PA-205 ETHICAL CHALLENGES IN DISCLOSING GENOMIC RESEARCH RESULTS IN A DEVELOPING COUNTRY

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Background Disclosure of research results may impose undesirable responsibilities and consequences on the participants. Locally and culturally applicable guidelines for protection of research participants from negative consequences of genomic research results disclosure have been not enunciated in many developing countries. Establishment of such guidelines needs to be guided by preferences of the indigenous research participants. This study therefore attempts to determine potential research participants understanding and expectations of disclosure of genomic research results and its implications to participants in genomic research in Nigeria.

Methods In a cross sectional descriptive study 150 participants were selected by systematic sampling from patients attending the laboratory of Adeoyo Maternity Hospital in Ibadan. Information was collected on socio-demographic characteristics of participants, awareness of genomic research studies, preferences on the mode of disclosure of their result and the recipients of such disclosure. Data were analysed using the SPSS version 17 and presented with the tables of frequencies.

Results Most participants were aware of genomic identification of diseases (68%). The main advantage expected from undergoing genomic testing is awareness of health status (58.7%) and main disadvantage is psychological trauma (71.0%). Respondents (94%) preferred genomic research results be communicated to the study participants and certain third parties (86.7%), mostly next of kins (30.7%) and spouses (20%). Reason for seeking disclosure is to obtain social (37.3%) and medical (22%) support. Participants suggested withholding result on account of mental health status of the recipient (10.7%), incurability of the disease (8.7%) and negative social consequence of the disease (8.7%).

Conclusion This study suggests that research participants welcomes disclosure of genomic research results specifically to certain third parties due to the expected benefits. However the consequences of disclosure should be considered before its undertaking. Genomic research undertakings therefore should consider and document research participants' preferences for disclosure while participants consent is being obtained.

PA-206 BREAKING THE SILENCE OF FEMALE GENITAL SCHISTOSOMIASIS IN GHANA'S HEALTH SYSTEM: A CASE OF HEALTH WORKERS WITHIN THE FAST PROJECT

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Background Female Genital Schistosomiasis (FGS) remains one of the most critical and neglected topics in Neglected Tropical Diseases (NTDs) and the health of women and girls worldwide. Health workers' knowledge of FGS is vital to the prevention and management of the disease. This study, therefore, conducted implementation research to identify and address the FGS knowledge gap among health workers in Ghana.

Methods This study was a 3-year (2020 -2022) implementation research study applying a pragmatic uncontrolled quasi-experimental study design. The study involved a baseline assessment, an intervention phase involving the training of health workers about FGS and an endline assessment. A mixed-method approach was applied to data collection. The qualitative data involved 20 In-depth Interviews while the quantitative data involved 116 health workers. NVIVO 12 and STATA 14 were used for qualitative and quantitative data analysis, respectively.

Results Before the intervention, there was little knowledge about FGS among health workers as most participants only understood FGS as merely urogenital schistosomiasis in females. Based on the baseline assessments, an FGS education intervention in the form of training of health workers and distribution of FGS educational materials was carried out. The impact of this intervention enhanced health workers' awareness and management of FGS. However, access (availability and affordability) to praziquantel (the main drug used in treating and preventing schistosomiasis) was cited as a challenge.

Conclusion The FGS intervention has improved health workers' awareness and understanding of FGS. However, there is a need to improve access to praziquantel to facilitate FGS management. In addition, a holistic strategy encompassing all stakeholders at the individual, community, and health-system levels is required to improve the general knowledge and management of FGS.

PA-213 ENHANCING PROTOCOL COMPLIANCE IN LARGE PRAGMATIC DRUG TRIALS IMPLEMENTED IN RESOURCE-LIMITED SETTINGS: EXPERIENCE FROM THE PREGNANZI-2 TRIAL IN THE GAMBIA

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Background The PregnAnZI-2 trial was conducted in The Gambia and in Burkina Faso to evaluate the efficacy of intrapartum azithromycin (AZI) to reduce neonatal sepsis and mortality and maternal infections. Overall, 11,983 birthing parents and their newborns (6,735 participants for Gambia Site) were recruited into the study and randomized at a 1:1 ratio to receive either AZI or placebo. The independent trial monitoring was conducted by the Clinical Trials Unit of the Medical Research Council Unit The Gambia at LSHTM and we report here the main quality measures implemented in the trial and the subsequent protocol deviations observed in The Gambia site.

Methods As part of quality control measures, the trial implemented frequent retraining of trial staff on study procedures, electronic data capture systems with integrated real-time eligibility and data quality checks, and pre-prepared drug blisters numbered similarly as the randomization list and envelopes.

