

# Ethical Issues in International Research: Case discussion

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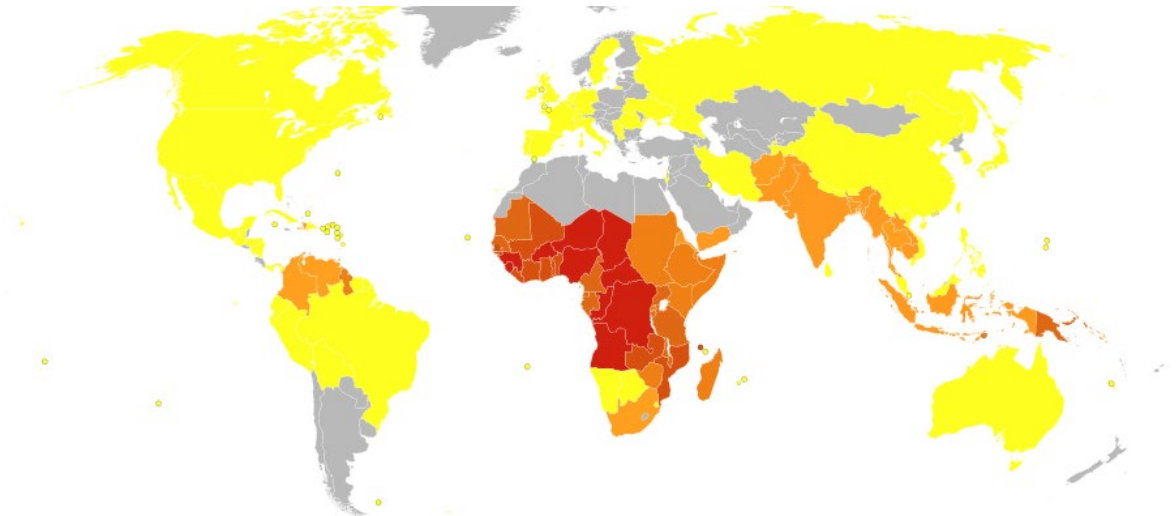
*3 November 2021*

The views expressed are my own and do not  
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# Background

# Malaria

- Mosquito-borne disease caused by parasitic infection
- Endemic in many tropical and sub-tropical regions
- Symptoms include fever, vomiting, headache
- Severe cases can lead to seizures, coma, and death



# Treatment and prevention

- There are effective drugs but resistance is a growing problem
- Prevention measures include vector control, repellants and insecticides, mechanical barriers, and chemical prophylaxis
- People living in malaria endemic regions develop partial immunity



# The proposed study\*

\*Adapted from a real study. Some important details have been changed.

# Overview

- A randomized, placebo-controlled clinical trial of a new antimalarial drug for prophylaxis against malaria infection with *P. falciparum* and *P. vivax*
- Main users will be travelers to malaria endemic regions
- Drug has been approved for treatment of malaria by US FDA



# Study population

- 300 adults drawn from recent immigrants to a malaria endemic island in Indonesia
- The population is moving from a malaria-free area and so is mostly naïve to the disease
- They would not usually use anti-malarial drugs for prevention



# Timeline

1. All participants receive two week radical cure with antimalarial drugs
2. Randomized 1:1 to drug or placebo for 20 weeks.
3. Participants will be followed up for four weeks after the last administered dosage.
4. Blood and CSF samples stored for future research



# Procedures

- Daily home visit by study staff
- Weekly clinical evaluations, including blood draws
- Lumbar puncture at weeks 12 and 24
- Treatment available any time for participants who report symptoms



# Discussion

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- Would you approve the study as described?
- If not...
  - What further information do you need?
  - What changes would you require?