

# VALIDATION STUDY COMPARING TABLET-BASED AND CONVENTIONAL AUDIOMETRY RESULTS IN STAGE 2 OF THE STREAM TRIAL

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# CONFLICT OF INTEREST DISCLOSURE

✓ I have no Conflict of Interest to report.

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- Receipt of grants/research supports: \_\_\_\_\_
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## BACKGROUND

- STREAM is the first large-scale phase III, multi-country clinical trial to examine shortened regimens for multidrug-resistant tuberculosis (MDR-TB)
- Stage 2 is evaluating the efficacy, safety, and cost-effectiveness of a 9-month all-oral, bedaquiline-containing regimen vs. a 9-month injectable-containing regimen
- A total of 588 participants have been recruited at 13 sites in Ethiopia, Georgia, India, Moldova, Mongolia, South Africa, and Uganda

## BACKGROUND

- Injectable aminoglycosides used for treatment of MDR-TB may cause irreversible hearing loss
- Access to conventional audiometry is limited or unavailable in some settings with a high burden of tuberculosis
- Tablet-based audiometry, used to monitor for hearing loss amongst STREAM Stage 2 trial participants, was compared to conventional audiometry

## METHODS

- Tablet-based and conventional audiometry testing were done in parallel for trial participants between April 2018 and November 2019
- Both testing platforms measured pure tone audiometry in decibels at 1000, 2000, 4000, 6000, and 8000 Hz
- Hearing loss was graded according to Brock's Criteria
- Sensitivity and specificity of tablet-based audiometry, and a Kappa-statistic assessing the level of agreement between the two testing methods were calculated for each ear

## RESULTS

- In total, 217 conventional audiometry results from 105 participants and 2,330 tablet-based audiometry results from 527 participants were available at the relevant frequencies
- After matching for test date, 56 participants from Uganda (59%), South Africa (38%), India (2%) and Mongolia (1%) had 126 paired test results
- Of these, 10 tests (6 left, 4 right) could not be graded, and seven tests (4 left, 3 right) were excluded after review by a trained audiologist due to errors with the test
- A total of 116 and 119 paired test results for the left and right ear, respectively, were analyzed

## RESULTS

- The majority of conventional tests detected no hearing loss (168 tests (71%))
- Hearing loss detected using conventional audiometry testing was predominantly mild
  - Grade 1: 49 tests (21%)
  - Grade 2: 17 tests (7%)
  - Grade 4: 1 test (0.4%)
- Tablet-based audiometry had high sensitivity and specificity
  - Sensitivity: 94% left ear, 100% right ear
  - Specificity: 93% left ear, 94% right ear

## RESULTS

- Using Brock's criteria to grade the results, the two tests agreed for 91.4% (106/116) of left ear and 95.8% (114/119) of right ear pairs
- Kappa-statistics for both ears showed substantial agreement between the two tests
  - Left ear:  $\kappa = 91.2$
  - Right ear:  $\kappa = 80.1$



## CONCLUSIONS

- Tablet-based audiometry was a sensitive tool for detecting hearing loss and an effective way to monitor clinical trial participants
- Tablet-based audiometry may be considered in settings where conventional audiometry is limited or unavailable

# THANK YOU!

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