NATIONAL TUBERCULOSIS ELIMINATION PROGRAMME

Tuberculosis (TB) control activities are implemented in the country for more than 50 years. The National TB Programme (NTP) was launched by the Government of India in 1962 in the form of District TB Centre model involved with BCG vaccination and TB treatment. In 1978, BCG vaccination was shifted under the Expanded Programme on Immunization. A joint review of NTP was done by Government of India, World Health Organization (WHO) and the Swedish International Development Agency (SIDA) in 1992 and some shortcomings were found in the programme such as managerial weaknesses, inadequate funding, over-reliance on x-ray, non-standard treatment regimens, low rates of treatment completion, and lack of systematic information on treatment outcomes.

Around the same time in1993, the WHO declared TB as a global emergency, devised the directly observed treatment – short course (DOTS), and recommended to follow it by all countries. The Government of India revitalized NTP as Revised National TB Control Programme (RNTCP) in the same year. DOTS was officially launched as the RNTCP strategy in 1997 and by the end of 2005 the entire country was covered under the programme.

During 2006–11, in its second phase RNTCP improved the quality and reach of services and worked to reach global case detection and cure targets. These targets were achieved by 2007-08. Despite these achievements, undiagnosed and mistreated cases continued to drive the TB epidemic. TB was the leading cause of illness and death among persons living with HIV/AIDS and large number of multidrug resistant TB (MDR-TB) cases were reported every year. During this period for achievement of the long-term vision of a "TB free India", National Strategic Plan for Tuberculosis Control 2012-2017 was documented with the goal of 'universal access to quality TB diagnosis and treatment for all TB patients in the community'.

Significant interventions and initiatives were taken during NSP 2012-2017 in terms of mandatory notification of all TB cases, integration of the programme with the general health services (National Health Mission), expansion of diagnostics services, programmatic management of drug resistant TB (PMDT) service expansion, single window service for TB-HIV cases, national drug resistance surveillance and revision of partnership guidelines.

However, to eliminate TB in India by 2025, five years ahead of the global target, a framework to guide the activities of all stakeholders including the national and state governments, development partners, civil society organizations, international agencies, research institutions, private sector, and many others whose work is relevant to TB elimination in India is formulated by RNTCP as National Strategic Plan for Tuberculosis Elimination 2017-2025.

'National strategic plan for tuberculosis elimination 2017-2025'-

RNTCP has released a 'National strategic plan for tuberculosis 2017-2025' (NSP) for the control and elimination of TB in India by 2025. According to the NSP TB elimination have been integrated into the four strategic pillars of "**Detect – Treat – Prevent – Build**" (**DTPB**).

DETECT:

The first objective of NSP is to find all drug sensitive TB cases (DS-TB) and drug resistant TB cases (DRTB) with an emphasis on reaching TB patients seeking care from private providers and undiagnosed TB cases in high-risk populations (such as prisoners, migrant workers, people living with HIV/AIDS, contacts etc.).

Early diagnosis and treatment of TB cases in the community is an important step in TB elimination, which will help in decreasing the risk of transmission of disease to others, poor health outcomes, and social and economic hardships of the patient and their family.

Notification of TB cases: Notification of all TB patients from all health care providers is made mandatory by Ministry of Health and Family Welfare, Government of India since 2012. All health care providers (clinical establishments run or managed by government (including local authorities), private, or NGO sectors, and /or individual practitioners) should notify every TB case to local health authorities (district health officer, chief medical officer of a district, and municipal health officer of a municipal corporation/ municipality) every month. With its amendment in 2015, all laboratories are also included to notify TB cases.

Till now, only medical practitioners, hospitals and laboratories were notifying TB patients to government health system, now according to 'Mandatory TB notification Gazette for private practitioners, chemists and public health staff' March 2018, all chemists will also inform about TB patients for whom they have dispensed the TB drugs. TB patients themselves are also encouraged to notify themselves. Every TB patient will be attempted to reach out by the local public health authority, namely, District Health Officer or Chief Medical Officer of a District and Municipal Health Officer of urban local bodies, so that the incentives and support to patients, families and communities can be properly extended.

