

The latest developments in the TB control program of India

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Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis* and is one of the major cause of morbidity and mortality in the high burden countries like India [1,2]. The disease is known for ages and is under the purview of the Revised National Tuberculosis Control Programme (RNTCP) [3]. The program has been running for quite some time without major changes, however, with the national target of TB elimination by 2025, a number of changes have been made [4]. The main motto for these changes is to achieve the national target of TB elimination well before time [5]. The national government has increased monitoring and supervision of the whole RNTCP. As a result, a number of changes have been made in the TB control program of India. In this paper, the authors highlight the latest developments in RNTCP and Programmatic management of drug-resistant TB (PMDT) of India.

Discontinuation of the Category II Previously Treated Regimen

The WHO recommended the Category II regimen for all previously treated cases since 1991 [6,7]. The regimen included the use of streptomycin and was of eight months duration [7]. However, since the time of this change the regimen has been under constant debate due to 60-80% success rates and relatively poor outcomes in failure and relapse cases [8-11]. Besides, the lack of manpower to administer the injectable to the patients and fear of the injection were also prevalent. Also, the frequent visits to the health facility for the injectable was a major contributor to the loss of wages in the already debilitated TB cases [5].

The Ministry of Health & Welfare, Government of India (GOI) based on the recommendations of the technical expert's group on treatment of TB had decided to discontinue Category II regimen for all previously treated cases [12]. In an open letter to the program managers across the country the recent changes have been detailed by the Dy. Director General, Head Central TB Division (CTD) [12]. All such cases will be treated with the standard first-line anti-tubercular drugs [12]. The duration of the treatment in such cases will be of six months [12]. The omission of injection streptomycin is a remarkable development in the RNTCP, as a number of countries have already omitted the same and WHO has itself recommended the use of it [7]. So the new regimen from all new and previously treated cases will be of an initiation phase of two months of Isoniazid (H), Rifampicin (R), Pyrazinamide (Z) and Ethambutol (E) and a continuation phase of four months of HRE (2HRZE+ 4HRE) [12].

The old cases which were on the previous regimen of category II involving injection streptomycin will continue to follow the same previous regimen and will not be shifted to the new regimen [12]. In all such cases, the appropriate duration of injection streptomycin is administered to the patients as per the old guidelines [12].

Universal Drug Susceptibility Testing (DST)

The WHO since 2010, has emphasized on the DST—using rapid, molecular tests where possible – for all previously treated patients [7]. The GOI has also stressed on the same efforts to determine the drug resistance in TB cases from the time of initiation of the anti-tubercular treatment (ATT) [12]. The universal DST involves the use of molecular DST [e.g. cartridge-based automated nucleic acid amplification test (CBNAAT) or line probe assay (LPA)]. All the notified previously treated TB cases are encouraged to submit the samples for the DST at the time of initiation or before the start of the ATT [12]. All possible efforts to ascertain the outcome of resistance to H and R are made and thus based on the results (if resistant) the most appropriate regimen for the case is designed based on the PMDT guidelines [12].

However, the standard first-line ATT (of six months) is started and the treatment is not delayed for the wait of results of DST [12]. Once the results are available the regimen can be modified based on the DST results [12].

In the cases where the appropriate specimen for DST is not available the standard first-line ATT (of six months) is started and these cases are monitored clinically/radiologically/microbiologically for evidence of no response to the ATT and efforts to get the specimen at any stage of ATT are encouraged to know about the resistance to the drugs [12].

The states are advised to strictly monitor the percentage of H and R resistance in all previously treated cases [12].

Categorization of all Previously Treated Cases, follow-up, Recording, and Reporting

The categorization of all newly diagnosed previously treated TB cases will continue as it is and the subclasses i.e., relapse, failure, lost to follow-up, other previously treated will exist [12]. The only change in these cases will be the omission of injection streptomycin, six-month ATT with first-line drugs and a higher emphasis on universal DST.

The follow-up schedule of all these cases will be similar to all category I TB cases [12]. The recording and reporting formats will also remain same till further notice [12]. The

honorarium for the treatment supporters will be the same as that of category I [5,12].

Modification in the Treatment for H-mono Resistance Cases

The standard protocol for the management of all H-mono resistance cases involved the use of Levofloxacin (Lfx), Kanamycin (K), R, E and Z for 3-6 months and Lfx, R, Z for six months [13]. However, in this regimen, the use of injection K has been omitted and the total duration is reduced to Lfx, R, E, Z for six months. The efforts to monitor the treatment response in all such cases is given prime importance. Second line DST is imperative in all such cases at the time or before the start of the new regimen [13]. Again, no new H-mono cases are delayed treatment in the absence of the results of the same [13].

Joint Efforts to Eliminate TB (JEET)

The TB elimination is impossible in a high burden country like India with a vast private sector [14]. The same is evident by the fact that in the year 2016, only 63 percent of an estimated 2.8 million TB cases were reported across public or private sectors—the private sector accounted for 19 percent of those reports [14].

This remarkable difference between the number of patients taking ATT and the low level of total reported cases highlights a significant level of underreporting from the same [15]. The lack of coordination between the national TB program and private labs means that the quality of care for patients cannot be appropriately ensured [15]. Although TB is a notifiable disease and those since 7th May 2012 and all TB cases from both private and public set-ups has to be notified [16].

To ensure 100% reporting from private set-ups the National Strategic Plan (NSP) for TB elimination advocates the strategies of “going where the patients go” thereby emphasizing on the importance of involving the private sector [15]. And thus, a Nationwide Project named JEET was launched in New Delhi on the 15th May 2018 with an aim to eliminate TB by 2025 [15]. The project is being implemented under the guidance of CTD, Ministry of Health & Welfare and in close collaboration with the SPOs, WHO and other stakeholders [15]. JEET aims to address the gaps in the patient care cascade in the private sector on account of underreporting, diagnostic delays and irrational and non-standardized regimen, through a pan-India engagement with private sector [15].

Project JEET aims to ensure optimum standards of diagnosis and treatment as per the standard guidelines for TB patients initiating care in private sectors. RNTCP will provide drugs and diagnostics support to JEET in the form of FDCs & CBNAAT in public sector labs [15]. The project will provide treatment adherence support measures and facilitate extension of RNTCP incentives to private sector patients [15].

Conclusions

The recent changes are a welcome step towards the aim of achieving universal DST and will be pivotal in the TB elimination by 2025 from India. The omission of the injectable in previously treated TB cases and H-mono cases will reduce the burden on both the service providers and the service recipients. Besides, the saved manpower could be utilized in efforts towards achieving universal DST. The fear of injectable was also one of the main reason for the default/loss to follow-up cases. The JEET will encourage the patients for treatment adherence and treatment completion. The efforts of JEET project will help in accelerating TB notification from the private sectors. The efforts will also encourage operational research and this help the overall TB control program.

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