MICROSCOPIC-OBSERVATION DRUG-SUSCEPTIBILITY ASSAY FOR RAPID, LOW-COST DIAGNOSIS OF TUBERCULOSIS AND MDR – HOW SHOULD WE USE IT?

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The microscopic-observation drug-susceptibility (MODS) assay is a low-cost, relatively low-tech tool for the sensitive, rapid diagnosis of TB and MDRTB. It was developed in Peru with the specific purpose of bringing high quality TB diagnosis to the resource-limited, high TB and MDRTB burden settings.

The key performance data, collected in a large operational evaluation within the Peruvian National TB Programme in Lima, are as follows: sensitivity of detection (98%) significantly exceeds automated MBBacT (BacTAlert) culture (89%) and Lowenstein-Jensen (84%) and renders a second MODS culture of very limited benefit; speed of detection (median 7 days) significantly exceeds MBBacT (13 days) and LJ (26 days) – add a further 9 and 42 days respectively for susceptibility testing by MBBacT and proportion method, but none for MODS – as this is direct DST [*NEJM 2006; 355:1539-50]*. All positive cultures are detected within 21 days and >98% within 2 weeks thus a negative MODS culture at 3 weeks is a confident rule-out. MODS delivers 99% concordance for MDR testing with gold-standard comparators. Material and running costs (excluding labour) for detection and MDR testing are USD $2 per sample, approximately 1/20th the cost of MBBacT. Evaluation of the methodology for 2nd line DST is currently underway.

MODS has been incorporated into the national guidelines of the Peruvian TB control programme and implementation into regional reference laboratories is ongoing, whilst roll-out to other international centres with subsequent scale-up is planned. This iterative experience and a prior pilot implementation project have yielded a number of important lessons which will be described. Specific attention will be paid to the issue of how best to implement and use a tool with two related functions (detection of TB and identification of MDRTB). The key question, particularly important where resources are scarce, is "how can benefit be optimized and cost minimized?" The elements of this question which will be discussed are: what are the concrete laboratory steps to implementation, what are the main obstacles to sustainable use, which patients should be selected for testing, what adjustments are necessary in a system only accustomed to near-patient smear microscopy, how (if at all) can MODS implementation contribute to stimulating a wider health system upgrade?