COMMENTARY

SCALE-UP OF TUBERCULOSIS LABORATORY SERVICES IN GUJARAT, INDIA

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ABSTRACT

M. tuberculosis has been classified as risk group 3 pathogen and has to be handled at appropriate containment level. The IRL, Ahmedabad got WHO accreditation in March 08 for Lowenstein-Jensen solid culture and first line anti-tuberculosis drug sensitivity. Immediately after WHO endorsement of line probe assay (LPA) for rapid MDR-TB testing in 2008, Gujarat state leaped forwarded and started research on "Genotype MTB DR Plus assay" in collaboration with WHO. In 2009 this effort gained momentum when the IRL, Ahmedabad was radically upgraded to BSL 3 facility. BSL 3 facility like this can balance risk of air-borne infection. As a minimum, countries embarking on drug-resistant tuberculosis programmes should establish laboratory capacity to diagnose MDR-TB and monitor culture conversion of patients on Category IV treatment. Gujarat has set the example of a truly dynamic tuberculosis management, demonstrating that rapid scale-up of laboratory services for MDR-TB diagnosis is feasible even at regional level, in resource-constrained settings.

Key-Words: RNTCP; Scale-up; Tuberculosis; Laboratory Services; Bio-Safety Level

The Revised National Tuberculosis Control Programme (RNTCP) pilot project started in Gujarat, India at Chansma and Patan taluka of Mehsana on 2 October 1993. From the 4th Quarter 1998, it was expanded to all the districts of Gujarat in a phased manner, achieving state-wide coverage on 7 April 2004. Very soon, a Gujarat state wide cross-sectional cluster survey to estimate the prevalence of drug resistance among Mycobacterium tuberculosis isolates recovered from new and previously treated smear positive pulmonary tuberculosis cases diagnosed in the RNTCP microscopy centres in Gujarat, India was conducted from November 2005 to October 2006.[1] This largest population-based survey of the prevalence of drug-resistant tuberculosis from Gujarat met with all the international recommendations for drug resistance surveillance.

M. tuberculosis has been classified as risk group 3 pathogen and has to be handled at appropriate containment level of Bio-Safety Level 2 or preferably BSL 3. The Intermediate Reference Laboratory (IRL), Ahmedabad was the major beneficiary of this scientific research protocol, as this tuberculosis laboratory successfully commissioned many vital instruments including class 2 bio-safety cabinets, and consolidated on its presence as a BSL 2 Intermediate Reference Laboratory.

B. J. Medical College, Ahmedabad is the DOTS Plus Site for Multi-Drug Resistant Category IV tuberculosis treatment since 2007, and it primarily relies on the IRL, Ahmedabad for MDR diagnosis and management. The IRL, Ahmedabad got WHO accreditation in March 08 for Lowenstein-Jensen solid culture and first line anti-tuberculosis drug sensitivity. Immediately after WHO endorsement of line probe assay (LPA) for rapid MDR-TB testing in 2008, Gujarat state leaped forwarded and started research on "Genotype MTB DR Plus assay" in collaboration with WHO, and Foundation for Innovative New Diagnostics (FIND) on 12 September 2008 (Figure 1). In 2009 this effort gained momentum when the IRL, Ahmedabad was radically upgraded to BSL 3 facility (Figure 2), which can perform almost 8000 liquid culture and drug sensitivity per year on automated Mycobacterial Growth Indicator Tube 960 system (Figure 3). The first ever external quality assurance of LPA was performed in 2009 based on in-country exchange and validation of LPA reforms.[2] The IRL now houses two state of the art BSL 3 rooms which meet all important

parameters like SOPs, trained man power, restricted entry, airlock, dedicated inlet air supply, exhausted air supply through HEPA filters, door-lock, alarm system, impervious floor, class 2 bio-safety cabinets, N 95 masks, ultra-violet irradiation, and regular maintenance. As tuberculosis laboratory workers have a 2 to 9 fold increased risk of acquiring tuberculosis compared to the general population[3], BSL 3 facility like this can balance risk of air-borne infection. Being the teaching facility, B. J. Medical College, Ahmedabad has a high burden of MDR-TB patients, and hence it needs the quality assured, high throughput laboratory with minimal diagnostic turn-around time and faster culture monitor system.

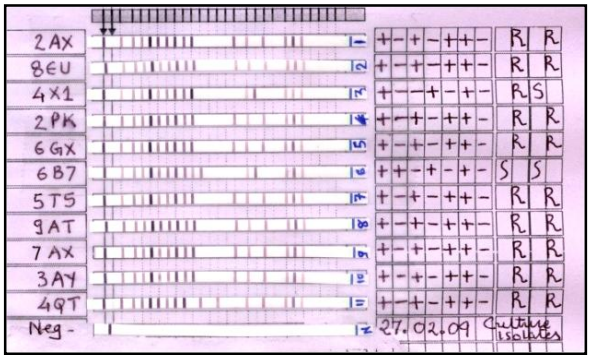

Figure-1: Genotype MTB DR Plus Assay

Figure-2: BSL 3 Facility

As a minimum, countries embarking on drug-resistant tuberculosis programmes should establish laboratory capacity to diagnose MDR-TB and monitor culture conversion of patients on Category IV treatment. The IRL, Ahmedabad now includes three WHO endorsed contemporary tuberculosis diagnostic technologies: rapid detection of MDR-TB by LPA, solid (L-J) and liquid growth detection (MGIT 960) and drug susceptibility testing for M. tuberculosis, and lateral-flow immuno-assay for identification of M. tuberculosis (Capilia).

Figure-3: Mycobacterial Growth Indicator Tube 960 System

On 24 March 2012, LPA technology was expanded to regional BSL 3 laboratory at Governmemt Medical College, Jamnagar, Gujarat. As the state has now full coverage of Cat-IV treatment for its 60 million population, rapid scale-up of LPA services for MDR-TB diagnosis will be commissioned at another regional BSL 3 laboratory at Governmemt Medical College, Surat, Gujarat. Gujarat has set the example of a truly dynamic tuberculosis management, demonstrating that rapid scale-up of laboratory services for MDR-TB diagnosis is feasible even at regional level, in resource-constrained settings.

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