

Publication

Communities and clinical trials: a case study from the RTS,S malaria vaccine trials in eastern Africa

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Keywords benefits; bioethics; burdens of research/beneficence; clinical trials; developing countries; indepth interviews; international research; non-maleficence; qualitative methods; risks; vaccine trials. When clinical trials enter human communities, two complex systems merge-creating challenges for the clinical trial team and the local human community. This is of particular relevance for clinical trials in low-resource settings where the resource scarcity can intensify existing inequities. Here we present a case study of a phase III malaria vaccine clinical trial. Through qualitative interviews with researchers and caregivers of pediatric participants we elucidate themes that shape the clinical trial system. These themes can be a useful complementary planning tool to existing research guidelines for clinical trial researchers. Respondents from both groups reported financial and social contextual realities to be major drivers in the system. We found a strong historical path dependency in the community that was closely tied to the relationships with researchers and indicative of the structural inequities. We elaborate on these findings and offer recommendations to improve trial design.

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