CDC 54.1 Justifications for Proposed Changes – July 21, 2008

Malaria is caused by a parasite that is transmitted from person to person by the bite of an infected Anopheles mosquito. These mosquitoes are present in almost all countries in the tropics and subtropics. Anopheles mosquitoes bite during nighttime hours, from dusk to dawn. Therefore, antimalarial drugs are only recommended for travelers who will have exposure during evening and nighttime hours in malaria risk areas.

Malaria was endemic throughout much of the United States in the late 19th and early 20th centuries. Interrupted human-vector contact, decreased anopheline populations, and effective treatment contributed to a decline in transmission and to subsequent eradication. However, environmental changes, the spread of drug resistance, and increased air travel could lead to the re-emergence of malaria as a serious public health problem. The potential for the reintroduction of malaria into the United States has been demonstrated by recent outbreaks of mosquito borne transmission in densely populated areas of New Jersey, New York, Texas, and Florida.

Surveillance activities include identifying outbreaks of local malaria transmission, identifying other cases acquired in the United States (for example, transfusion-induced cases) and monitoring trends in imported cases that guide CDC prevention recommendations.

Changes to the form will be made to clarify certain questions in order to capture better surveillance data. Additionally, many of the changes will allow a field to accommodate data that is often written manually on the margins of the form by clinicians, health care providers, and the State Department of Health staff. These proposed changes will not affect burden hours or burden costs, in any way.

The following addresses the changes to the Malaria Case Surveillance Report form.

- (1) DASH No. This question has been changed to "**CSID No**" Justification: DASH name has been changed to CSID (CDC Specimen Identifier) to conform to the new changes in laboratory specimen identification system in place at CDC.
- (2) County The placement of this question has been moved to another section of the form.

Justification: Field placement has been moved underneath "State/territory reporting this case"

(3) Age/ (yrs)(mos) – The format of this field has been reconstructed as "**Age/ yrs. mos. wks. days (circle units)**"

Justification: Change to account for various reporting age units.

(4) Lab results: {Smear positive, smear negative, No smear taken} – This question has been changed to "Positive lab test result (check all that apply): {Smear, PCR, RDT, No test done/unknown}"

Justification: Change to capture PCR and RDT (RDT [rapid diagnostic tests] are now available in the US) positive test results.

(5) Species (check all that apply) – The answer "Other species (specify)" has been added to the answer value set.

Justification: Change to capture other plasmodium species

- (6) NEW FIELD The field "Parasitemia (%)" has been added.

 Justification: This field was added to capture parasitemia results which are many times written in the margins by manually by the clinician completing the form.
- (7) Has patient traveled or lived outside the US during the past 4 year? This question has been changed to "Has patient traveled or lived outside the US during the past 2 year?"

 Justification: Change to 2 years sufficiently captures travel history
- (8) Duration of stay in foreign country (days) The format of this field has been reconstructed as "Duration in country: yrs. mos. wks. days (circle units)".

 Justification: Reworded field to account for various reporting duration/time units
- (9) Did patient reside in US prior to most recent travel? {Yes, for ≥12 months, Yes, for <12 months, No (specify country), Unknown} The answer value set for this question has been changed to "{Yes, No (specify country), Unknown}"

 Justification: Simplified value set to capture the same data; Added unknown as a possible value to collect accurate data
- (10) If yes, which drugs were taken: {Chloroquine, Mefloquine, Doxycycline, Primaquine, Malarone, Other} The answer value set for this question has been changed to "{Chloroquine, Mefloquine, Doxycycline, Primaquine, Atovaquone/proguanil, Other, Unknown}" Justification: Used chemical name, Atovaquone/proguanil instead of the brand name for Malarone; Added unknown as a possible value to collect more accurate data
- (11) Were all pills taken as prescribed? {Yes missed no doses, No missed one to a few doses, No missed more than a few but <half of the doses, No missed doses but not sure how many, Don't know} The answer value set for this question has been changed to "{Yes missed no doses, No missed doses, Unknown}"

Justification: Simplified value set to capture the same data

(12) If yes, species (check all that apply): {Vivax, Falciparum, Malariae, Ovale, Not determined} - The answer value set for this question has been changed to "{Vivax, Falciparum, Malariae, Ovale, Not determined, Other (specify)}"

Justification: Change to capture other plasmodium species

- (13) Clinical Complications: {Cerebral malaria, Renal Failure, ARDS, Anemia (Hb<11, Hct<33), None, Other} The answer value set for this question has been changed to "{Cerebral malaria, Renal Failure, ARDS, Severe anemia (Hb<7), None, Other}"

 Justification: Changed Anemia value to better identify associated clinical complications
- (14) Therapy for this attack (check all that apply): {Chloroquine, Tetracycline/Doxycycline, Mefloquine, Exchange transfusion, Unknown, Primaquine, Quinine/quinidine, Pyrimethamine-sulfadoxine, Malarone, Other (specify)} The answer value set for this question has been changed to "{Chloroquine, Tetracycline, Doxycycline, Mefloquine, Exchange transfusion, Unknown, Primaquine, Quinine, Quinidine, Clindamyacin, Atovaquone/proguanil, Artesunate, Other (specify)}"

Justification: Used chemical name of Malarone; Updated answer value set to capture drugs available for treatment

(15) Date - This guestion has been changed to "Date Submitted".

Justification: Change to clarify date description

(16-23) The value set answer **UNKNOWN** has been added to the following questions/fields:

- 16- Patient admitted to hospital
- 17- Specimen being sent to CDC
- 18- Principal reason for travel from/to US for most recent trip
- 19- Was malaria chemoprophylaxis taken?
- 20- If doses were missed, what was the reason?
- 21- History of malaria in last 12 months (prior to this report)
- 22- Blood transfusion/organ transplant within last 12 months
- 23- Was illness fatal?

Justification: Added unknown as a possible value to collect more accurate data

Form Name #Respondents #Responses Avg. Burden Total Burden Malaria Case Surveillance Report 55 20 5/60 275