MONITORING AND MANAGING THE THREAT OF ANTIMALARIAL RESISTANCE IN GUYANA

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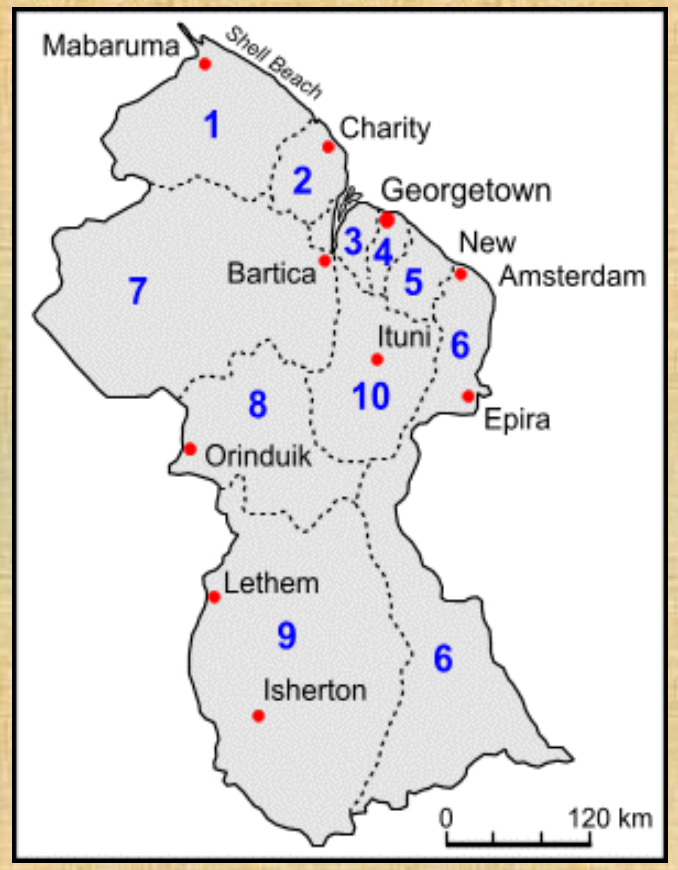
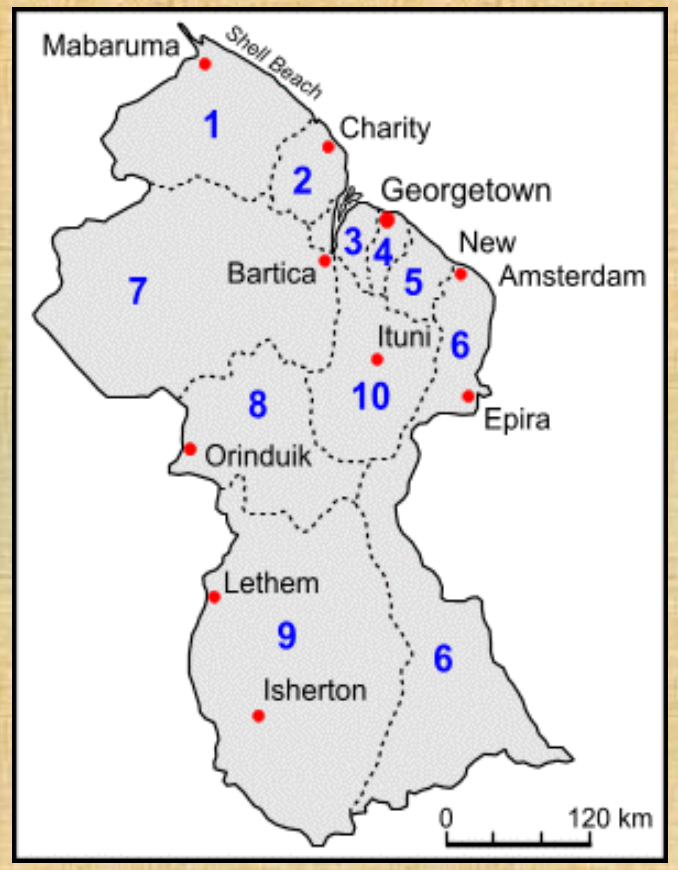
DISTRIBUTION OF C580Y MUTATIONS WORLDWIDE: UPDATE FOR GUYANA

SURVEILLANCE OF ARTEMISININ RESISTANCE: DISTRIBUTION OF C580Y MUTATIONS IN GUYANA



- Collaboration with Institut Pasteur Cayenne
- Sample collected in 2010 for HRP2 survey; 5 samples carried the mutant C580Y (4 from Region 7 and 1 Region 1);
- All five samples had similar K13 flanking microsatellite profiles and were different to the ones observed in Southeast Asia;

SURVEILLANCE OF ARTEMISININ RESISTANCE: DISTRIBUTION OF C580Y MUTATIONS IN GUYANA



- June-Nov 2014: 7-day artesunate trial (4 mg/kg/day) + primaquine single dose; 2% day-3 positivity rate; 100% efficacy and 100% of K13 wild type; N = 50 (26% from Region 1; 54% Region 7; 16% Region 8)
- Survey conducted in 2016 (n = 691) confirmed presence of C580Y mainly in Region 1.

2018 THERAPEUTIC EFFICACY STUDY

- Efficacy and safety of Artemether-Lumefantrine for the treatment of uncomplicated *Plasmodium falciparum* malaria in Georgetown and Region 1, Guyana
- There are two study sites (Port Kaituma-Region 1 and Georgetown-Region 4)each with a target sample size of 94 patients.

2018 THERAPEUTIC EFFICACY STUDY

- One arm prospective study of clinical and parasitological responses to directly observed treatment for uncomplicated *falciparum* malaria.
- People who meet the study inclusion criteria are enrolled, treated on site with Artemether + Lumefantrine and monitored for 28 days.
- The follow-up includes clinical and laboratory examinations.
- The patients are classified as having therapeutic failure (early or late) or an adequate response.

2018 THERAPEUTIC EFFICACY STUDY

- A minimum of 94 febrile patients aged between 5 and 70 years old, with confirmed uncomplicated *P. falciparum* infection enrolled in each site.
- **Primary endpoints:** The proportion of patients with early treatment failure, late clinical failure, late parasitological failure or an adequate clinical and parasitological response as indicators of efficacy.

2018 THERAPEUTIC EFFICACY STUDY

Secondary endpoints:

- to determine the frequency and nature of adverse events.
- to determine polymorphisms of *Plasmodium falciparum K13 (pfK13)* molecular marker of artemisinin resistance;
- to determine polymorphisms in genes associated with resistance to artemisinin partner drugs.

Optional exploratory endpoints:

- to assess the *in vitro* susceptibility of *P. falciparum* isolates if needed;
- to evaluate the presence of HRP2/HRP3 deletion protein in parasites.

2018 THERAPEUTIC EFFICACY STUDY

- 99 patients were enrolled and followed up at the Georgetown site-completed by the end of the fourth month.
- The data for 84 of these patients will be used in the analysis (15 invalid enrolments).
- There are 48 patients enrolled in Port Kaituma after almost 5 months.
- There have been adjustments to the strategies at Port Kaituma in effort to improve enrolment of patients.


THANK
YOU