Strengthening infrastructure in management of drug resistant tuberculosis in India

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ABSTRACT

The emergence of resistance to first-line drugs used to treat tuberculosis (TB) has become a significant public health concern and an obstacle in implementation of effective TB control activities globally. In India, Revised National TB Control Program (RNTCP) introduced the programmatic management of drug-resistant TB (PMDT) services to address the needs of MDR-TB patients. To execute the plan with perfection, RNTCP has devised MDR suspect criteria – A, B, and C so that gradually PMDT services can be extended to the whole country. These criteria were framed to run in tandem with the strengthening of the laboratory services so that the existing certified laboratories can carry out the culture and DST services without being overburdened. Altogether, RNTCP is committed for the strengthening and capacity building of its resources to offer culture and DST services right at the time of diagnosis.

Key words: Tuberculosis, Revised National Tuberculosis Control Program, multi-drug resistant, India

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The emergence of resistance to first-line drugs used to treat tuberculosis (TB) has become a significant public health concern and an obstacle in implementation of effective TB control activities globally [1]. A multidrug-resistant (MDR) TB case is one whose sputum culture is positive for Mycobacterium tuberculosis and is resistant to isoniazid and rifampicin with or without other anti-tubercular drugs, provided the drug sensitivity test (DST) results have been obtained from a Revised National TB Control Program (RNTCP) certified culture & DST laboratory [1]. Global TB control report – 2012 has revealed that globally, 3.7% (2.1-5.2%) of new cases and 20% (13-26%) of retreated cases are estimated to have MDR-TB [2]. Further, almost 310000 MDR-TB cases were reported among notified TB patients with pulmonary TB in 2011 [2]. Almost 60% of the reported global burden of MDR-TB is contributed by India, China and Russia. However, the exact burden of MDR-TB is still not clear as most of the high burden countries have not completely expanded the coverage of surveillance of drug resistance to obtain accurate estimates of the burden of MDR-TB [2].

Most of the high burden countries have a weak public health care delivery system and thus have scarce resources – financial support / bio-safety laboratory of level-3 / trained health care providers [3,4]. Thus, to diagnose a maximum number of MDR-TB cases with available resources; MDR-TB suspects (or high-risk groups have to be identified so that transmission of this life-threatening disease can be interrupted at the earliest [1-3]. In India, after successful geographical coverage of the entire country in 2006 with the Directly Observed Treatment (DOT) services, RNTCP introduced the programmatic management of drug-resistant TB (PMDT) services in 2007 to address the needs of MDR-TB patients who are now being rapidly scaled up across the country with a mission to achieve universal access of TB care. PMDT evaluates TB patients for drug-resistance so that they can be initiated on appropriate treatment regimen at the earliest. Initially, the strategy was to screen patients who were at very high risk of MDR-TB with DST and subsequently expand the gamut of services to whole of the community. To execute the plan with perfection, RNTCP has devised MDR suspect criteria – A, B, and C so that gradually PMDT services can be extended to the whole country [1]. These criteria were framed to run in tandem with the strengthening of the laboratory services so that the existing RNTCP certified laboratories can carry out the culture & DST services without being overburdened [5]. Hence, Criteria-A was first implemented in most of the parts of the country and depending on the load of MDR-TB cases, Criteria-B and Criteria-C were subsequently either implemented or would be implemented in a time-bound manner [1].

Criteria-A includes - all failure of new TB cases (viz. Cat I failure at 5th month); smear positive retreated TB cases who remain smear positive at fourth month and onwards (viz. Cat II smear positive at 4th month); and all pulmonary TB cases who are contacts of known MDR-TB cases. The main limitation of the Criteria-A was that despite the knowledge that 2-3% of the newly treated TB patients and 12-17% of retreatment TB cases who are bound to be resistant to first-line drugs even before initiation of treatment, are still treated with drugs which are ineffective due to resistance and thus, patients lose out on five months and four months in category-I and category-II respectively till their smear comes out to be positive and then only they are considered to be MDR-TB suspect. More importantly, such patients remain a potential source of transmission of MDR-TB for almost four to five months owing to such ineffective line of treatment. Another operational and technical concern observed is that, even though findings of National Family Health Survey-3 has revealed that almost 70% of TB patients avail the services of private sector initially, but still as per the Criteria-A only those patients, who are availing TB treatment from public health sector, are to be considered eligible for free MDR-TB diagnostic / treatment services [6,7].

In order to expand the coverage of PMDT services and to improve upon the limitations of Criteria-A, Criteria-B was implemented, which in addition to Criteria-A incorporated - all smear-positive retreatment pulmonary TB cases at diagnosis; and any smear-positive follow-up of new cases at the end of intensive phase (IP) / later or retreatment cases [1,5]. Thus, for patients who are on Category-I treatment, almost three months could now be saved (viz. IP in Cat-I is of two months duration, and if the end-IP smear result is positive, patient will be directly considered MDR-TB suspect, and he/she has to not wait for three more months as was the scenario in Criteria-A); while for retreatment cases, all of them are to be considered as MDR-TB suspect right at the time of diagnosis (viz. four months are saved contrary to the provisions under Criteria-A). However, the best part of Criteria-B was the extension of free diagnostic / therapeutic services to even those patients who were not a part of the public health system. The only limitation of Criteria-B was that no services were proposed to cater to smear negative retreatment TB cases [1].

MDR suspect Criteria-C has been proposed in the mission to achieve universal access of TB care, which includes all smear negative retreatment pulmonary TB cases at the time of diagnosis; and HIV-TB co-infected cases; in addition to Criteria-B. Still nothing has been mentioned about individuals who are diagnosed with pulmonary TB for the first time. India has achieved complete geographical coverage for PMDT services in all 692 reporting districts of country on March 2013 [8]. It is expected that all districts in the country would be implementing Criteria-C by 2015. Until August-2013, solid culture, liquid culture, Line Probe Assay and cartridge-based nucleic acid amplification test has been certified by RNTCP and started in 37, 12, 41 and 30 sites respectively in India for fast-tracking the process of culture and drug sensitivity testing. In order to reach the desired targets and to lessen the burden on the three existing national reference laboratories (NRLs) for performing culture & DST, two additional NRLs and multiple intermediate reference laboratories have also been proposed [1]. In addition, the government has developed a partnership with Foundation for innovative new diagnostics (FIND) and multiple international agencies to achieve the proposed goals of offering diagnostic and therapeutic services within the anticipated time [8,9].

To conclude, RNTCP is committed for the strengthening and capacity building of its resources to offer culture & DST services to all types of patients who were diagnosed with any form of drug-resistant TB right at the time of diagnosis.

Conflicts of interest

There was no conflict of interest to be stated.

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