We conducted a total of 20 monitoring visits (a site initiation visit, 18 interim monitoring visits and close out visit) and captured all the protocol deviations identified in a purposively developed database.
Results Overall, there were 55 protocol deviations (PDs) identified in The Gambian site among the 6,735 women enrolled, giving a PD rate of 0,82% per participant. The most common PDs were delayed safety reporting of serious adverse events (SAEs) to ethics and sponsor (30.9% [17/55]), wrong sequence in treatment allocation (13% [7/55]) and delayed/out of window visit (7.3% [4/55]). PDs related to inappropriate consenting, and inclusion of ineligible participants represented 18% [10/55] and all other deviations 30.9% [17/55].
Conclusion With robust quality control measures, frequent onsite monitoring, and by tapping into the potential of electronic data capture systems, research teams can efficiently implement large clinical trials of high quality with very few protocol deviations in resource-limited settings.

PA-216 CONTRIBUTION OF NEXT GENERATION SEQUENCING (NGS) TOOLS FOR MOLECULAR SURVEILLANCE OF MALARIA DRUG RESISTANCE MARKERS IN BURKINA FASO

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Background Antimalarial drug resistance represents an increasing public health concern in Africa. Indeed, since the introduction of IPTp-SP and SMC in moderate-to-high transmission settings, the prevalence of Sulfadoxine-Pyrimethamine and Amodiaquine resistance markers are increasing. This calls into question the effectiveness of these preventive strategies in the future. In this project, we aim to evaluate how NGS tools may contribute to the molecular surveillance of malaria drug resistance markers in target populations in Burkina Faso.
Methods The study will be conducted in Nanoro Health District in Burkina Faso. A retrospective analysis of archived samples collected in 2015 from pregnant women receiving IPTp-SP and in 2016 from their children within the ''COSMIC'' trial. Archived samples collected in 2020 from children participating in a study known as ''In-Host'' project will be included as well. In addition, prospective cross-sectional studies will be conducted in 2023 and 2025 in children and pregnant women, respectively. The identification of P. falciparum infections will be performed by microscopy and qPCR. Resistance markers will be investigated using the AmpliSeq Assay and a sequencer machine (MiSeq, Illumina, USA). The multiple nucleotide sequence alignments method will be used to identify the resistance markers.
Results The expected results include the impacts of IPTp-SP and SMC on the evolution of targeted resistance markers in pregnant women in a 10 year-time and in children under 5 years in a 6 year-time. In addition, the level of P. falciparum resistance to Artemisinin-based combination therapies will be known in the two study groups.
Conclusion Regarding the pressure of antimalarial drugs on the selection of resistance markers, it is necessary to use NGS techniques to monitor these markers and assess current strategies for target populations in order to inform and guide the national malaria control programs.

PA-219 IMPLEMENTING MOLECULAR DIAGNOSTICS FOR SOIL TRANSMITTED HELMINTHS IN A MULTICENTRIC CLINICAL TRIAL: EXTERNAL QUALITY ASSESSMENT IN THE EDCTP_STOP PROJECT

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Background The EDCTP_STOP project is a multicentric clinical trial (ALIVE trial ct.gov: NCT05124691) that aims to interrupt the transmission of soil-transmitted helminths using novel treatment regimens. While cure rate measured by microscopy is the primary efficacy outcome, limitations in sensitivity after successful treatment pose a challenge. Nucleic acid amplification tests are a promising alternative. One objective in the EDCTP_STOP project is to assess real-time polymerase chain reaction (qPCR) as a secondary efficacy outcome, which necessitates implementing an external quality assessment scheme (EQAS).
Methods The Helminth External Molecular Quality Assessment Scheme (HEMQAS), provided by the Dutch Foundation for Quality Assessment in Medical Laboratories (SKML), was implemented in the study. The sample distribution consists of blinded ethanol-preserved stool samples to assess DNA extraction, and purified DNA samples in stabilizing buffer to assess the amplification technique. Four consortium partners participated in the 2022 assessment. LUMC scored 99% (91/92 targets correctly identified). KEMRI scored 74% (68/92 targets). CISM scored 99% (75/76) and ULE scored 100% (62/62 targets).
Results For stool samples, the outcomes demonstrated that ineffective DNA extraction caused multiple false negative outcomes, particularly for Trichuris trichiura. Pipetting-error during DNA extraction may explain false positive outcomes. For DNA samples, false negative outcomes most likely resulted from handling errors. Systematic errors such as qPCR channels used to detect targets may account for false positive outcomes as spectral overlap in a multiplex qPCR may cause incorrect data interpretation. The use of validated positive control DNA elucidated which primer and probe pairs required optimization.
Conclusion These outcomes facilitated targeted molecular optimization per trial site prior to testing trial samples. Participating in an EQAS facilitates capacity building by identifying training and laboratory validation needs, and ensures reliable reproducible results.