CHALLENGES IN ESTABLISHING A COHORT-EVENT MONITORING DRUG SAFETY STUDY IN IFAKARA AND RUFIJI HDSS, TANZANIA

Mbaraka Amuri1, Brown Kigahe1, Mustafa Njozi1, Irene Masanja1, Majige Selemani1, Dan Kajungu2, Rashid Khatib1, Sharon Ako- Adounvo3, Salim Abdulla1, Fred Binka3, Alexander Dodoo3

1Ifakara Health Institute, Morogoro, United Republic of Tanzania, 2INDEPTH Network Effectiveness and Safety Studies of Antimalarial in Africa

(INESS), Dar es Salaam, United Republic of Tanzania, 3INDEPTH Network Effectiveness and Safety Studies of Antimalarial in Africa (INESS), Accra, Ghana

The recommended artemisinin combination therapy (ACT) for treatment of uncomplicated malaria in Tanzania is artemether-lumefantrine (AL). Although Artemisinin and its derivatives are generally thought to be safe, there is currently little or no data on its safety among populations in Tanzania. In view of this INESS established a phase IV study to

evaluate safety of AL through comprehensive pharmacovigilance in large populations with the aim of documenting rare adverse drug reactions and to characterize known effects in 'real-life'. The methodology employed is cohort event monitoring which is observational, longitudinal and prospective. Patients with diagnosis of malaria for whom AL was prescribed were recruited into the cohort from four health facilities in each HDSS. Information on demographics, use of all medicines, mode of

diagnosis of malaria, presenting signs and symptoms, co-diagnoses, events suspected as adverse drug reactions, reasons for stopping the drug and cause of death (if any) were collected using standardized questionnaire. They were followed up on 7 to 10 days after AL was dispensed. This

report is on the number recruited so far and the challenges in getting the cohort going. 9028 patients were recruited. 9016 (99.8%) completed follow-up on day 7, of which 668 (7.4%) were done by telephone calls.

12 (0.13%) were lost during follow-up. The main challenges encountered are getting enough trained staff to recruit and follow up patients since CEM is quite labour intensive. 38 health providers and 10 field workers were recruited and offered the relevant training in collaboration with regulatory authorities. This helped to overcome the human resource challenge. Another challenge involved is the difficult to reach areas which are cut off especially during the rainy season. Follow up by telephone

was adopted for these areas and this helped to reduce number of lost to follow-up. Setting up a cohort event monitoring program takes time and is demanding in terms of human resource. Training is very important in overcoming this. Involvement of all stakeholders and sponsors is a key to

success.