Reproducibility of results and performance of TB diagnostics in East Africa Public Health Laboratory Networking Project in Kenya

Dr. (Ms) Willie A. Githui Officer and Regional Chairperson East Africa Public Health Laboratory Networking Project Kenya Medical Research Institute Nairobi, Kenya January, 2018



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Introduction

- Reproducibility of laboratory results and performance of diagnostic tools form major part of quality assurance in diagnosis, which is key to patient care.
- There are no documented comparisons of reproducibility of results and performance of TB diagnostics in different geographical settings.
- These were determined in an East Africa Public Health Laboratory Networking Project- Operational Research (EAPHLN-OR) TB study sites including cross-border regions in Kenya.
- This was part of the regional project involving five countries; (Burundi, Kenya, Rwanda, Tanzania and Uganda) coordinated by EACSA-HC.

Methods - 1

- People presumed to have TB, aged 18 years and above were enrolled in a cross-sectional study between 2013 and 2016 at nine selected public health facilities in Kenya.
- Spot and morning sputum specimens collected from 2928 participants on two consecutive days with a total of 5715 specimens.
- At study site, a proportion of each specimen was processed for ZN, FM and GeneXpert MTB/RIF®.
- The remaining portion was shipped to the Kenya Medical Research Institute (KEMRI) laboratory, Nairobi for ZN, FM, GeneXpert, LJ culture and ID were done according to standard procedures.

Methods - 2

- KEMRI laboratory personnel were blinded of the results from the site results.
- ► Data processed with MySQLTM and IBM SPSS version 24 software.
- Reproducibility of results were determined by Kappa values using specimen as unit of analysis
- Performance by diagnostic values (sensitivity, specificity, positive/ negative predictive values) using the patient as unit of analysis.
- LJ culture was used as gold standard.
- Study sites results were compared with those from KEMPI

Results-1: Reproducibility of results for different TB diagnostic tools between study sites and KEMRI research laboratory

Diagnostic tool		Z	N KEMRI		
		Positive	Negative	Total	Kappa value (95% CI)
ZN sites	Positive	345	125	470	0.721(0.708-0.734)
	Negative	93	2689	2782	
	Total	438	2814	3252	
		F			
		Positive	Negative	Total	
FM sites	Positive	324	116	440	0.749(0.736-0.762)
	Negative	61	2315	2376	
	Total	385	2431	2816	
		Gene			
		Positive	Negative	Total	
GeneXpert sites	Positive	130	19	149	0.855(0.834-0.876)
	Negative	14	497	511	
	Total	144	516	660	

Results 2: Performance of different TB diagnostic tools at study sites and KEMRI research laboratory

Diagnostic tool	n	Sen. (95% CI)		n	Spec. (95% CI)		n	ppv (95% CI)			n	npv (95% CI)				
ZN sites	259	69.9	64.3	75.5	1367	94.7	93.5	95.9	253	71.5	66.0	77.1	1373	94.3	93.1	95.5
ZN kemri	259	68.7	63.1	74.4	1367	93.3	92.0	94.7	269	66.2	60.5	71.8	1357	94.0	92.8	95.3
FM sites	219	76.7	71.1	82.3	1189	94.2	92.9	95.5	237	70.9	65.1	76.7	1171	95.6	94.5	96.8
FM kemri	219	70.8	64.8	76.8	1189	94.4	93.1	95.7	222	69.8	63.8	75.9	1186	94.6	93.3	95.9
GeneXpert sites	59	81.4	71.4	91.3	271	88.6	84.8	92.4	79	60.8	50.0	71.5	251	95.6	93.1	98.2
GeneXpert KEMRI	59	81.4	71.4	91.3	271	89.3	85.6	93.0	77	62.3	51.5	73.2	253	95.7	93.1	98.2

Conclusions and recommendations

- GeneXpert indicated excellent reproducibility of results between KEMRI and study sites in Kenya suggesting that under ideal conditions. It also provides reliable results irrespective of site setting.
 - Microscopy had significantly lower reproducibility values than GeneXpert.
- Microscopy, with both higher specificity and positive/negative predictive values, could complement GeneXpert in detection of mycobacteria to enhance best practices based on settings including infrastructure, human resource and workload.

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ASANTE SANA

THANK YOU VERY MUCH