

Homework Assignment (Reference Key)

Date Due: Wednesday, August 14, 2013

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Assigned Article: "Two fixed-dose artemisinin combinations for drug-resistant falciparum and vivax malaria in Papua, Indonesia: an open-label randomised comparison"

1. Name: Answers will vary.

2. Using any resources available to you, define complicated and uncomplicated malaria.

What's the difference between the two?

→ **Complicated Malaria:** Complicated Malaria according to Wikipedia and several other medical sources cites: A condition in which the patient experiences multiple symptoms of malaria and is unable to be promptly cured with anti-malarial drugs.

Uncomplicated Malaria: Often times a form of Malaria that causes a patient to experience a symptom of Malaria such as fever, however, uncomplicated malaria is malaria that is swiftly cured with oral anti-malarial drugs.

Both forms of Malaria are unfavorable and very much is an inconvenience in regards to good health. The distinction between the two forms is that with Complicated Malaria there is no "quick fix", but rather a series of therapies and treatments in order to extract the parasite from its host. With complicated Malaria patients often times experience intense changes to their everyday routine and are more prone to the challenges of living with Malaria as opposed to uncomplicated diagnosed patients.

3. Why are these scientists focused on researching the less common *P. vivax* while they could be researching *P. falciparum*?

→ *P. vivax* is a more prevalent strain outside of Africa specifically seen in Southeast Asia. *P. falciparum* in contrast is often looked to as the "main" strain in respects to media focus. Although symptoms of both strains will vary in degrees it is important for scientists to pursue both drugs and vaccines to remedy these viral infestations in order to better uplift the lives of the people in these 3rd world countries. From this research it revealed that although there was no significant difference in the treatment Malaria via either drug dihydroartemisinin-piperaquine or artemether-lumefantrine in *P. falciparum* there was a significant treatment response through *P. vivax* from artemether-lumefantrine.

4. What patient parameters did the scientists take use to administer the drug to those who qualified for the clinical trial? Also, which individuals were excluded from the clinical trial?

→ Patient parameters the scientists took to administer the drug was specified in the following passage, "Patients with slide-confirmed malaria (*P. falciparum*, *P. vivax*, or mixed infections) and fever or a history of fever during the preceding 48 h, who presented to the outpatient clinic, were eligible for enrolment. Pregnant or lactating women and children under 10 kg were excluded, as were patients with WHO danger signs or signs of severity, 20 a parasitaemia greater than 4%, or concomitant disease requiring hospital admission. To focus resources and ensure adequate follow-up of the patients enrolled, we restricted recruitment to a maximum of five patients per day from each clinic."

5. What was the follow-up process for the patients in this clinical trial?

→ The follow up process for the patients in the clinical trial included but not limited to: “The cumulative risk of failure was assessed by survival analysis with the Kaplan Meier method on a modified intention to treat basis. Anyone lost during follow-up or, in the case of secondary endpoints, presenting with a different outcome, were censored on their last day of follow-up and regarded as not being treatment failures. Patients failing to complete a 42- day follow-up for any other reason were regarded as treatment failures. Those with recurrent vomiting or adverse drug effects, who required early cessation of treatment and rescue therapy, were regarded as early therapeutic failures. Groups were compared by use of the Mantel-Haenszel log rank test and the hazard ratio (HR) was presented. Furthermore, treatment outcomes were compared and HR calculated after stratification for the initial infecting parasite species with Cox proportional hazards model.”
A good reference or basis for a homework response would have extrapolated the framework involved in interpreting Table 1.

6. How do the relapse frequencies compare under the two drug regimens (dihydroartemisinin-piperaquine versus artemether-lumefantrine)? (Hint: refer to Figure 2.)

→ The relapse frequency of dihydroartemisinin-piperaquine is much lower than that of artemether-lumefantrine. With the delay in relapse of dihydroartemisinin-piperaquine this gave patients a chance to regenerate their blood cells and reduce the risk of anaemia.