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Evaluation of ultrasound for screening and diagnosis of pulmonary tuberculosis, KwaZulu Natal, South Africa, 2019-20: images

Study Documentation

May 19, 2026

Metadata Production

Metadata Producer(s)	Africa Health Research Institute (AHRI)
Identification	AHRI.PoCUS.images

Table of Contents

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Overview

Identification	AHRI.PoCUS.images
Version	v1.0.0

Abstract

Improved tests for screening and diagnosing TB in low-income settings are an essential component of the End TB strategy. Transthoracic ultrasound has generally been considered to perform poorly for the diagnosing pulmonary TB, but newer devices may offer better performance characteristics. The current research was a proof-of-concept study to determine the performance characteristics of thoracic and abdominal ultrasound for the diagnosis of TB in adults compared to a microbiological reference standard under ideal conditions, to inform whether future evaluation and development of the technique is needed.

We recruited participants during the period from October 2019 to March 2020 from two sources:

1) Vukuzazi: A population-based health care screening study (named Vukuzazi), which aimed to describe the frequency and distribution of multimorbidity, including an extensive TB screening component, among adults in the AHRI demographic surveillance area in northern KwaZulu-Natal (Gunda et al., 2021). Participants from this source were eligible if they had undergone a chest radiograph and had results from a sputum sample tested for mycobacteria in the AHRI lab;

2) Clinic: Individuals who attended a primary healthcare clinic in KwaZulu-Natal to start TB treatment.

Participants were eligible to take part in the study if they were adults (aged 18 years or above) and healthy enough to travel and participate in the study. We recruited participants from the Vukuzazi study into four groups based on the following criteria:

- group 1: no TB symptoms, negative sputum Xpert MTB/RIF Ultra, normal chest radiograph;
- group 2: negative sputum Xpert MTB/RIF Ultra, abnormal chest radiograph;
- group 3: positive sputum Xpert MTB/RIF Ultra, abnormal chest radiograph;
- group 4, positive sputum Xpert MTB/RIF Ultra, normal chest radiograph.

Participants sampled from the clinic were classified into group 3. This allowed the comparison of those without evidence of TB (group 1) to those with either microbiological or radiological evidence of TB (groups 2-4). Participants from the clinic completed a questionnaire aligned to that used in Vukuzazi concerning health care history, TB symptoms, and HIV and TB treatment. All participants gave venous blood for testing for HIV antibodies. For the primary analysis all participants underwent comprehensive thoracic and focused abdominal ultrasound examination performed according to the study protocol by clinicians masked to all clinical and imaging data. Experienced ultrasonographers interpreted the resulting ultrasound images for the presence of typical chest radiography features of pulmonary or extrapulmonary TB. A comparison of these features between the study groups allowed us to estimate the sensitivity and specificity of individual and combined ultrasound features to detect TB (microbiological/radiological).

Kind of Data	HIV Genomic Data
Unit of Analysis	Study participant

Scope & Coverage

Keywords	Tuberculosis, Ultrasonography, Point-of-Care Testing, Sputum samples, sputum Xpert MTB/RIF testing, TB symptom screening
Topics	Tuberculosis, Ultrasonography, Point-of-Care Testing

Time Period(s)	2019-2020
Countries	South Africa

Geographic Coverage
Demographic surveillance area of the Africa Health Research Institute in uMkhanyakude district, KwaZulu-Natal, and a TB clinic near Durban, KwaZulu-Natal.

Universe
As above, participants were drawn from two populations. The first population was that covered by the ongoing ARHI demographic surveillance located in rural KwaZulu-Natal which was established in 2000 (Gareta et al., 2021). In 2018, within the ongoing surveillance, the 'Vukuzazi' study offered community-wide health screening and bio-sampling to understand the frequency and distribution of major health care needs in the population (Gunda et al., 2021). For this study we selected adult (18 years and above) participants of Vukuzazi who had completed the full set of TB screening tests and were healthy enough to travel to Durban to undergo the imaging for this the study. This allowed us to sample healthy participants and participants with varying degrees of microbiological and radiological evidence for TB. The second population were adults (18 years and above) who attended a primary healthcare clinic in KwaZulu-Natal to start TB treatment who had microbiologically-confirmed TB.

Producers & Sponsors

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Other Producer(s)	Africa Health Research Institute (AHRI)
Funding Agency/ies	Bill & Melinda Gates Foundation (BMGF) , Full funding

Sampling

Sampling Procedure

Sample size was based on precision estimates. With 50 participants with bacteriologically-confirmed TB, we calculated that we would be able to demonstrate ultrasound sensitivity of 80% with a 95% confidence interval (CI) of 67%-89%, and with 100 participants without active TB, we would be able to demonstrate specificity of ultrasound of 80% with a 95% CI of 71%-87%. The study was designed to be exploratory, with a relatively small number of participants, aiming to estimate sensitivity and specificity relatively imprecisely to guide whether larger-scale evaluation was warranted. We did not calculate predictive values because our sample purposively included more people with active TB than would usually be found in routine populations being screened for TB, and thus predictive values from this study could not be generalized.

Data Collection

Data Collection Dates	start 2019-10-01 end 2020-03-31

Data Processing & Appraisal

Data Editing

Clinical and demographic data from the Vukuzazi population-based screening and the participants from the primary health care clinic were combined and harmonised. Participants were categorised into groups by their microbiological and radiological evidence for TB and these variables were used to define the reference standard for the TB diagnosis. Ultrasound variables for the various features were constructed based on study definitions and composite outcomes combining multiple radiologic features were created

Accessibility

Access Conditions

Access to the data requires accurate completion of the online data access application form accessible on the AHRI Data repository(<https://data.ahri.org/>). Data users are required to abide by the data use conditions stipulated on the application for access to the data. Failure to do so may result in their data access privileges revolved by the Data Custodian. In order to recognise the effort and intellectual contributions of AHRI investigators in producing and curating the data, users of AHRI data must acknowledge the source of the data and abide by the terms and conditions under which the data is accessed. All analytical datasets published on the AHRI Data Repository are assigned digital object identifier (DOIs) and the DOIs can be found on the Data Repository under Study Description tab - Access policy. AHRI data users are required to always cite the dataset using the DOI.

Due to the size of the zip file(>50GB), the images could not be published on the AHRI Data Repository. The images are therefore stored on the AHRI SharePoint. Users must request for access on the AHRI Data Repository by completing the online data request application form. Access to the SharePoint will only be granted to the data user once the Data Custodian has approved the user data request.

Citation Requirements

Dayi, N., Myeza, N., Mkwanazi, N., Dube, S., Gareta, D., Mnomiya, M., Mtshali, T., Mhlane, Z., Ngcobo, N., Lab data collection and analysis , Khan, D., Mitha, M., Caligiuri, P., Olivier, S., Ramjit, D., Edwards, A., Karim, F., Edwards, T., Wong, E., … Grant, A. (2026). Evaluation of ultrasound for screening and diagnosis of pulmonary tuberculosis, KwaZulu Natal, South Africa, 2019-20: images. Africa Health Research Institute.

DOI:https://doi.org/10.23664/AHRI.POCUS.IMAGES

Files Description

Dataset contains 0 file(s)

Variables List

Dataset contains 0 variable(s)