

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

**Sweetness H Dube**

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## Overview

### Identification

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#### ID NUMBER

AHRI.Pocus.AnalyticalDataset.2022.v1

### Version

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#### VERSION DESCRIPTION

V1.0.0

### Overview

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#### 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

Clinical Data

## UNITS OF ANALYSIS

Study participant

## TOPICS

Topic	Vocabulary	URI
Tuberculosis, Ultrasonography, Point-of-Care Testing	Africa Health Research Institute	www.ahri.org

## KEYWORDS

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

## Coverage

## 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 and Sponsors

## PRIMARY INVESTIGATOR(S)

Name	Affiliation
Prof. Alison Grant	Africa Health Research Institute, Durban, South Africa, London School of Hygiene & Tropical Medicine, UK
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## OTHER PRODUCER(S)

Name	Affiliation	Role
Africa Health Research Institute		

## FUNDING

Name	Abbreviation	Role
Bill & Melinda Gates Foundation	BMGF	Full funding

## OTHER ACKNOWLEDGEMENTS

Name	Affiliation	Role
Dickman Gareta	Africa Health Research Institute	Data management
Njabulo Dayi	Africa Health Research Institute	Data management
Njabulo Myeza	Africa Health Research Institute	Data management
Mthokozisi Mnomiya	Africa Health Research Institute	Data collection
Thabani Mtshali	Africa Health Research Institute	Data collection
Zoey Mhlane	Africa Health Research Institute	Data collection
Nokwanda Ngcobo	Africa Health Research Institute	Data collection
Theresa Smit and the AHRI Laboratory Team	Africa Health Research Institute	Lab data collection and analysis
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Stephen Olivier	Africa Health Research Institute	Statistical analysis
Dirhona Ramjit	Africa Health Research Institute	Study coordination
Anita Edwards	Africa Health Research Institute	Study coordination
Farina Karim	Africa Health Research Institute	Study coordination
Tansy Edwards	LSHTM	Advised on approach to statistical analysis
Butterfly Network	Butterfly	Provided an ultrasound device

## Metadata Production

METADATA PRODUCED BY

Name	Abbreviation	Affiliation	Role
Africa Health Research Institute	AHRI		

DDI DOCUMENT ID

DDI.AHRI.PoCUS.AnalyticalDataset.2022.v1

## Sampling

### Sampling Procedure

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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.

## Questionnaires

No content available

## Data Collection

### Data Collection Dates

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<b>Start</b>	<b>End</b>	<b>Cycle</b>
2019-10-01	2020-03-30	N/A

## Data Processing

No content available

## Data Appraisal

No content available

## **File Description**

## **Variable List**

**AHRI.Pocus.AnalyticalDataset.2022.v1**

Content	
Cases	92
Variable(s)	40
Structure	Type: Keys: ()
Version	
Producer	
Missing Data	

**Variables**

ID	NAME	LABEL	TYPE	FORMAT	QUESTION
V2660	PocusId	PoCUS Unique Identifier	discrete	character	
V2661	Site	Site	discrete	character	
V2662	TBBacteriologic	TB (Bacteriologic)	discrete	numeric	
V2663	TB_bact_rad	TB (Bacteriologic or Radiologic)	discrete	numeric	
V2664	TBBacteriologicHealthy	TB (Bacteriologic vs Healthy - Excludes CXR abnormalities)	discrete	numeric	
V2665	Sex	Sex	discrete	numeric	
V2666	Age	Age (years)	contin	numeric	
V2667	HIVStatus	HIV Status	discrete	numeric	
V2668	OnArt	On ART self reported	discrete	numeric	
V2669	CD4	CD4 Lymphocytes Abs	contin	numeric	
V2670	TBSymptom	Any TB symptoms	discrete	numeric	
V2671	CurrSmoker	Current smoker	discrete	numeric	
V2672	BMI	Body Mass Index	contin	numeric	
V2673	BMICat	Body Mass Index (Categories)	discrete	numeric	
V2674	HighBSugarInformedEver	Raised blood sugar (Ever been informed by health care worker)	discrete	numeric	
V2675	TBStatus	TB group	discrete	numeric	
V2676	PrevTB	Prior TB treatment	discrete	numeric	
V2677	ConsolidationAny	Any consolidation	discrete	numeric	
V2678	ConsolidationUpper	Consolidation (Upper)	discrete	numeric	
V2679	SPC	Small Subpleural consolidation	discrete	numeric	
V2680	SPCUpper	Small Subpleural consolidation (Upper)	discrete	numeric	
V2681	SSPCNumber	Small Subpleural consolidation (Number)	discrete	numeric	
V2682	SPC2More	Small Subpleural consolidation (2 or more)	discrete	numeric	
V2683	B1B2Pattern	(B-lines) B1 or B2 pattern	discrete	numeric	
V2684	B2Pattern	(B-lines) B2 pattern	discrete	numeric	
V2685	IPL	Irregular pleural line	discrete	numeric	
V2686	PleuralEffusionAny	Pleural effusion (any)	discrete	numeric	

V2687	CavityAny	Any cavity	discrete	numeric
V2688	PericardialEff	Pericardial effusion	discrete	numeric
V2689	HepaticLesions	Hepatic lesions	discrete	numeric
V2690	LAN	Periaortic Lymphadenopathy	discrete	numeric
V2691	Ascites	Ascites	discrete	numeric
V2692	LUS1FASH1	Any thoracic or FASH pathology	discrete	numeric
V2693	LUS1	Any Thoracic pathology	discrete	numeric
V2694	LUS2	Thoracic combo 1	discrete	numeric
V2695	LUS3	Thoracic combo 2	discrete	numeric
V2696	LUS4	Thoracic combo 3	discrete	numeric
V2697	FASH2	FASH combo 1	discrete	numeric
V2698	LUS2FASH2	Thoracic combo 1 or FASH combo 1	discrete	numeric
V2699	FASH1	Any FASH pathology	discrete	numeric



