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Session: C15 TB Game Changers: Diagnostics, HIV, Drug-Resistance, and Treatment

Tuesday, May 17, 2016, 10:15–10:30 a.m.

Location: Room 3016/2018 (West Building, Level 3), MOSCONE CENTER

**Simple, Rapid TB Diagnosis Feasible in Low-Resource, High-Burden Settings**

ATS 2016, SAN FRANCISCO – A streamlined approach to tuberculosis (TB) diagnosis requiring a single sputum sample and providing rapid, accurate results to patients proved feasible in rural Uganda, according to research presented at the ATS 2016 International Conference.

At four community health centers, patients learned the same day as their visit if their sputum was positive for TB when analyzed using fluorescence microscopy. If negative, the sputum was sent immediately to a lab, where it was reanalyzed using GeneXpert® MTB/RIF (Xpert), a much more sensitive test. Xpert results were reported back to the health center via automated text messaging.

The goal of the pilot was two-fold (1) to test the feasibility of this approach in a country where TB is endemic and (2) to assess its ability to increase the numbers of patients tested and initiated on treatment for TB, said lead author Priya B. Shete, MD, clinical instructor and research fellow at the University of California, San Francisco. Before the study, patients were typically required to provide two sputum samples, often on separate days, and microscopic analysis was rarely completed the day of the patient's visit. Access to Xpert testing relied on sputum being transported on average once per week to a testing facility with results brought back the following week.

Of the 822 patients referred for TB testing, researchers found :

- 12 percent had TB, of whom 75 percent were diagnosed using fluorescence microscopy and 25 percent were diagnosed using Xpert.
- 67 percent testing positive for TB using fluorescence microscopy began treatment within 1 day.
- 67 percent testing positive for TB using Xpert began treatment, on average, within 6 days.
- 20 percent testing positive for TB did not start treatment.

The researchers are now expanding their study to 20 Ugandan health centers, where they will measure cost effectiveness of the approach and test different tools for further increasing treatment initiation rates, including sending text messages to the patient and offering financial incentives to patients. Although the cost of TB diagnosis and treatment is free in Uganda, as it is in most countries where the burden of TB is high, Dr. Shete said direct and indirect costs are often “catastrophic for patients in Uganda with chronic cough.” Those costs include lost wages, childcare and transportation.

Dr. Shete added that performing rapid molecular testing on-site, which may be possible with newer technology, could be needed to maximize diagnosis and treatment initiation rates.

The researchers were encouraged that pilot clinics increased the percentage of TB testing for patients whose symptoms were consistent with TB. In previous studies, researchers found that only 21 percent of such patients were worked up for TB.

“Clinicians in Uganda can see 50 to 100 patients a day, so they often can’t focus on one disease,” Dr. Shete said. “We identified people at each clinic, however, who could focus on TB and worked with the clinic to improve the training of all clinicians who might see TB patients. The results are promising, but there is more work to be done.”

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Abstract 11955

### **Feasibility of a Streamlined Single-sAMPLE (SIMPLE) TB Diagnosis and Treatment Initiation Strategy in Uganda**

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### **Background**

In high burden countries, many patients with tuberculosis (TB) who present to community health centers are lost to follow-up before TB can be diagnosed or treated, leading to ongoing transmission. A primary reason is that the standard approach of collecting sputum specimens over multiple days for microscopic examination is not only insensitive but also inconvenient and costly for patients. We report on the feasibility of a patient-centered, SIngle-saMPLE (SIMPLE) TB diagnosis strategy.

## **Methods**

The SIMPLE TB diagnosis strategy includes: 1) Single-sample LED fluorescence microscopy (analysis and reporting of two smear results from the initial specimen within two hours) and 2) Daily transport of smear-negative sputum samples to GeneXpert® MTB/RIF (Xpert) testing sites. In a single-arm interventional pilot study, we evaluated the feasibility of these components of the SIMPLE TB diagnosis strategy at four community health centers in Uganda. Using data from TB laboratory and treatment registers, we evaluated process measures that reflect implementation of each intervention component and TB diagnosis outcomes.

## **Results**

Of 822 consecutive patients referred for TB testing, 465 (57%) were female and their median age was 37 years (IQR 26-48). Overall 100/822 (12%) patients were diagnosed with TB. Two smears from the initial spot specimen were analyzed and reported on the same-day for 779/822 (95%) patients. Overall, 73 (9%) were smear-positive (68 on sputum1/smear1, 3 on sputum1/smear2 and 2 on sputum2). Of the 71 smear-positive patients identified from the first sample, 31 (44%) started treatment on the same-day, 16 (23%) on the next day, and 12 (17%) did not start treatment. Sputum was transported to an Xpert testing site within one business day of the initial visit for 670/706 (95%) patients with negative smear results from the first sputum sample. Xpert results were positive for TB in 27 smear-negative patients (incremental TB yield 27%), of whom 18 (67%) initiated therapy (mean time to treatment initiation 6 days, 95% CI 1.7-8.3 days).