NIKSHAY: To facilitate TB notification, RNTCP has developed a case-based web-based TB surveillance system called "NIKSHAY" (<u>https://nikshay.gov.in</u>) for both government and private health care facilities. Future enhancements under NIKSHAY are for patients support, logistics management, direct data transfers, adherence support and to support interface agencies which are supporting programme to expand the reach.

Public private partnership: For promotion of public-private mix (PPM) in TB prevention and care, private providers are provided incentives for TB case notification, and for ensuring treatment adherence and treatment completion. The incentives are provided through direct beneficiary transfer.

The incentives to the Private Sector TB Care Provider are as follows:

- Rs 250/- on notification of a TB case diagnosed as per Standards for TB Care in India (STCI)
- Rs 250/- on completion of every month of treatment
- Rs 500/- on completion of entire course of TB treatment
- Rs 2750/ for notification and management of a drug-sensitive patient over 6-9 months as per STCI
- Rs 6750/-for notification and correct management of a drug-resistant case over 24 months as
 per STCI

Free drugs and diagnostic tests to TB patients in private sector- Free drugs and diagnostic tests are provided to TB patients seeking treatment from private health sector. There are two approaches for ensuring access to free drugs and diagnostic tests to TB patients in private sector, first is access to programme- provided drugs and diagnostics through attractive linkages; and second is reimbursement of market- available drugs and diagnostics.

Significant cost reduction of select diagnostics is achieved by 'Initiative for Promoting Affordable and Quality TB Tests' (IPAQT). 131 private sector labs networked to provide four quality tests for TB at or below the 'ceiling prices.

For TB diagnosis more than 14,000 designated microscopy centres spread across the country. Cartridge Based Nucleic Acid Amplification Tests (CBNAAT) / Line Probe Assay (LPA) have been established at district levels for decentralised molecular testing for drug resistant TB. Reference laboratories have been established at state and national levels which provide culture and dug sensitivity test (DST) services as well as molecular diagnosis.

TREAT:

Next step under the programme is initiation and sustaining all TB patients on appropriate anti-TB treatment wherever they seek care, with patient friendly system and social support. Provision of free TB drugs in the form of daily fixed dose combinations (FDCs) for all TB cases is advised with the support of directly observed treatment (DOT).

(DOT is a specific strategy, to improve adherence by any person observing the patient taking medications in real time. The treatment observer does not need to be a health-care worker, but could

be a friend, a relative or a lay person who works as a treatment supervisor or supporter. If treatment is incomplete, patients may not be cured and drug resistance may develop).

Screening of all patients for rifampicin resistance (and for additional drugs wherever indicated) is done. For drug sensitive TB, daily fixed dose combinations (FDCs) of first-line anti-tuberculosis drugs in appropriate weight bands for all forms of TB and in all ages should be given. First line treatment of drug-sensitive TB consists of a two-months (8weeks) intensive phase with four drug FDCs followed by a continuation phase of four months (16 Weeks) with three drug FDCs.

For new TB cases, the treatment in intensive phase (IP) consists of eight weeks of Isoniazid (INH), Rifampicin, Pyrazinamide and Ethambutol (HRZE) in daily doses as per four weight band categories and in continuation phase three drug FDCs- Rifampicin, Isoniazid, and Ethambutol (HRE) are continued for 16 weeks.

For previously treated cases of TB, the Intensive Phase is of 12 weeks, where injection streptomycin is given for 8 weeks along with four drugs (INH, Rifampicin, Pyrazinamide and Ethambutol) and after 8 weeks the four drugs (INH, Rifampicin, Pyrazinamide and Ethambutol) in daily doses as per weight bands are continued for another four weeks. In continuation phase Rifampicin, INH, and Ethambutol are continued for another 20 weeks as daily doses.

The continuation phase in both new and previously treated cases may be extended by 12-24 weeks in certain forms of TB like skeletal, disseminated TB based on clinical decision of the treating physician.

Patients eligible for retreatment should be referred for a rapid molecular test or drug susceptibility testing to determine at least rifampicin resistance, and preferably also isoniazid resistance status. On the basis of the drug susceptibility profile, a standard first-line treatment regimen (2HRZE/4HR) can be repeated if no resistance is documented; and if rifampicin resistance is present, shorter regimen for MDR-TB (multi drug resistant TB) regimen should be prescribed according to WHO's recent drug resistant TB treatment guidelines.

