Methods Selected community health workers (CHWs) were initially trained for simple malaria management among children under five years old using artemisinin-based combination therapy (ACT) and to perform rapid diagnostic tests for malaria (RDTs), and then equipped to provide service. This was a retrospective and prospective study using a mixed-methods approach between September-October 2017. Data before CCMM initiation (2013–2014) were collected from the Kabonga health centre, then compared to data from 2015–2016 corresponding to CCMM implementation. Data were from health records and stakeholders and were processed using SPSS.

Results In total, 5922 children were treated for malaria between 2013–2014 and 5249 between 2015–2016, an 11.3% case decrease. CHWs managed in total 1751 children using ACTs between 2015–2016. Of them, 1297 (74%) had a consult within 24 hours of fever onset and the cure rate was approximately 90%. Mortality decreased with up to 75%. Ownership level was encouraging among beneficiary communities and was low among district and health center’s staff. Some stock-outs were also reported.

Conclusion Using trained CHWs increased access to timely and appropriate treatment in sampled communities which was associated with improved health outcomes among children under 5 years old. However, regular supply to CHWs and strong ownership is needed.

PO 8468 DETERMINE TB-LAM LATERAL FLOW ASSAY: DOES M. TUBERCULOSIS LINEAGE INFLUENCE ITS PERFORMANCE?

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Background Among HIV-positive individuals with CD4 ≤100 cells/mm³, M. tuberculosis (MtB) bacteraemia is associated with a positive tuberculosis urine lipoarabinomannan (LAM) test. We conducted a retrospective study, to determine the effect of MtB lineage on the performance of the Determine TB LAM lateral flow (LF-LAM) assay.

Methods This was nested in a prospective TB diagnostics accuracy study among HIV-positive presumptive TB patients from Mulago National Referral Hospital, Kampala, Uganda, including both inpatients and outpatients. We considered data of 51 HIV-positive individuals with both pulmonary and MtB bacteraemia. We also evaluated the effect of having mixed MtB strains using both spoligotyping and MIRU-VNTR 24 loci methods.

Results LF-LAM was; negative among 4 (7.8%; 95% CI, 2.17% to 18.8%), positive among 39 (76.5%; 95% CI, 62.5% to 87.2%) and indeterminate among 8 (15.7%; 95% CI, 7.0% to 28.5%) participants. MtB lineages from blood samples were: Central Asian Strain (CAS); L3) 10/51 (19.6%) and Euro-American lineage (L4) 41/51 (80.4%). MtB lineages from sputum samples were 7/51 (13.7%) L3 and 44/51 (86.3%) were L4. Among participants with L3 in blood, LF-LAM was positive in 9 (90%; 95% CI, 55.4%–99.7%) whereas those with L4, LF-LAM was positive among 30 (72.7% 95% CI, 57.0% to 85.7%). For those with L3 in sputum, LF-LAM was positive among 7 (100%) and those with L4 was 32 (72.7%; 95% CI 57.2% to 85.0%). Two participants had mixed MtB strains (all L4) and all LF-LAM positive (2+ and 4+).

Conclusion Our study shows that M. tuberculosis lineage 3 may have more sensitivity to LF-LAM assay than lineage 4. The high number of indeterminate results with L4 requires more investigations. Our findings suggest that LF-LAM performance may differ by geographical regions depending on the dominant M. tuberculosis lineage.

PO 8470 FIRST INDEPENDENT ASSESSMENT OF PHARMACEUTICAL COMPANY ACTION ON AMR

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Background Antimicrobial resistance (AMR) is one of the most significant threats to public health globally. It will worsen without concerted efforts to spur the development of new antibiotics and ensure access and stewardship of existing ones. Pharmaceutical companies have a critical role to play in these efforts. The Access to Medicine Foundation developed the AMR Benchmark to measure how pharmaceutical companies are responding to AMR and to share and push best practices within the industry.

