Bonferroni p-value adjustment. We also assessed factors associated with the baseline confidence of the trainees and the contribution of baseline confidence to a successful course completion using logistic regression, and Fisher's exact test, respectively.

Results Confidence in conducting a trial complying with ethical principles, informed consent process, securing approval, and managing ISF were relatively high among the trainees. However, the confidence of participants in financial, project, and external partner management, as well as closing out a trial was low. The differences in confidence in the various domains were statistically significant. After the training, the trainees' confidence was significantly increased in all the domains, though the confidence in the four domains remained relatively low.

Conclusion Training efforts aiming to augment the knowledge and skills of study coordinators should give better attention to financial, project, and external partner management, as well as closing out a trial to ensure study coordinators with holistic clinical trial knowledge and skills.

PA-296 INTERMITTENT PREVENTIVE TREATMENT (IPT) OF MALARIA IN PREGNANCY WITH MEFLOQUINE MAY REDUCE NEVIRAPINE LEVELS AMONG HIV-INFECTED WOMEN

[1]Linda Stoeger*, [2]Anifa Valá, [2]Esperança Sevene, [3]Mercè Brunet, [2]Arsénio Nhacolo, [2]Eusébio Macete, [1]Clara Menéndez, [1]Raquel González. *[1]ISGlobal, Hospital Clínic-Universitat de Barcelona, Spain; [2]Manhiça Health Research Center (CISM), Mozambique; [3]Department of Toxicology and Pharmacology, Hospital Clínic of Barcelona, Spain*

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Background Sub-Saharan Africa is the region with the highest burden of malaria and HIV worldwide, being pregnant women the most vulnerable populations. Mefloquine (MQ) for intermittent preventive treatment (IPTp) of malaria in pregnancy has shown to significantly reduce malaria-related adverse maternal outcomes. However, while effective in HIV-uninfected pregnant women, results from an EDCTP-funded placebo-controlled trial assessing the safety and efficacy of IPTp-MQ among HIV-infected pregnant women showed that MQ recipients had a two-fold increased risk of HIV mother-to-child transmission (MTCT) compared to the control group. In this analysis we aimed to determine the antiretroviral (ARV) drug levels among a sub-sample of pregnant women participating in the aforementioned trial by treatment arm.

Methods ARV drug levels were determined by UPLC/MS/MS methodology (LLQ 2.5ng/mL, for all drugs) in venous and cord blood samples of 249 pregnant women enrolled from 2010 to 2012 in Manhiça, Southern Mozambique.

Results No significant differences in the maternal and foetal levels of nevirapine (NVP), lamivudine (3TC) and zidovudine (AZT) were found across groups. However, maternal levels of NVP tended to be decreased in MQ recipients compared to the placebo one among the subset of women transmitting the HIV to their infants (344.64 [558.99] vs 926.4 [619.67], p=0.054).

Conclusion Our findings suggest potential pharmacological interactions between MQ and NVP that warrant caution in the administration of antimalarial drugs to HIV-infected women on ARV treatment.

PA-297 CHARACTERISING THE VAGINAL VIROME OF WOMEN LIVING WITH AND WITHOUT HIV USING SEQUENCE INDEPENDENT SINGLE PRIMER AMPLIFICATION

[1]Adijat Jimoh, [2,3]Bryan Brown, [2]Colin Feng, [4,5]Kathleen Powis, [1,6]Arvind Varsani, [1,2,3]Heather Jaspan, [1]Anna Happel*. *[1]University of Cape Town, South Africa; [2]Seattle Children's Research Institute, USA; [3]University of Washington, USA; [4]Harvard T.H. Chan School of Public Health, USA; [5]Massachusetts General Hospital, USA; [6]Arizona State University, USA*

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Background The cervicovaginal mucosa is inhabited by an ecosystem of bacteria, fungi and viruses, which likely interact with each other. The vaginal virome may influence vaginal immunity directly, or though modulation of the bacterial component via bacterial-phage dynamics. These interactions may play an important role in sexual and reproductive health outcomes. However, it is predicted that over 60% of the human DNA virome has not yet been identified, and the RNA virome is even less explored, nor has the impact of HIV on the vaginal virome composition been described.

Methods We optimised viral particle extraction from vaginal swabs. We then optimised a Sequence Independent Single Primer Amplification (SISPA) approach to enable deep sequencing of the viral metagenome that decreases the GC and genome size bias introduced by commonly used methods such as Multiple Displacement Amplification and Rolling Circle Amplification, while also yielding a greater diversity of near-complete metagenome-assembled genomes.

Results SISPA was able to recapitulate almost exactly the relative abundance of a viral mock community. Storing swabs in universal transport media (UTM) directly after collection and treating the sample with a 18G needle prior to viral particle extraction resulted in the greatest yield of viral nucleic acid and subsequent read depth, over storing swabs dry or in a 1:1 dilution of UTM and SM buffer. We have applied this method to vaginal swabs from Sub-Saharan African women with and without HIV.

Conclusion This work lays the ground work for project TMA2020CDF-3192, which will assess the interaction of vaginal virome and bacteriome in pregnant women with HIV in sub-Saharan Africa and risk of preterm birth.

PA-298 PREDICTING DISEASE EFFECT ON THE PHARMACOKINETICS (PK) OF SUSTAINED AND IMMEDIATE RELEASE FORMULATIONS BY APPLYING PHYSIOLOGICALLY BASED PHARMACOKINETIC (PBPK) MODELLING

[1]Johanna Eriksson, [1]Eric Sjögren, [2]Jean-Yves Gillon, [2]Vishal Goyal, [2]Vijay Satam, [2]Stephen Robinson, [2]Henri Caplain, [2]Isabela Ribeiro, [1]Marylore Chenel*. *[1]Pharmatheus, Sweden; [2]DNDi, Switzerland*

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Background 5-flucytosine (5FC) is used for the treatment of cryptococcal meningoencephalitis (CM) in patients with advanced HIV. The current dosing is four times a day involving high risks of low adherence and not adapted for severely ill patients. To address this, a sustained release (SR) pellet formulation was developed. Two PK studies in healthy subjects were performed, evaluating the immediate release (IR) and SR formulations. To estimate the SR formulation exposure of 5FC in patients, PBPK modelling was applied.