OC 8566 THE UNIVERSIDADE EDUARDO MONDLANE AND UNIVERSITY OF CALIFORNIA SAN DIEGO PARTNERSHIP, A PARADIGM FOR INSTITUTIONAL AND HUMAN RESOURCES CAPACITY BUILDING

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Background Collaborations between lower- and middle-income countries (LMICs) and high-income countries (HICs) are often scientifically and structurally driven by the HICs. Here we aim to describe a paradigm shift in collaboration, exemplified by the collaboration between the Universidade Eduardo Mondlane and University of California, San Diego through the Medical Education Partnership Initiative (MEPI), in which the formulation of priorities and administrative infrastructure reside in the LMICs.

Methods We outline critical features of the MEPI partnership and compare with traditional models of collaboration, key features of success, lessons learned and the way forward.

Results LMIC programme partners translate broad programme goals and define metrics into priorities tailored to local conditions. Programme funds flow to a LMIC-based leadership group that contracts with HIC-based peers to provide technical and scientific advice and consultation in a reverse funds flow model. Emphasis is placed on strengthening administrative capacity within LMIC institutions and on creating communities of practice with common goals that resulted in expanded collaboration with European, Latin American, and African institutions. A rigorous monitoring and evaluation process modify programme priorities based on evolving opportunities to maximise programme impact.

Over five years, more than 63 research projects were designed, 19 of which received external funding and more than 40 manuscripts were published. Mozambican first-authored publications rose from 29% in 2001–2010% to 38% in 2011–2013.

Eighteen (18) residents completed internal medicine specialty training between 2010 and 2014. This represents a four-fold increase from over 1991 to 2000. Three (3) Master's programmes were created at Lurio University and 50 students successfully finished dissertations.

Conclusion Vesting LMIC partners with the responsibility for programme leadership and building administrative capacity in LMIC institutions substantially enhances programme relevance, impact and sustainability, and facilitates continuing acquisition of research and training funds to support professional development and institutional capacity building.

OC 8568 A RANDOMISED CONTROLLED TRIAL OF ORAL IRON FOR TREATMENT OF POST-MALARIA ANAEMIA IN MALAWIAN CHILDREN COMPARING IMMEDIATE VERSUS DELAYED ADMINISTRATION

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Background Although universal provision of iron supplements to children is recommended by the WHO, it is not yet clear whether the administration of the supplements poses a risk in children in malaria-endemic areas. We investigate the effects of iron supplementation in children with post-malaria anaemia and haematological response with immediate and delayed (2 weeks) iron administration.

Methods A randomised double-blind clinical trial was conducted in Zomba and Blantyre between 2009 and 2013. All children aged 4 to 36 months with uncomplicated malaria and with iron deficiency were enrolled into the study. Malaria treatment was administered to all the children and they were randomly assigned to 3 groups as follows: immediate iron administration, delayed iron administration, or placebo. The children were followed up for 10 weeks, with their haematological recovery indices and adverse effects being monitored at 2, 4, 8 and 10 weeks. The primary outcome of the study was the proportion of children without anaemia (defined as Hb >10.9 g/dl) at the end of the iron supplementation period.

Results A total of 538 participants were randomised to immediate iron administration (n=183), delayed iron administration (n=183), or placebo (n=172). The incidence rate ratio (IRR) of being non-anaemic at the end of the follow-up period (10 weeks post-malaria infection) was 1.51 (95% CI 1.17–1.94, p<0.001) among immediate group versus the placebo group. There was no significant difference between delayed and placebo group (IRR 1.18, 95% CI 0.91–1.55). Secondary analysis of risk of malaria and bacterial infection and iron markers at the end of the intervention period is underway and shall be presented at the conference.

Conclusion The results so far support the administration of iron immediately after completing antimalarial treatment in anaemic children, however safety results will be needed to be reviewed before conclusive recommendations.

OC 8582 A PHASE IA/B STUDY TO ASSESS SAFETY AND IMMUNOGENICITY OF PLACENTAL MALARIA VACCINE CANDIDATE: PRELIMINARY RESULTS OF THE PRIMALVAC TRIAL

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Background Adhesion of *P. falciparum*-infected erythrocytes (PEs) to placental chondroitin-4-sulfate (CSA) has been linked to severe placental malaria (PM) outcomes. Evidence strongly supports the VAR2CSA variant surface antigen mediating PEs CSA-binding phenotype as the leading candidate for a PM vaccine. This study was conducted to assess the safety and immunogenicity of 3 different dosages (20 µg, 50 µg and 100 µg) of the recombinant VAR2CSA protein (PRIMVAC), formulated with Alhydrogel or GLA-SE administered at days 0, 28 and 56.