Methods The AMR Benchmark assessed the AMR activities of 30 pharmaceutical companies in 106 low- and middle-income countries. Survey data on company activities were collected across three research areas: research and development (R&D); manufacturing and production; and access and stewardship. For each research area, specific metrics were developed to evaluate company performance. These metrics were defined through consultation with experts working across the AMR field and represent a broad consensus on where companies can and should be taking action to limit AMR.

Results The Benchmark found that there are good practices in all research areas. Out of 276 R&D projects targeting infectious diseases, 175 target pathogens identified as priority by WHO/CDCE. Of these, 88 are in preclinical stage, 87 are in clinical stage, and 54 target gram-negative bacteria. Out of 28 antibiotics in late clinical stage, only two have access and stewardship plans in place. Nearly half of companies evaluated are involved in AMR surveillance and eight companies set limits on antibiotic wastewater discharge. Lastly, four companies separate sales agent bonuses from antibiotics sales volumes to reduce overuse of antibiotics.

Conclusion The Benchmark identified the good ideas being implemented by companies to limit AMR and mapped opportunities to amplify current efforts. Although companies are taking some action, the R&D pipeline needs to be further strengthened and candidates reaching late clinical stage must be supported by concrete plans to ensure access and stewardship.

PO 8471 A SURVEY OF CURRENT CLINICAL DATA MANAGEMENT PRACTICES IN SUB-SAHARAN AFRICA

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Background Antimicrobial resistance (AMR) and antimicrobial stewardship are significant threats to public health globally. It will worsen without concerted efforts to spur the development of new antibiotics and ensure access and stewardship of existing ones. Pharmaceutical companies have a critical role to play in these efforts. The Access to Medicine Foundation developed the AMR Benchmark to measure how pharmaceutical companies are responding to AMR and to share and push best practices within the industry.

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Conclusion The Benchmark identified the good ideas being implemented by companies to limit AMR and mapped opportunities to amplify current efforts. Although companies are taking some action, the R&D pipeline needs to be further strengthened and candidates reaching late clinical stage must be supported by concrete plans to ensure access and stewardship.
Background Information on clinical data management (CDM) practices in clinical trials in sub-Saharan Africa is scarce. As part of ALERRT (the African coalition for Epidemic Research, Response and Training, an EDCTP-funded project) we want to gauge current CDM and ICT practices and identify possible gaps within different research institutions in sub-Saharan Africa. This information will be used to develop a scalable, GCP-compliant, robust CDM/ICT infrastructure suitable for resource-poor settings and response-ready in the event of an outbreak.

Methods An online survey was designed to assess the experience of the participating sites with the various CDM processes, CDM documentation and facilities, the availability of dedicated staff and their experience with GCP. In addition, ICT features essential to CDM will be assessed. Lastly, information on the use of CDM software will be obtained. Respondents can request to receive personalised feedback (aimed to improve their CDM practices) based on their results. The survey, in English and French, will be sent out to 100 sites in sub-Saharan Africa. Sites with intermittent internet connections will receive an MS-Office Word-version of the survey.

Results The survey will be closed after a month. Personalised feedback (if requested) will be sent to the respondents. Descriptive analysis of the survey results will be done, and results will be used to design standard data management tools, tailored to the needs of research sites in sub-Saharan Africa and suitable for emergency research. Both results and tools will be disseminated to the scientific community.

Conclusion The results of this survey will provide relevant information on the current CDM and ICT practices in sub-Saharan Africa. Potential pitfalls will be identified and opportunities for improvement will be addressed. Furthermore, the survey will offer a chance to exchange ideas between African and European partners on how to implement good CDM and ICT practices.

An Institutional Review Board (IRB) is in place and it reviews both academic research proposals and large multicentre clinical trials before studies are carried out. However, the members lack appropriate training in bioethics. Acute staff shortage, reagent stock-outs, space constraints, and faulty equipment limit the laboratory’s capacity. Insufficient IT support and internet access cause delays in data entry. A lack of expertise in monitoring, data analysis and statistics, of financial management systems and library services were also identified.

Conclusion The hospital’s capacity to conduct clinical research is low. Assessment findings highlighted funding constraints faced at the referral hospital in a country burdened by disease. North-South partnership through EDCTP will contribute towards addressing part of these gaps.