RNTCP has introduced Bedaquiline CAP for MDR-TB under conditional access programme in 2016 across six sites, with a country wide scale up plan in 2017-2020.

Nikshya poshak yozana: It is centrally sponsored scheme under National Health Mission (NHM), financial incentive of Rs.500/- per month is provided for nutritional support to each notified TB patient for duration for which the patient is on anti-TB treatment. Incentives are delivered through Direct benefit transfer (DBT) scheme to bank accounts of beneficiary*.

Expending options for ICT based treatment adherence support mechanisms:

- Mobile based "Pill-in-Hand" adherence monitoring tool
- Interactive Voice Response (IVR), SMS reminders.
- Specially designed electronic pill boxes or strips with GSM connection and pressure sensor
- Patient Compliance toolkit: a mobile app for patients to report treatment compliance using video, audio or text message
- Automated pill loading system
- innovatively designed ICT enabled smart cards SMS gateway

Intensifying TB control activities in following key populations is addressed in NSP:

- TB-HIV
- Diabetics, Tobacco use and Alcohol dependence
- Poor, undernourished, economically and socially backward communities
- TB control in hilly and difficult terrains
- Substance dependence and sexual minorities
- TB and pregnancy
- Paediatric population
- Prison Inmates and staff of prisons/jails
- management of extra pulmonary TB

PREVENT:

With the objective to prevent emergence of TB in susceptible population various measures are indicated as:

- Scale up air-borne infection control measures at health care facilities
- Treatment for latent TB infection in contacts of bacteriologically-confirmed cases
- Address social determinants of TB through intersectoral approach.

a) **Air borne infection control measures**-TB infection control is a combination of measures aimed at minimizing the risk of TB transmission within population and hospital and other settings. The foundation of such infection control is:

- Early diagnosis, and proper management of TB patients.
- Health education about cough etiquettes and proper disposal of sputum by patient. Cough etiquette means covering nose and mouth when coughing or sneezing. This can be done

with a tissue, or if the person doesn't have a tissue they can cough or sneeze into their upper sleeve or elbow, but they should not cough or sneeze into their hands. The tissue should then be safely disposed of.

- Houses should be adequately ventilated.
- Proper use of air borne infection control measures in health care facilities and other settings

b) Contact tracing-Since transmission can occur from index case to the contact any time (before diagnosis or during treatment) all contacts of TB patients must be evaluated. These groups include:

- All close contacts, especially household contacts
- In case of paediatric TB patients, reverse contact tracing for search of any active TB case in the household of the child must be undertaken.
- Particular attention will be paid to contacts with the highest susceptibility to TB infection

c) Isoniazid Preventive Therapy (IPT)- Preventive therapy is recommended to Children < 6 years of age, who are close contacts of a TB patient. Children will be evaluated for active TB by a medical officer/ pediatrician and after excluding active TB he/she will be given INH preventive therapy

In addition to above, INH preventive therapy will be considered in following situation:

- For all HIV infected children who either had a known exposure to an infectious TB case or are Tuberculin skin test (TST) positive (>=5mm induration) but have no active TB disease.
- All TST positive children who are receiving immunosuppressive therapy (e.g. Children with nephrotic syndrome, acute leukemia, etc.).
- A child born to mother who was diagnosed to have TB in pregnancy will receive prophylaxis for 6 months, provided congenital TB has been ruled out. BCG vaccination can be given at birth even if INH preventive therapy is planned.

Close contacts of index cases with proven DR-TB (drug resistant-TB) will be monitored closely for signs and symptoms of active TB as isoniazid may not be prophylactic in these cases.

d) BCG vaccination- It is provided at birth or as early as possible till one year of age. BCG vaccine has a protective effect against meningitis and disseminated TB in children.

e) Addressing social determinants of TB like poverty, malnutrition, urbanization, indoor air pollution, etc. require inter departmental/ ministerial coordinated activities and the programme is proactively facilitating this coordination.

BUILD:

Health system strengthening for TB control under the National Strategic Plan 2017-2025 is recommended in the form of building and strengthening enabling policies, empowering institutions and human resources with enhanced capacities.

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