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Title: Rapid testing for drug susceptibility

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Body: The rapid detection of drug resistance is critical to appropriate treatment of TB. The Global Consortium for Drug-Resistant TB Diagnostics (GCDD; funded by NIH Grant #5U01AI082229) was formed to develop and study rapid XDR-TB at three clinical sites in Mumbai (India), Chisinau (Moldova) and Port Elizabeth (South Africa). Primary study aims include reducing XDR-TB detection time to a week and determining agreement between rapid tests and standard DST. TB patients with risk factors for drug-resistance were recruited from 3 multinational sites. We performed AFB smear, MGIT960 culture and DST, pyrosequencing (PSQ), line probe assay (LPA) and MODS assays. We evaluated resistance to the TB drugs isoniazid (INH), rifampin (RIF), moxifloxacin (MOX), ofloxacin (OFX), amikacin (AMK), capreomycin (CAP) and kanamycin (KAN). The presentation will be based on samples collected from ~1000 subjects April 2012-July 2013. Analysis has not been done at this time since the enrollment is not complete. We can make some general statements at this time based on an interim analysis. Median time-to-result was 25 days for the MGIT DST;15 days for the MODS assay;8 days for PSQ and 5 days for the Hain LPA (plus and sl). Rapid test concordance was relative to MGIT960 DST. For INH, PSQ was 96%, MODS 96% and LPA 96%; for RIF, PSQ was 97%, MODS 98% and LPA 97%; for AMK, PSQ was 98%, MODS 99% and LPA 98%; for CAP, PSQ was 98%, MODS 99% and LPA 98%; for KAN, PSQ was 92%, MODS 91% and LPA was 92%; for MOX, PSQ was 95%, MODS 98% and LPA 96%; and for OFX, PSQ concordance was 96%, MODS 98% and LPA 97%. Based on our preliminary data we can conclude that the MODS, PYRO and LPA are both rapid and accurate.