

Diagnostic accuracy of Computer-Aided Detection for Tuberculosis® and Stool Xpert for detecting TB in prospectively recruited West African children.

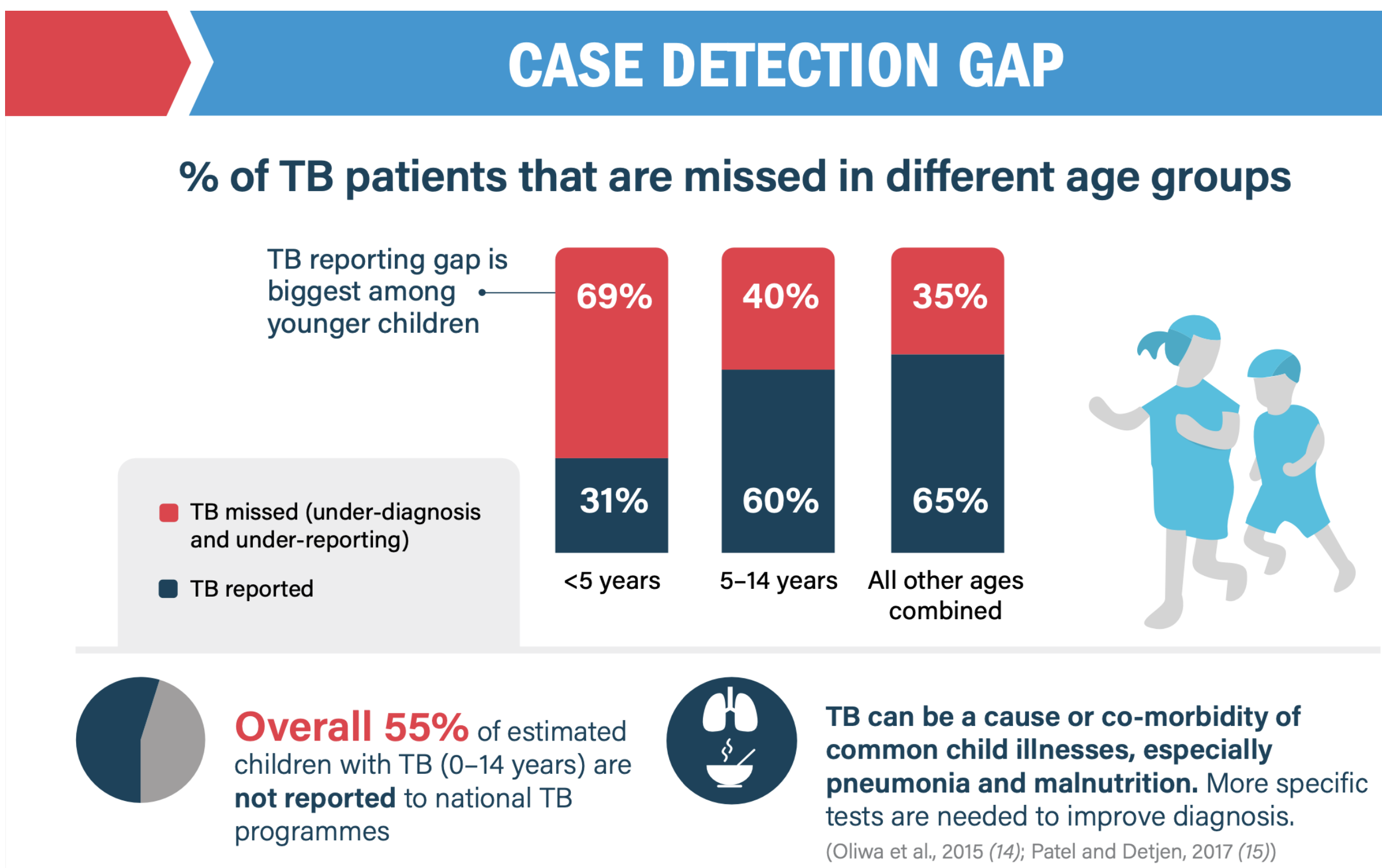
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Introduction

