**Title:** TB Control Programmes remain an important gateway to HIV diagnosis in the era of expanded access to HIV care

**Running Head:** Universal ART eligibility and TB in Malawi

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In 2016, Malawi adopted a Universal HIV Test and Treat policy, with antiretroviral therapy (ART) provided regardless of CD4 count 1. We explored HIV status and degree of immunosuppression in Malawian patients presenting with tuberculosis (TB) before and after these changes were implemented.

The Malawi National TB Control Programme (NTP) provides a ‘one-stop shop’ for the delivery of TB and HIV care, offering provider-initiated testing and counselling and issuing both anti-TB drugs and ART 2, 3. The NTP referred new sputum smear-positive TB patients to 2 clinical cohort studies in Blantyre, Malawi, for recruitment: the SPUTuM Study (2010-12) and the SPITT Study (2016-17). Baseline sociodemographics, HIV status, and CD4 counts were captured. All TB suspects and patients were offered HIV testing if their HIV status was unknown, or previously reported negative 3.

Sixty-six percent (111/169) of participants in the 2010-11 cohort recalled undergoing an HIV test prior to developing symptoms of their current TB illness, compared to 98% (118/121) in the 2016-17 cohort (p<0.001). However, after being offered repeat testing at study recruitment the proportion of new TB patients with HIV was similar between cohorts (98 [58%] in 2010-11 vs. 63 [52%] in 2016-17, p=0.378).

In the 2010-11 cohort, 53% (52/98, Table 1) of HIV-positive patients were unaware that they were HIV-positive until tested by the study team, including 16 (16%) who recalled a prior negative test. In the 2016-17 cohort, 98% (62/63) of HIV-positive patients reported prior HIV testing. However, 52% (33/63) were unaware that they were HIV-positive until tested by the study team, all of whom recalled a prior negative test. In over half of the patients from both cohorts, baseline CD4 counts were below 200 cells/mm3.

These data give a positive snapshot of advances in TB/HIV treatment in Malawi: once patients present with TB, HIV diagnoses are confirmed quickly, and patients are initiated on ART earlier than in the past. Ninety-eight percent of patients were on ART by the end of the intensive phase of TB treatment in 2016-17, compared to 28% in the earlier cohort.

New TB patients in Malawi were more likely to have been previously tested for HIV in 2016-17 than 2010-11, but a significant number of new HIV diagnoses were made at TB presentation. Capturing the approximate timing of previous HIV tests would provide useful additional information. The high number of ‘new’ HIV diagnoses in those reporting previous testing may reflect a prolonged time between HIV tests with subsequent HIV infection in the interim period, denial of previous positive results, or patients choosing not to link into ART care on receiving an earlier positive result 4. Despite increased access to HIV testing, personal factors also influence the timing of ART initiation. Ultimately, repeat HIV testing, particularly at gateways to care, provides important opportunities to identify new diagnoses and initiate ART.

While universal ART eligibility is likely to be of huge public health benefit, increasing awareness of HIV status through the first 90 of the 90-90-90 targets will be essential to reduce TB incidence in high burden settings.

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**TABLES**

*Table 1: Characteristics of new TB/HIV co-infected patients in Malawi, 2010-12 vs. 2016-17*

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic | SPUTuM Study, 2010-12  (n=98) | SPITT Study,  2016-17  (n=63) | p value a |
| Age in years (mean (SD)) | 32.3 (8.8) | 36.3 (8.7) | 0.005 |
| Male sex (n, %) | 65 (66) | 43 (68) | 0.935 |
| Ever previously HIV tested (n, %) | 62 (63) | 62 (98) | <0.001 |
| New HIV diagnosis (n, %) | 52 (53) | 33 (52) | 0.604 |
| CD4 stratification (n, %)   * < 50 cells/mm3 * 50-199 cells/mm3 * 200-349 cells/mm3 * > 350 cells/mm3 | 8 (9)  39 (46)  20 (24)  18 (21) | 10 (16)  25 (40)  19 (30)  9 (14) | 0.375 |
| On ART at baseline (n, %)   * Not on ART * < 1 year * <= 4 years * > 4 years | 84 (88)  1 (1)  9 (9)  1 (1) | 33 (52)  9 (14)  8 (13)  13 (21) | <0.001 |
| Timing of ART initiation (n, %)   * On ART at baseline * On ART by Intensive Phase * On ART by Continuation Phase * On ART by Follow-Up Phase | 14 (14)  27 (28)  43 (44)  71 (72) | 30 (48)  62 (98)  62 (98)  62 (98) | <0.001 |

a Normally distributed continuous variables were assessed by one-way analysis of variance, and non-normally distributed data by Kruskal-Wallis test. Categorical variables were assessed by chi-squared or Fisher’s exact tests.