address

Has the patient traveled or lived outside the U.S. during the past 4 years?

- Country
- Date returned to U.S. (mm/dd/yyyy)
- Duration of stay in foreign country (days)

Did patient reside in U.S. prior to most recent travel?

Principal reason for travel from/to U.S. for most recent trip

Was malaria chemoprophylaxis taken?

- Chloroquine
- Mefloquine
- Doxycycline



- Primaquine
- Atovaquone/proguanil
- Other: \_
- Were all pills taken as prescribed?

History of malaria in last 12 months (prior to this report)?

- Date of previous illness
- Species

Blood transfusion/organ transplant within last 12 months?

Clinical complications for this attack

Therapy for this attack

# VII. Case Definition for Case Classification:

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

#### Laboratory Criteria

Detection of circulating malaria-specific antigens using rapid diagnostic test (RDT)

OR

Detection of species specific parasite DNA in a sample of peripheral blood using a Polymerase Chain Reaction test. (Note: Laboratory-developed malaria PCR tests must fulfill CLIA requirements, including validation studies)

#### OR

Detection of malaria parasites in thick or thin peripheral blood films, determining the species by morphologic criteria, and calculating the percentage of red blood cells infected by asexual malaria parasites (parasitemia).

#### Case classification

#### Confirmed

Detection and specific identification of malaria parasite species by microscopy on blood films in a laboratory with appropriate expertise in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country.

#### OR

Detection of *Plasmodium* species by nucleic acid test\* in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country.

OR

Detection of unspeciated malaria parasite by microscopy on blood films in a laboratory with appropriate expertise in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country.

#### Suspected

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Detection of *Plasmodium* species by rapid diagnostic antigen testing without confirmation by microscopy or nucleic acid testing in any person (symptomatic or asymptomatic) diagnosed in the United States, regardless of whether the person experienced previous episodes of malaria while outside the country.

Clinical samples including Blood smears or EDTA whole blood from all cases can be referred to the CDC Division of Parasitic Diseases and Malaria Diagnostic Laboratory for confirmation of the diagnosis and antimalarial drug resistance testing. Any questionable cases should be referred to the CDC Division of Parasitic Diseases and Malaria Diagnostic Laboratory for confirmation of the diagnosis.

# Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance

A subsequent attack experienced by the same person but caused by a different *Plasmodium* species is counted as an additional case. A subsequent attack experienced by the same person and caused by the same species in the United States may indicate a relapsing infection or treatment failure caused by drug resistance or a separate attack.

Cases also are classified according to the following World Health Organization categories:

- Autochthonous:
  - Indigenous: malaria acquired by mosquito transmission in an area where malaria is a regular occurrence
  - *Introduced*: malaria acquired by mosquito transmission from an imported case in an area where malaria is not a regular occurrence
- Imported: malaria acquired outside a specific area (e.g., the United States and its territories)
- *Induced*: malaria acquired through artificial means (e.g., blood transfusion, common syringes, or malariotherapy)
- *Relapsing*: Recurrence of disease after it has been apparently cured. In malaria, true relapses are caused by reactivation of dormant liver-stage parasites (hypnozoites) of *P. vivax* and *P. ovale*.
- Cryptic: an isolated case of malaria that cannot be epidemiologically linked to additional cases

#### **B. Classification Tables**

Table VII-B lists the criteria that must be met for a case to be classified as confirmed.

Table VII-B. Criteria for defining a case of malaria.



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Criterion	Case Definition	
	Confirmed	Suspected
Laboratory Evidence		
Demonstration of <i>Plasmodium</i> species in blood film	S	
Demonstration of <i>Plasmodium</i> species by molecular testing (e.g. PCR)	S	
Demonstration of unspeciated malaria parasite in blood film*	S	
Detection of <i>Plasmodium</i> species by rapid diagnostic antigen testing without confirmation by microscopy or nucleic acid testing in any person (symptomatic or asymptomatic)		S

Notes: S = This criterion alone is Sufficient to classify a case.

\*Efforts should be made to determine a species for all cases of malaria either by expert microscopists or by molecular methods such as PCR.

# VIII. Period of Surveillance:

Surveillance should be ongoing.

# IX. Data sharing/release and print criteria:

Notification to CDC for confirmed and suspected cases of malaria is recommended.

- Malaria cases reported to Malaria Branch staff directly from the appropriate divisions within each state and electronic reports of confirmed malaria cases that are received via NNDSS are aggregated and summarized on an annual basis. The analysis of malaria case data is summarized annually in the National Malaria Surveillance Summary published in the MMWR.
- States and territories will be provided the results of the compiled malaria case data annually in National Malaria Surveillance Summary published in the MMWR.
- State-specific compiled data will continue to be published in the annual MMWR Surveillance Summaries. All cases are verified with the state (s) before publication. The report is readily available to the public and other organizations on the MMWR website.
- No formal re-release of the case data is provided. The National Malaria Surveillance Summary is
  readily available to the public and other organizations in the MMWR Surveillance Summary
  publication.

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