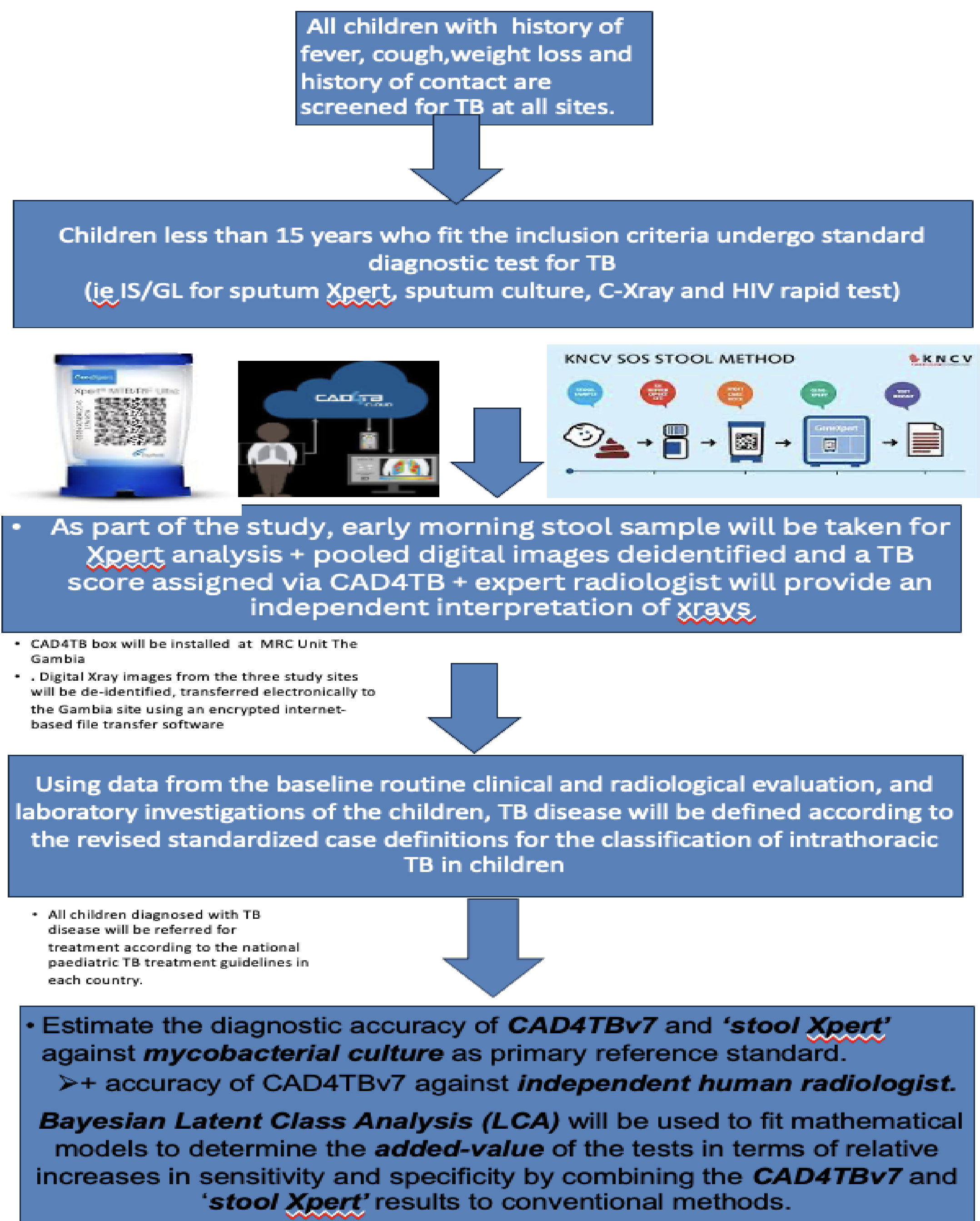
- Tuberculosis (TB) diagnosis in children is challenging due to the difficulty in obtaining sputum and the subjectivity of Chest X-ray interpretation.
- Therefore, most of these cases are clinically diagnosed, resulting in a wide case detection gap. Non-sputum-based TB diagnostic tests remain a priority.
- We evaluated the diagnostic accuracy of CAD4TB software and Stool Xpert for diagnosing TB in prospectively recruited children in three West African countries



Methodology

- This is an ongoing multi-country study with consecutive recruitment of children aged less than 15 years assessed for presumptive pulmonary TB at study sites in Benin, Gambia, and Ghana. Participants undergo standardized conventional investigations for TB.
- In addition, morning stool samples are simultaneously collected for testing with GeneXpert Ultra ('stool Xpert'), while Computer-aided Detection for TB-version 7 ('CAD4TBv7') abnormality scores are derived for digital chest radiographs.
- The performance of stool Xpert and CAD4TBv7 were measured against a microbiological reference standard (MRS) and area under the receiver operating characteristic (AUROC) curve, point estimates of sensitivity and specificity were determined.

Study Flow



Preliminary results

- A total of 186 participants were enrolled, with a median age of 3.7 (IQR, 1.4-8.7) years, and 28/164 (17.1%) were HIV positive.
- Twenty-five (14.8%) had confirmed TB, 17 (10.1%) had unconfirmed TB, and 127 (75.1%) had unlikely TB.
- Using the MRS, the AUROC, sensitivity, and specificity of CAD4TBv7 were 0.65 (95%CI 0.53-0.76), 33.3% (95%CI 13.3-59.0), and 96.3% (95%CI 90.8-99.0%), respectively.
- The AUROC, sensitivity, and specificity of stool Xpert were 0.82 (95%CI 0.72-0.92), 63.6% (95%CI 40.7-82.8), and 100% (95%CI 97.2-100%) respectively.
- Comparing the AUCROC of CAD4TBv7 to a human reader while using the MRS as the reference, there was no statistical difference (CAD4TBv7: 0.65 (0.53-0.76); human reader: 0.68 (0.56-0.80), DeLong p= 0.558).

Table: Diagnostic Performance of Stool, CAD4TB, and Human Reader against MRS.

Test	AUC	Sensitivity % (95%CI)	Specificity % (95%CI)	PPV % (95%CI)	NPV % (95%CI)
Stool Xpert	0.82 (0.72-0.92)	63.6 (40.7-82.8)	100 (97.2- 100)	100 (76.8- 100)	94.2 (89.0- 97.5)
CAD Abnormality Score	0.65 (0.53-0.76)	33.3 (13.3-59)	96.3 (90.8- 99.0)	60.0 (26.2- 87.8)	89.7 (82.6- 94.5)
Human Reader	0.69 (0.60-0.79)	78.3 (56.3-92.5)	60.0 (51.2- 68.3)	25.0 (15.5- 36.6)	94.2 (87.0- 98.1)

PPV=Positive Predictive Value NPV = Negative Predictive Value Value (95% CI) AUC= area under receiver operating characteristics

Conclusion

- While the performance of CAD4TBv7 is comparable to human readers, it does not meet the WHO recommendation as a stand-alone screening test.
- The high specificity of stool Xpert makes it a good add-on as a microbiological test..

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