

Abstract

Background: The common problem in tuberculosis (TB) management is misdiagnosis or under-diagnosis of cases leading to high morbidity and mortality. In order to reverse this, new diagnostic tools for detection of *Mycobacterium tuberculosis* (MTB) the causative agent of TB disease have been developed. However, in the evaluation process of these tools many studies have not considered attributes of sputum quality in their testing algorithm. This study aimed at evaluating the effect of sputum quality in detection of MTB when using Xpert® MTB/RIF (geneXpert) among patients presumed to have pulmonary TB.

Methods: Spot and morning sputum specimens were collected from persons presumed to have pulmonary TB enrolled in nine East Africa Public Health Laboratory Networking (EAPHLN) Project study sites in Kenya. The specimens were appropriately packaged and transported to KEMRI Mycobacteriology research laboratory where they were macroscopically characterized into muco-purulent; mucoid, salivary or blood stained. Each specimen was processed for GeneXpert testing and culture.

Results: Between February 2013 and August 2014 a total of 3073 sputum specimens were received. Upon macroscopic characterization, 46.1% were mucoid, 44% were salivary, 7.5% were Muco-purulent, while 2.4% were blood stained. Bivariate analysis revealed that there was a significant association between sputum quality and gender ($p < 0.001$), age ($p = 0.022$), specimen type ($p < 0.001$), and HIV status ($p = 0.003$). Performance of GeneXpert on the different specimen categories, muco-purulent (85.7%; CI 95%, 67.4-100%) and mucoid (85.3%, 95%CI: 77.3-93.3%) specimens had higher sensitivity when compared to salivary specimens (76.7%, 95%CI: 64.1-89.3)). However when stratified by HIV status, GeneXpert detected more MTB on salivary specimens produced by HIV positive (85.7%, 95%CI: 67.4-100%).patients than those from HIV negative patients (71.4%, 95%CI: 52.1- 90.7%).

Conclusions: By macroscopic characterization, any sputum specimen type from HIV Positive or Negative persons presumed to have tuberculosis can be used in diagnosis of tuberculosis regardless of sputum quality classification. However, the sensitivity of geneXpert was higher in morning sputum specimens which are more likely to be muco-purulent and mucoid with high MTB yield than in spot sputum specimens which are more likely to be salivary with low MTB yield. Also, geneXpert sensitivity was higher, though not significant, in salivary specimens from HIV positive individuals than those of HIV negative individuals. Sputum

specimen quality assessment should be considered as an integral part of routine laboratory diagnosis of TB especially in HIV negative individuals.