Abstract

Introduction: The clinical diagnosis of pulmonary tuberculosis(PTB) is based on occurrence of four cardinal signs and symptoms which include current cough, night sweats, weight loss, or low grade fever. However few studies have determined the validity and reliability of these diagnoses by intra and inter-examiner calibration of clinicians for appropriateness of detection of TB in resource constrained settings.

Objective : The aim of the study was to determine the sensitivity of concordance and reliability (Kappa values) of inter-examiner and intra-examiner findings of clinicians in the EAPHLN project.

Methods: The study was designed as a cross-sectional study in nine sites. It included 155 patients for intra-examiner and 57 patients for inter-examiner calibrations selected from eligible people with symptoms or signs suggestive of TB during the implementation of the East African Public Health Laboratory Network Project (EAPHLNP) in Kenya. TB clinical symptoms and signs were recorded in a structured medical form included the following: productive cough, weight loss, night sweats, low grade fever (classical cardinal signs and symptoms). Using quality assurance sampling for a total population of ten thousand people with symptoms or signs suggestive of TB from the sites with a minimum defective sample acceptable of 0 and a probability of defect accepted of 1% and an alpha of 5%, the sample size of repeatable samples is 262 for total patients for the sites per year. Intra-examiner calibration involved examination of the same patient independently by the same clinician within one day interval. Inter-examiner calibration involved examination of the same patient by two clinicians independently the same day. Calibration of the clinical tools used during examination of patients was done. TB laboratory diagnosis was first done by sputum smear microscopy Ziehl–Neelsen stain.(ZN), secondly by optimized sputum smear microscopy with a Light Emitting Diode microscope (LED) or fluorescent microscopy(FM), and thirdly by Geneexpert technique (Gene Xpert or Gx). The results from the clinicians and reference laboratory findings for these patients were entered in a computer, verified and analyzed in SPSS for reliability statistics. These unweighted Cohen Kappa scores were interpreted as follows: poor 0.01–0.20, moderate 0.21–0.40, fair 0.41–0.60, good 0.61–0.80, or excellent 0.81–1.0 based on the agreement between the intra-examiner and inter-examiner findings

Results: A significant difference was found between concordant diagnosis of a least 4 signs and symptoms of TB compared to fewer by the same examiner on the same patient in all TB test/HIV status categories except the ZN positive /HIV positives and Genexpert negative /HIV positives and HIV negative categories. The highest sensitivity was 81.8%(95%CI=52.3-94.9) in the Gx+ve/HIV+ve category. The significance difference in senstiviity results of TB/HIV test vs at least presence of the 4 signs and symptoms however did not occur in ZN+ve/HIV+ve, FM+ve/HIV+ve , Gx+ve/HIV+ve Gx+ve/HIV-ve categories. Kappa values for cough and fever were consistently significantly higher than zero kappa.

Conclusion: Excellent kappa can be achieved in low resource settings by clinician using all four cardinal signs and symptoms of TB with laboratory results. There is possibility of using the clinical diagnosis using the four signs and symptoms where laboratory diagnosis is not present but specificity is low. Good clinical practice would improve the specificity.