The realization that each random passerby is living a life as vivid and complex as your own.
Vaccine clinical trials in low-resource settings: perspectives from Uganda, Tanzania and Kenya

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Malaria – an overview

• Infectious parasitic disease
  – Majority of cases caused by *Plasmodium falciparum* (>90%)
  – 219 million cases of malaria in 2017
  – 435 000 malaria-related deaths (61% of those were under 5 years)

• Mosquito vector

Source: Albert Bonniers Forlag
Malaria – epidemiology

2000

2015

Source: Malaria Atlas Project
Malaria – prevention

- Insecticide spraying
- Insecticide treated bed nets
- Early diagnosis
- Early treatment

Problem: Malaria parasite resistance to treatments and mosquito vector desensitized to insecticides.

Source: Antonio Mendes/Swiss Malaria Group
**Name:** RTS,S

**Target group:** Children aged 5-17 months

**Goal:** Reduce severe malaria in children <5 years of age

Source: Frederic Courbet
RTS,S malaria vaccine phase III trial was carried out between March 2009 and January 2014 in 7 African countries (Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, Tanzania) across 11 clinical trial sites.
Understand the researcher and caregiver experience during clinical trials in low-resource settings to identify the associated ethical challenges and their implications for vaccine research design.

Interviews with caregivers of pediatric participants enrolled in a malaria vaccine clinical trial (n = 78)

Interviews with frontline researchers involved in the phase III RTS,S clinical trial (n = 11)
“Before the research study, when you would visit the government hospital, after the tests they would tell you to go and buy the medicines and sometimes you don’t have the money. But after my child joined the research study, the situation changed. I am grateful as my child was getting malaria tests and given medicines in a sealed bottle not the opened ones.”

“it is difficult as a person, as a human, as a mother”
- Researcher, Kenya
Structural disparity leads to limited autonomy (lack of viable medical options)

Malaria vaccine an act of beneficence, as is providing medical care and reducing child mortality
Complexity theory
Complex adaptive systems (CAS) describe systems that have components of unpredictability, non-linearity, iteration, interdependence and emergence.

A CAS is a system with a history that impacts the current state and the direction of its evolution, a system that has many concurrent interactions which are characterized by feedback loops and is open to the external environment.
Outcomes
1) Recognize the role of the frontline researchers and the tools they need to build trust with caregivers and the community

2) Identify ways in which to support frontline researchers in a way that is appropriate for the context and its structural capacity

3) Develop collaborative partnerships with local stakeholders to reduce structural inequities and foster sustainable health system strengthening

Vaccine clinical trial design