OA-715 RECEIPT OF INTRAVENOUS CO-AMOXICLAV CHALLENGES ELIGIBILITY SCREENING FOR THE PEDICAP TRIAL IN JOHANNESBURG, SOUTH AFRICA

[1]David Moore*, [1]Zainab Waggie, [2]Sandisiwe Nkosi, [2]Lethabo Nkosi, [2]Ntombifuthi Kumalo, [2]Nomhle Nkumana, [2]Nomakhathi Zulu, [2]Ziyaad Dangor, [3]Mike Sharland, [2,4]Shabir Madhi. [1]*University of the Witwatersrand, South Africa*; [2]*South African Medical Research Council Vaccines and Infectious Diseases Analytics Research Unit, South Africa*; [3]*St George's University of London, UK*; [4]*Faculty of Health Sciences, University of the Witwatersrand, South Africa*

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Background In 2020, updated South African guidance on management of children with community-acquired pneumonia were published by the South African Thoracic Society. These guidelines recommend intravenous co-amoxiclav as first-line therapy for children hospitalised with World Health Organisation (WHO) defined severe pneumonia. We evaluated how this guideline change impacted on participant enrollment into the PediCAP Trial (https://projectpedicap.org/) at the Trial site in Johannesburg, as receipt of intravenous co-amoxiclav is an exclusion criterion for PediCAP enrollment.

Methods A line list of all paediatric admissions to the Johannesburg PediCAP site is maintained, to facilitate screening for age-eligible paediatric patients with respiratory illness on weekdays. The total number of children hospitalised at the site, the total number of respiratory admissions, and the characteristics of children screened for PediCAP were assessed descriptively.

Results From 15 July 2021 to 15 May 2023, 11,998 children were hospitalised at the study site. On PediCAP screening days, 4,829 age-eligible children were hospitalised, 2,377 (49.2%) of whom had respiratory admission diagnoses. Five-hundred, twenty-seven children underwent point-of-care C-reactive protein (CRP) testing for eligibility screening into PediCAP and 239 (45.4%) were enrolled. A clinician decision to initiate intravenous co-amoxiclav was a common reason for non-eligibility (in 316 [13.1%] of 2,417 children). Formal CRP levels were significantly higher in children enrolled into PediCAP compared to those treated with intravenous co-amoxiclav (median 51.0 mg/L [Interquartile range (IQR), 29.0–111.0] vs. 18.0 mg/L [IQR, 5.0–57.5]; corrected P-value<0.001).

Conclusion National guideline recommendations to use intravenous co-amoxiclav as first-line therapy for children hospitalised with severe pneumonia have impacted participant recruitment into PediCAP at the Trial site in Johannesburg. Significantly lower CRP levels in children treated empirically with intravenous co-amoxiclav indicates a disparity between clinician prescribing and the likely aetiology of disease in children hospitalised with severe pneumonia at the study site, warranting optimisation of antimicrobial stewardship practice.

OA-721 LEVERAGING DIGITAL PLATFORMS TO SUPPORT A SUSTAINABLE NATIONAL RESEARCH INFORMATION MANAGEMENT SYSTEM FOR RESEARCH ETHICS AND REGULATION IN UGANDA

[1]Maxwell Otim Onapa*, [1]Ronald Mulebeke, [1,2]Peter Olupot-Olupot. [1]*Busitema University, Uganda*; [2]*Mbale Clinical Research Institute, Uganda*

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Background In Uganda, complex clinical research projects that require regulatory oversight are a growing phenomenon. Although there are functional national regulatory agencies (NRAs) to provide oversight, various constraints, including the lack of a robust digital platform to facilitate their work make them inefficient. This scenario has necessitated the establishment of a sustainable digital system to support the work of the NRAs and research ethics committees (RECs). Against this background, the EDTCP-II grants supported a project on Scaling up the Capacity of RECs in Uganda (SCRECU), 2019–2022, and facilitated further development of a National Research Information Management System (NRIMS) which had been developed with support from an earlier EDCTP grant. The overarching objective of SCRECU was to build sustainable capacity for the NRIMS with capabilities of facilitating multi-REC ethical reviews, national registration of research protocols, and their subsequent monitoring by NRAs and RECs.

Methods We trained RECs personnel on the use of NRIMS for online protocol submissions and management; post-approval processes and enrolment of RECs. We provided the RECs with ICT equipment and followed them up to ensure utilization. We tested the effectiveness of the NRIMS, evaluated its adoption, and developed guidelines for its operationalization.

Results We trained the chairperson, an administrator, and an IT officer from each of the 26 RECs in Uganda on the use of NRIMS and equipped them with Internet services and other relevant tools. Our study demonstrated the affordability of NRIMS and how digital tools can be leveraged to strengthen ethics and regulatory capacity in resource-constrained settings. The study also generated an inventory of equipment required for the operationalization of an NRIMS. The NRIMS has registered over 13,000 users, received over 6,000 applications, and granted 2,500 approvals online. The NRIMS has enhanced institutional workflows, reduced paperwork by over 95%, and turnaround time for protocol approvals by 50%. It has enhanced research ethics regulatory capacity in Uganda.

Conclusion The NRIMs has revolutionized and strengthened research ethics and regulation in Uganda. It provides a secure, web-based solution for efficient submission, review, approval, and monitoring of research projects. Its success in Uganda provides a paradigm shift for other NRAs in sub-Saharan Africa.

OA-722 ASSESSMENT OF NATURALLY ACQUIRED HUMORAL IMMUNITY AGAINST MALARIA PROTECTING AGAINST CONTROLLED HUMAN MALARIA INFECTION (CHMI)

[1,4,6]Nouhoun Barry*, [1,4]Stephanie Sefried, [1,4]Nicole Peter, [2]Freia-Raffaella Lorenz, [3]Raffiou Adamou, [5]Thomas L Richie, [5]Stephen L Hoffman, [1,3,4]Peter Kremsner, [3]Jeannot Zinsou, [1,3,4]Ayola Akim Adegnika, [2]Benjamin Mordmüller, [2]Matthew McCall, [1,3,4]Rolf Fendel. [1]*Universitätsklinikum Tübingen, Deutschland*; [2]*Radboud University Medical Center (RadboudUMC), The Netherland*; [3]*Centre de Recherche Medical de Lambaréné (CERMEL), Gabon*; [4]*Naval Medical Research Center (NMRC), Unites States*; [5]*Sanaria inc, USA*

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Background A successful malaria vaccine should, depending on the targeted stage of the malaria life cycle, induce both humoral and cellular immune responses. Naturally acquired immunity (NAI) against malaria is thought to target mostly the blood stage and protects individuals against symptomatic and severe disease, but often fails to protect against infection