**Diagnostics and biomarkers**

**OC - (8215) - DIAGNOSTIC ACCURACY OF XPERT MTB/RIF ULTRA FOR PULMONARY TUBERCULOSIS IN CHILDREN: A MULTICENTRE COMPARATIVE STUDY**

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**Background**

Xpert MTB/RIF (Xpert) has suboptimal sensitivity for the diagnosis of pulmonary tuberculosis in children. The next-generation Xpert MTB/RIF Ultra assay (Xpert Ultra) is substantially more sensitive than Xpert and may allow improved detection of paediatric tuberculosis. We evaluated the diagnostic accuracy of Xpert Ultra versus Xpert in the detection of pulmonary tuberculosis in children.

**Methods**

From May 2011 to September 2012, children with presumptive pulmonary tuberculosis were enrolled at two Tanzanian research sites in the EDCTP-funded TB CHILD project. Sputum samples were collected and examined for tuberculosis using sputum smear, Xpert and culture. Xpert Ultra analysis was performed between January and June 2017 at both sites using decontaminated sputum pellets which had been stored at -80°C. The diagnostic accuracy of Xpert and Xpert Ultra was determined using well-defined case definitions as reference standard.

**Results**

In total, 215 children were included in the analysis. The median age was 5.4 years (IQR, 1.5 to 9.9), the HIV prevalence was 52%, and 28 children (13%) had culture confirmed pulmonary tuberculosis. When only the first available sample of each patient was taken into account, the sensitivity of Xpert Ultra was 64.3% (95% CI: 44.1 to 81.4) while that of Xpert was 53.6% (95% CI: 33.9 to 72.5). The specificity of Xpert Ultra based on the analysis of all available samples was 98.1% (95% CI: 93.4 to 99.7), whereas that of Xpert was 100%.

**Conclusions**

In settings with a high burden of tuberculosis and HIV, Xpert Ultra had a better sensitivity than Xpert in children. However, the specificity was slightly lower than that of Xpert. Thus, Xpert Ultra has the potential to increase the reliability and the speed of tuberculosis diagnosis in children.