Methods A randomised double-blind phase Ia/Ib dose-escalation vaccine trial was conducted in healthy adult women. Within 4 sequential cohorts, volunteers were randomised to 2 arms (PRIMVAC adjuvanted with Alhydrogel or GLA-SE) in the first phase conducted in France and then to 3 arms (PRIMVAC with Alhydrogel or GLA-SE or placebo) in Burkina Faso. Enrolled volunteers were observed for at least 1 hour following each vaccination then seen at 1 day and 7 days later for safety evaluations. Serious adverse events (SAE) were recorded throughout the study duration. Routine clinical laboratory safety analyses were performed prior to first injection and at each subsequent visit.

Results A total of 68 subjects were recruited in the four study cohorts. No SAE was reported in any of the cohort A volunteers and enrolment in cohort B was started. A Data Safety Monitoring Board (DSMB) reviewed the safety data for cohorts A (20 µg) and B (50 µg) before the trial was initiated in Burkina Faso. The DSMB also reviewed the safety data in Burkina to authorise the progression from the cohort C (50 µg) to cohort D (100 µg). The last vaccination of the last subject occurred in September 2017.

Conclusion This was the first placental malaria vaccine phase Ia/b clinical trial conducted in France and Burkina Faso. No serious adverse events have been recorded. Preliminary safety and immunogenicity results will be presented.

OC 8586 INSTITUTIONAL RESEARCH CAPACITY BUILDING FOR MULTI-DISCIPLINARY HEALTH RESEARCH TO SUPPORT THE HEALTH SYSTEM REBUILDING PHASE IN SIERRA LEONE

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Background The EDCTP-funded project 'Institutional capacity development for multi-disciplinary health research to support the health system rebuilding phase in Sierra Leone' (RECAP-SL) created a solid platform on which sustainable research capacity can be built at the College of Medicine and Allied Health Sciences (COMAHS) at the University of Sierra Leone. This in turn will support the much-needed evidence-based health systems reconstruction phase in Sierra Leone and support the evolution of the research landscape at COMAHS.

Methods and results We established a research centre at COMAHS and conducted a research needs assessment. This informed the development of short- and long-term action plans to support sustainable institutional research capacity development and enabled the development of a four-year research strategy. These plans also served as a guide for subsequent research partnerships in terms of capacity building efforts to address identified challenges.

We also focused on training four research fellows and developed a wider student engagement platform to help cultivate a research culture. The research fellows will support other researchers at COMAHS, thus promoting sustainability of the research centre. Continued professional development opportunities for the fellows are also being actively sought, to develop them up to doctoral level, which addresses one of the gaps identified in the capacity assessment report.

Conclusion To support sustainability, capacity building efforts are being designed to ensure that these gains are maintained over time, with international and national research partners and funders recognising the importance of further developing local research capacity. Through a multi-pronged approach, health systems research capacity has been strengthened in Sierra Leone. This will support the generation of evidence that will inform building sustainable health systems fit for responding cohesively to outbreaks and for delivering services across the country, especially for the most disadvantaged populations.

OC 8711 EARLY BIOMARKERS OF LUNG INFLAMMATION AND FUNCTION IN TRIALS OF HOST-DIRECTED TUBERCULOSIS THERAPIES (TB-HDT)

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Background Permanent lung injury and impaired function are common despite TB cure. Host-directed anti-inflammatory therapies may prevent this injury. Early biomarkers of lung inflammation and function can facilitate their evaluation.

Methods In an ongoing study supported by the Bill and Melinda Gates Foundation, HIV-uninfected patients with radiographically moderately or far advanced sputum smear-positive pulmonary tuberculosis receive rifabutin-substituted standard therapy plus either CC-11050 (phosphodiesterase inhibitor), everolimus (mTOR inhibitor), auranofin (gold salt), cholecalciferol, or control, during months 1–4. Study leadership is blinded as to assigned treatments. 18F-fluorodeoxyglucose positron emision tomography (PET) and computed tomography (CT) are performed at baseline and at week 8. Total lung glycolytic activity (SUVbw*ml) and radiodensity (modified HU*ml) are measured using MIM software. Sputum culture, spirometry, 6 min walk test (6MWT), and other biomarkers are performed at multiple time points. Follow-up continues to month 18. This analysis includes only baseline and week 8 data.

Results Presently, 160/200 participants are enrolled. At baseline, patients have a high burden of infection (median time to detection [TTD] in automated liquid culture 5 days). Median baseline FEV1% of predicted (63%) and 6MWT (402 meters) are typical of moderate to severe chronic lung disease. Baseline TTD, PET, CT, FEV1% and 6MWT are all highly correlated (median rank test $p=0.0018$). All 5 parameters changed significantly during 8 weeks of treatment ($p<0.001$). Analysis of adjusted log change from baseline shows PET and CT remain highly correlated ($p<0.001$), and weakly correlated with FEV1% and 6MWT. TTD shows no correlation with any other endpoint.

Conclusion Quantitative markers of infection, inflammation, and function are markedly abnormal and highly correlated at baseline in patients with pulmonary tuberculosis. Quantitative CT may substitute for PET as a more readily-performed measure of lung inflammation. The dissociation of microbiologic responses from inflammation and function supports a role for HDTs in TB.