and DOR (67.1%). Within entry inhibitors, 7.9% (31/391) CXCR4 coreceptor usage was observed, indicating low prevalence of MVC-resistance. A total of 113/626 (18.1%) MDR individuals presented FTR-resistance. T20-resistance was observed in 313/623 (50.2%) of MDR individuals. ART experience, virologic failure at VL> 400 copies/mL and being male were significantly associated with developing MDR.

Conclusion The study reports high prevalence of resistance to second generation NNRTIs and T20 in individuals with MDR HIV variants which reduces their potential use as alternative therapy for this group of PLWH. In contrast, low prevalence of FTR-and MVC-resistance allows for their potential use although we suggest genotypic testing prior to use of these drugs to avoid selection of ineffective ARV regimens.

PA-830 STUDY OF BIOLOGICAL REFERENCE VALUES IN THE RESEARCH SITES AT THE ABDOU MOUMOUNI UNIVERSITY, NIGER

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Background The West the African Network of clinical trial of anti-malarial drug (WANECAM-II) is building a new clinical study team in Niger. There are no country-specific normal ranges for haematology and biochemistry parameters which are required for biological safety assessments in local trial participants. In preparation for upcoming Phase III trials of anti-malarial drugs the aim this study was to determine the references values of biological parameters in Niger population and establish ranges of normal reference values for basic biochemical parameters and haematological parameters in the different seasons of the year.

Methods A first cross sectional studies was conducted from September to October 2021 (rainy season) and a second from March to May 2022 (dry season). Venous blood was drawn from consenting participants in appropriate tubes for haematology and biochemistry parameters assessment. Parameters were analysed in three ages groups (3months- to 5 years, 6–14 years and 15–50 years) to refine the laboratory ranges by age-groups and by gender. Data were entered through Redcap, extracted, and analysed by RStudio. A Protocol specific training provided to the investigators before running the study. New calibrated Cobas c311 analyser for biochemistry and SYSMEX for haematology were provided to the team.

Results We enrolled 533 and 519 volunteers with 65.3% and 33.9% male for the first and second cross-sectional respectively. The age group of 15–50 years was most represented with 48.9% in both seasons while the two other groups were at 25% each. The median values of each parameter, the Lower and Upper normal Limit were determined, and a references document for haematology and biochemistry parameters for clinical study purpose was generated. Detailed results will be presented at the Forum.

Conclusion Through these two cross-sectional studies, we established the first biological parameters for safety evaluation ready to be used for the EDCTP-WANECAM-II KALUMA study in Niger.

PA-836 ANTIMICROBIAL RESISTANCE PATTERNS AND MOLECULAR CHARACTERISATION OF SHIGELLA ISOLATES FROM UNDER-FIVE CHILDREN IN ZAMBIA

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Background Shigella is one of the top five causative agents of childhood diarrhoea, particularly in lower-middle-income countries, and is one of the vaccine-preventable diseases prioritised for vaccine development by the WHO. The emergence of antibiotic-resistant strains of Shigella is a major public health concern as it reduces the effectiveness of available diarrhoeal treatment and management options. We performed drug susceptibility testing using the BD Phoenix 100 automated microbiology system on shigella isolates from Zambian children under five years presenting with diarrhoea at selected health facilities.

Methods We tested 86 shigella isolates from children U5 from outpatient and hospitalised children during a Shigella surveillance study in Lusaka and Ndola collected between 2020–2021.

Results A high proportion of the Shigella isolates showed resistance to trimethoprim/sulfamethoxazole (79.1.4%), Ampicillin (56.9%), amoxicillin-clavulanate (49.4), Cefuroxime (55.8.1%), and gentamicin (49.4%). Resistance to Ciprofloxacin was observed in only two isolates. Overall, 83.7% (n=72) of the isolates exhibited resistance to at least one class of antibiotics. This included 59.3% (n=51) resistance to Cephalosporins, 79.1% (n=68) to Sulfonamides, 57% (n=49) to Penicillin, 48.8% (n=42) to Aminoglycosides and 25.6% (n=22) to beta-lactams. Multi-drug resistance (resistance to 3 or more drug classes) was observed in 62.8% (n=54) of the isolates. More MDR was observed in in-patient isolates, 71.4%(n=10/14), compared to 61.1% (n=44/72) in outpatient isolates. At the species level, multi-drug resistance was observed in 25/29 isolates identified as S. sonnei and 24/33 S. flexneri isolates.

Conclusion Our research indicates a high proportion of antibiotic resistance among the Shigella isolates from young children, which has significant implications for managing Shigella infections. The results support the urgent need for action on effective strategies for Stewardship (i.e. revision of guidelines) and interventions such as vaccines to mitigate the evolution and spread of AMR.

