assessment with sonography for HIV-associated TB (FASH) at six abdominal and thoracic positions has shown promise for diagnosis in children and adults, but few infants have been included in published studies.

Methods EMPIRICAL (#NCT03915366) is a randomized, controlled trial funded by EDCTP (RIA2017MC-2013) recruiting HIV-positive infants <12 months hospitalized with severe pneumonia without current/past TB diagnosis or exposure. All participants have Xpert Ultra (stool, nasopharyngeal aspirate) and urine LAM testing, and in an ongoing blinded diagnostic ancillary study at 5 hospitals in Mozambique, FASH is performed. An interim descriptive analysis was done for participants no longer active in the trial as of April 2023.

Results For the 39 participants included, the median age was 3 months (IQR:3.17–5.13), 48.7% were female, and the median CD4% was 13% (IQR:9.90–17.55). There was ≥1 positive FASH finding in 10/39 (25.6%); all had pericardial effusion 10/39 (25.6%), with focal splenic lesions and ascites also noted in 2/39 (5.1%) and 1/39 (2.6%), respectively. No participants had pleural effusion, focal liver lesions, or abdominal lymphadenopathy. In participants with laboratory-confirmed TB, 42.9% (3/7) had ≥1 positive FASH finding. There were 2 positive FASH findings in 7.6% (3/39) participants, of whom 66.7% (2/3) had laboratory-confirmed TB.

Conclusion Positive FASH findings were frequent in HIV-positive infants hospitalized with severe pneumonia and even more common in the subset of participants with laboratory-confirmed TB, with pericardial effusion noted on all positive FASH exams. Future analysis will attempt to define which abnormalities on FASH exam are most predictive of TB disease and assess the use of FASH to monitor TB treatment response.

PA-456 FIELD TESTING OF A NOVEL POINT-OF-CARE GENITAL INFLAMMATION TEST (GIFT) IN LOW- MIDDLE-INCOME COUNTRIES IN AFRICA: AIMING TO PREVENT HIV INFECTION AND IMPROVE REPRODUCTIVE HEALTH

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Background Sexually transmitted infections (STIs) and bacterial vaginosis (BV) are major risk factors for HIV infection and reproductive complications in women living in sub-Saharan Africa, in part because of inflammation associated with these conditions. In women, most STIs and BV are asymptomatic, and therefore not diagnosed in low and middle income countries (LMICs), where etiologic testing is not common and infections are treated based on presence of signs or symptoms (syndromic management). To improve STI/BV case finding in LMICs, we have been developing a true point-of-care low cost lateral flow test based on inflammation biomarkers – called the Genital Inflammation Test (GIFT) – to screen women who would benefit from further etiologic testing.

Methods Through an EDCTP2 RIA2020I funding mechanism, the first version of the GIFT device has been developed in South Africa and is currently being evaluated in three parallel clinical studies in South Africa, Zimbabwe and Madagascar. Field testing is intended to inform optimisation of the final prototype device.

Results The GIFT-Africa consortium (www.GIFT-Africa.org.za) includes a cross-disciplinary team of experts, including those working on design, optimisation, manufacture and laboratory validation of the first in field GIFT device, clinical performance in each region compared to inflammation biomarkers measured by ELISA, STIs measured using NAATs, and BV measured by Nugent. In addition to assessing sensitivity/specificity in different LMIC settings, implementation of the GIFT device into reproductive health services will be evaluated using: in-depth interviews with patients and healthcare professionals (user experience); discrete choice experiments with end-users; cost, budget impact and cost-effectiveness analyses, and; a DELPHI survey to evaluate key stakeholder recommendations for implementation.

Conclusion The GIFT device is positioned to cost-effectively increase STI/BV case-finding, but also to improve STI/BV management for women in LMICs, who are at high risk of HIV infection and reproductive complications.

PA-459 THE EFFECT ON TREATMENT OUTCOMES OF BASELINE RESISTANCE TO PYRAZINAMIDE AFTER 6-MONTHS OF BPAMZ IN THE SIMPLICITB CLINICAL TRIAL

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Background The combination of bedaquiline, pretomanid, moxifloxacin, and pyrazinamide (BPaMZ) provides the shortest duration of treatment required to sterilize mice in relapsing mouse models. SimpliciTB was an open-label study to evaluate the safety and efficacy of 4-months BPaMZ (4BPaMZ) compared to standard therapy (4HRZE/2HR) in DS-TB participants. The trial also included a cohort of DR-TB participants who received 6-months BPaMZ (6BPaMZ). The primary efficacy endpoint was time to culture negative status through 8 weeks; the key secondary endpoint was relapse-free cure at week 52.

The proportions of patients with culture conversion by 8 weeks and of favorable outcome at week 52 (MITT analysis) for 4HRZE/2HR, 4BPaMZ and 6BPaMZ were 47.3%, 84.1%, 85.7% and 93.1%, 85.3%, 83.1%, respectively. The lower rates of favorable outcomes in BPaMZ arms were largely due to higher rates of hepatotoxicity-related trial discontinuations, in which PZA may have contributed.