## PoCUS Unique Identifier (PocusId)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: character  
Width: 11

Valid cases: 92  
Invalid: 0

## Site (Site)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: character  
Width: 8

Valid cases: 92  
Invalid: 0

## TB (Bacteriologic) (TBBacteriologic)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 84  
Invalid: 8

## TB (Bacteriologic or Radiologic) (TB\_bact\_rad)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## TB (Bacteriologic vs Healthy - Excludes CXR abnormalities) (TBBacteriologicHealthy)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 71  
Invalid: 21

## Sex (Sex)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

**Overview**

Type: Discrete	Valid cases: 92
Format: numeric	Invalid: 0
Width: 10	
Decimals: 0	
Range: 1-2	

Age (years) (Age)  
 File: AHRI.Pocus.AnalyticalDataset.2022.v1

**Overview**

Type: Continuous	Valid cases: 92
Format: numeric	Invalid: 0
Width: 10	Minimum: 18
Decimals: 0	Maximum: 74
Range: 18-74	Mean: 41.9
	Standard deviation: 13.7

HIV Status (HIVStatus)  
 File: AHRI.Pocus.AnalyticalDataset.2022.v1

**Overview**

Type: Discrete	Valid cases: 92
Format: numeric	Invalid: 0
Width: 10	
Decimals: 0	
Range: 0-1	

On ART self reported (OnArt)  
 File: AHRI.Pocus.AnalyticalDataset.2022.v1

**Overview**

Type: Discrete	Valid cases: 48
Format: numeric	Invalid: 44
Width: 10	
Decimals: 0	
Range: 0-1	

CD4 Lymphocytes Abs (CD4)  
 File: AHRI.Pocus.AnalyticalDataset.2022.v1

**Overview**

Type: Continuous	Valid cases: 43
Format: numeric	Invalid: 49
Width: 10	Minimum: 66
Decimals: 0	Maximum: 1356
Range: 66-1356	Mean: 631.8
	Standard deviation: 324.9

Any TB symptoms (TBSymptom)  
 File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
 Format: numeric  
 Width: 10  
 Decimals: 0  
 Range: 0-1

Valid cases: 92  
 Invalid: 0

## Current smoker (CurrSmoker)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
 Format: numeric  
 Width: 10  
 Decimals: 0  
 Range: 0-1

Valid cases: 92  
 Invalid: 0

## Body Mass Index (BMI)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Continuous  
 Format: numeric  
 Width: 10  
 Decimals: 0  
 Range: 7.62084482508347-54.942767950052

Valid cases: 92  
 Invalid: 0  
 Minimum: 7.6  
 Maximum: 54.9  
 Mean: 23.2  
 Standard deviation: 6.7

## Body Mass Index (Categories) (BMICat)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
 Format: numeric  
 Width: 10  
 Decimals: 0  
 Range: 1-4

Valid cases: 92  
 Invalid: 0

## Raised blood sugar (Ever been informed by health care worker) (HighBSugarInformedEver)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
 Format: numeric  
 Width: 10  
 Decimals: 0  
 Range: 0-1

Valid cases: 44  
 Invalid: 48

## TB group (TBStatus)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 1-4

Valid cases: 92  
Invalid: 0

## Prior TB treatment (PrevTB)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-3

Valid cases: 92  
Invalid: 0

## Any consolidation (ConsolidationAny)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Consolidation (Upper) (ConsolidationUpper)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Small Subpleural consolidation (SPC)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Small Subpleural consolidation (Upper) (SPCUpper)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Small Subpleural consolidation (Number) (SSPCNumber)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-9

Valid cases: 92  
Invalid: 0

## Small Subpleural consolidation (2 or more) (SPC2More)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## (B-lines) B1 or B2 pattern (B1B2Pattern)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## (B-lines) B2 pattern (B2Pattern)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Irregular pleural line (IPL)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Pleural effusion (any) (PleuralEffusionAny)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Any cavity (CavityAny)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Pericardial effusion (PericardialEff)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Hepatic lesions (HepaticLesions)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Periaortic Lymphadenopathy (LAN)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Ascites (Ascites)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Any thoracic or FASH pathology (LUS1FASH1)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Any Thoracic pathology (LUS1)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Thoracic combo 1 (LUS2)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

## Thoracic combo 2 (LUS3)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

### Thoracic combo 3 (LUS4)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

#### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

### FASH combo 1 (FASH2)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

#### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

### Thoracic combo 1 or FASH combo 1 (LUS2FASH2)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

#### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

### Any FASH pathology (FASH1)

File: AHRI.Pocus.AnalyticalDataset.2022.v1

#### Overview

Type: Discrete  
Format: numeric  
Width: 10  
Decimals: 0  
Range: 0-1

Valid cases: 92  
Invalid: 0

# Documentation

## Technical documents

### DDI:Pocus.AnalyticalDataset.2022

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Title	DDI:Pocus.AnalyticalDataset.2022
Author(s)	Sweetness H Dube
Date	25/08/2022
Country	South Africa
Language	English
Publisher(s)	Sweetness H Dube
Filename	AHRI.Pocus.AnalyticalDataset.2022.v1.pdf

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