PA-837 A COMBINED HEALTH CARE PROVIDER AND LAY PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT IN APT SEPSIS AND LACTATE STUDIES. A CASE FOR MALAWI

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Background Patient and Public Involvement (PPI) significantly contribute to clinical and implementation science research to

make it relevant, acceptable, and beneficial to the public concerned. Research poses challenges to the lay public contributors to understand Medical Jargon, procedures, processes, and practice. Yet the need for their contribution towards research that is context specific remain critical. We formed a combined professional committee including medical professionals and lay members of the Public to contribute to the conduct of LACTATE and Active Prevention and Treatment of Maternal Sepsis (APT Sepsis) studies.

Methods The research team contacted health care providers, staff, and fellow PPI members to help identify and nominate sepsis survivors, carers, and spouses to survivors to contribute to LACTATE and APT SEPSIS studies. Health care providers experienced in Maternal and Fetal health were contacted to be part of the committee. The committee reviews Study document, receive implementation updates and discuss progress of studies in a combo approach. Health care providers provide a learning platform to lay public contributors to understand medical jargon and contribute effectively to clinical research while the public contributors provide personal, community and public perspectives about research and care services. Together they shape the research conduct.

Results Twelve members, both lay public contributors and health care professionals formed a strong committee in Maternal and Fetal health research group. No negative power imbalances have been observed within the members. The committee successfully informed the development of participant information sheet for LACTATE Study, provided guidance on dissemination of the APT sepsis study during the intervention phase. More protocols use the committee to guide the development and implementation of the research studies.

Conclusion Combining health care professional and lay public contributors is feasible and effective in contributing to research. Combination approach provides instant learning.

PA-840 INFECTIOUSNESS OF PREGNANT WOMEN IN THE SEASONAL MALARIA TRANSMISSION ZONE OF SAPONÉ IN BURKINA FASO

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Background Burkina Faso has a high burden of malaria in pregnancy despite mass deployment of insecticide-treated nets (ITN) and use of intermittent preventive treatment in pregnancy (IPTp). Understanding how pregnant women contribute to the infectious reservoir will enable development of tools to effectively address malaria transmission.

Methods A community-based longitudinal cohort with mosquito infection assays was carried out in pregnant women in Saponé Health District, central Burkina Faso. Pregnant women who were parasite positive were followed monthly after their antenatal care visits (ANC). Venous blood samples were collected for direct membrane feeding assays (DMFA) prior Sulfadoxine-Pyrimethamine (SP) dosing and on day 7 or 14 post DMFA to assess infectiousness to mosquito.

Results A total of 63 pregnant women were enrolled in the survey. 153 mosquitoes feeding experiments were conducted and 7,736 mosquitoes were dissected. 3.9% of feeds were infectious to mosquitoes with 18,3% of mosquito infection rate and 3.6% oocyst prevalence per infected midgut.

Conclusion Key findings related to parasite and gametocyte density, duration of infection and mosquito exposure will be presented during the conference to address the hypothesis that pregnant women under IPTp may still constitute a significant source of mosquito infection.

PA-841 INTRA-COLLABORATION TOWARDS A HARMONIZED WORKING ENVIRONMENT FOR CLINICAL TRIALS IN ZAMBIA – ZAHRSSP (EDCTP PROJECT)

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Background Past years have seen an increase in clinical trials being conducted in Zambia and other countries, which demand for the need to enhance the capacities of ethics committees and regulators to provide ethical oversight. In Zambia, there are multiple institutions tasked with the mandates to provide regulatory oversight over clinical trials, with each having specific legal mandates that include the National Health Research Authority, Zambia Medicines and Regulatory Authority and National Biosafety Authority. As such, clinical trial oversight has been highly segmented causing duplications of efforts, increased turnaround time, worsened by linear approach to submission of applications.

NHRA proposed harmonization of key processes amongst the key regulators within Zambia in the Zambia Health Research Systems Strengthening Project: Working Towards a Harmonized Regulatory Framework Project (ZAHRSSP) implemented by NHRA and supported by EDCTP.

Methods Desk review of existing Acts, guidelines and mandates was done during the implementation of the ZAHRSSP project.

Results a) Capacity building was conducted through provisions of training in research ethics, GCP, and protocol reviews. b) Transition from linear to parallel submission. In the implementation of ZAHRSSP project, the approach was changed into parallel submissions. c) Development of new clinical trial guidelines and regulations. The guidelines describe applications procedures for approvals, reviews, and approval of clinical trials. Key aspects of the harmonization process was realigning the submission forms amongst the key regulators. d) Memorandum of Understandings aimed at harmonizing key processes between NHRA and ZAMRA including conducting of joint clinical trial reviews and inspections.

Conclusion Steps have been taken for intra-collaboration towards a harmonized working environment for clinical trials oversight in Zambia with key regulators working together. However, need for sustaining the key collaborations aspects after the ZAHSSP project and ensure actualization of the key aspects of the guidelines, MOUs and regulations.