PO 8538 STRENGTHENING SOCIAL STRATEGIES TO ENGAGE SUB-SAHARAN AFRICAN SOCIETIES TO VALUE CLINICAL RESEARCH: THE EXPERIENCE IN CONDUCTING CLINICAL TRIALS IN LAMBARÉNÉ

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Background Over the last two decades, clinical research activities have increased significantly in sub-Saharan Africa but societal engagement to make research socially and economically valuable is limited. Thus, engaging communities when designing clinical research and promoting social impacts of research are becoming key objectives among stakeholders involved in clinical research in sub-Saharan Africa. However, there is a need to define concepts and indicators to assess the strength of community engagement as well as the social impacts of clinical research.

Here, we hypothesised that the social meanings of willingness to participate and compliance to clinical trial procedures are relevant indicators to assess community engagement.

Methods We conducted a retrospective, prospective case study of clinical trials conducted in CERMEL between 1995 and 2017. We performed a social meaning framework analysis of the following processes: protocol design, ethical and regulatory clearance, informed consent and medical study procedures. We identified the social meanings of each procedure according to the involvement of social components (actors, ideas, communication strategies).

Results A total of 42 clinical trials were identified in the ClinicalTrials.gov and Pan-African Clinical Trials Registry databases and confirmed by the top management of CERMEL. Between 1995 and 2004, there was little social meaning connected to trial procedures. This period was associated with poor compliance to study procedures. Between 2005 and 2017, compliance to study procedures improved. Detailed results will be presented during the meeting.

Conclusion The rise in willingness to participate in clinical research and improved compliance with study procedures were associated with the introduction of social components to medical procedures. Both indicators may be relevant to assess the strength of community engagement.

PO 8542 CLINICAL ILLNESS AND OUTCOMES IN NIGERIAN CHILDREN WITH PERSISTENT EARLY-APPEARING ANAEMIA FOLLOWING ARTEMISININ-BASED COMBINATION TREATMENTS OF UNCOMPLICATED PLASMODIUM FALCIPARUM MALARIA

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Background Early-appearing anaemia (EAA) is not uncommon in malarious children following artemisinin-based combination treatments (ACTs) of uncomplicated infections and it may become persistent (PEAA). There is little evaluation of the

factors contributing to and the kinetics of the resolution of haemoglobin deficit characteristic of ACT-related PEAA.

Methods PEAA was defined as haemoglobin concentration <10 g/dL for at least 1 week after treatment initiation with artemether-lumefantrine (AL), artesunate-amodiaquine (ASAQ) or dihydroartemisinin-piperaquine (DP) in malarious children with haemoglobin ≥10 g/dL pre-treatment. Drug-attributable fall in haemoglobin (DAFHB) was defined as the difference between pre-treatment and the lowest recorded haemoglobin value in the first week after treatment initiation. Stepwise multiple logistic regression model was used to evaluate independent predictors of PEAA. Time course of deficits in haemoglobin from baseline was used to estimate the disposition kinetics of haemoglobin deficits using a one compartment model.

Results Asymptomatic PEAA occurred in 46 of 540 children. A duration of illness ≤3 days before presentation, haemoglobin <11.7 g/dL pre-treatment and 8.3 g/dL 1 day after treatment initiation. DAFHB ≥2 g/dL and treatment with DP independently predicted PEAA. Time to 90% reduction in haemoglobin deficit was significantly longer in AL-treated children compared with other treatments. Declines in haemoglobin deficits were monoexponential with the following overall estimated parameters: C_{max} 2.6 g/dL (95% CI 2.3–2.9), T_{max} 3.2 days (95% CI 2.2–4.1), AUC 31.9 g.dL⁻¹.day (95% CI 25–38.8), K_{el} 0.3 day⁻¹ (95% CI 0.3–0.4), t_{1/2} 3.9 days (95% CI 2.6–5.1), CL_p 0.6 L.day⁻¹ (95% CI 0.5–0.7), and V_d 2.4 L (95% CI 1.7–3). Overall, mean anaemia recovery time of 17.9 days (95% CI 15.5–20.2, n=39) was equivalent to 5 multiples of half-time of haemoglobin deficit on Bland-Altman analysis. Eight children, after recovery from PEAA progressed to asymptomatic late-appearing anaemia (LAA).

Conclusion Asymptomatic PEAA, which may progress to LAA, is not uncommon in young children following ACTs. Its occurrence, and progression to LAA, may have implications for case management and control efforts for ACT-related anaemia in sub-Saharan Africa.

PO 8544 USE OF XPRT MTB/RIF ASSAY AND FDA MICROSCOPY RELATIVE TO MONTHLY CULTURES IN MONITORING MULTIDRUG-RESISTANT TUBERCULOSIS PATIENTS IN BAMAKO, MALI

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Introduction Xpert MTB/RIF assay is used extensively for the detection of rifampicin-resistant TB (RR-TB). RR-TB treatment monitoring is culture-based, although, in resource-limited settings, access to TB culture is poor. Alternative methods are needed. We therefore conducted a pilot study to determine