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REVIEW ARTICLE

TUBERCULOSIS: EPIDEMIOLOGY, STATUS OF DISEASE BURDEN AND CONTROL INITIATIVES IMPLEMENTED IN INDIA, 2018 : A REVIEW

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ABSTRACT:

Tuberculosis (TB) is a dreadful infectious bacterial disease that has severely affected large segment of population in India. RNTCP (Revised National Tuberculosis Control Programme) was implemented in 1997 to control TB. As per 2018, India TB Report, TB incidence in India is declining at about 1-2% per year and to achieve the TB elimination goal by 2025, a decline in TB incidence by about 15-20% annually is required. However, late diagnosis of the disease, non-adherence or non-completion of treatment, co-morbidities, drug resistant TB and inter and intra-state difference in health system response are some of the challenges reported. Newer techniques, ideas and incentives are now implemented by the government of India to overcome these challenges. This article summarizes epidemiology, recent status and developmental steps taken by the government of India to control the disease.

KEYWORDS: Epidemiology, disease burden, control initiatives, Tuberculosis 2018

INTRODUCTION

Tuberculosis (TB) is a dreadful infectious bacterial disease that has severely affected communities and nations caused by ***mycobacterium tuberculosis***. India is one of the high TB burden countries. It has been reported that in India large segment of population suffers from tuberculosis than other infectious diseases.[1]

The National Tuberculosis Programme of India (NTP) was started in 1962 and was originally designed for domiciliary treatment, using self administered standard drug regimens. A combined review of the programme in 1992 concluded that the NTP could not achieve its objectives of TB control and hence, on the recommendations of an expert committee, a revised strategy to control TB control and TB was pilot-tested in 1993. A full-fledged programme was started in 1997 and rapidly expanded with excellent results. This Revised National Tuberculosis Control Programme (RNTCP) that uses the DOTS

(Directly Observed Treatment, Short-course chemotherapy) strategy achieved country coverage on World TB Day, 24thMarch, 2006. The Programme has achieved several milestones related to diagnosis and treatment services of TB since 2006. Since inception in 1997 and up to December 2015, more than 19 million patients were initiated on treatment and more than 3.5 million additional lives have been saved.[2]

EPIDEMIOLOGY:

The epidemiology of Tuberculosis have three approaches namely,

- The Etiologic Approach
- The Descriptive Approach
- The Predictive Approach

a) The Etiologic Approach-mainly dealing with the risk factors associated with the agent-***M tuberculosis*.**

b) The Descriptive Approach-dealing with the traditional incidence and prevalence of tubercular infection.

c) The Predictive Approach-dealing with what happens next-forecasting the tubercular epidemic.

Epidemiology is essential for the successful implementation of a national tuberculosis control programme.[3] Understanding the risk factors for a given community provides the insight to develop tools for cure, whereas descriptive and predictive epidemiology are invaluable for an effective and efficient TB control programme. Poverty, HIV and drug resistance are major contributors to the resurging global TB epidemic.[4,5]

INFECTION WITH TUBERCLE BACILLI

Infection with the tubercle bacilli again depends upon a variety of factors. The Pathogenic species-***Mycobacterium tuberculosis, Mycobacterium Africana* and *Mycobacterium bovid*** are capable of causing tuberculosis disease in humans. Tubercle bacilli transmission occurs primarily through the air. Robert Koch initially suspected this in his seminal line of reasoning for proof that tubercle bacilli was the causative agent of tuberculosis and this was later experimentally confirmed by the works of O'Grady and Riley in 1963.[6,7] This was, however, not in air without evaporating and small enough to reach the alveoli in the periphery of the lungs. This is schematically depicted in figures.

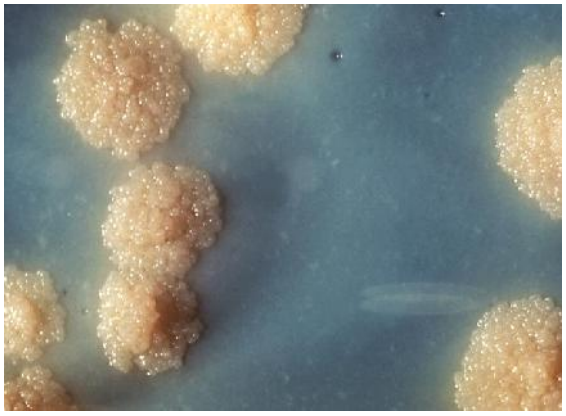

Fig No:- 1 Culture of *Mycobacterium tuberculosis* adapted from[8]

Infectious sputum-positive TB patients with pulmonary disease produce droplet nuclei through coughing, sneezing and talking. The probability of infection following exposure to a case of infectious sputum-positive tuberculosis decreases with decreasing contiguity of the contact person.[9] It can, therefore, be concluded that infection with tubercle bacilli is possible whenever there is an infectious case present in the community.

Tuberculosis (TB), even though it is an airborne disease, is not as easily transmissible as certain other droplet infectious disease.[10] First of all, the relative concentration of infectious droplets has to be high to be transmissible. Factors such as the presence of adequate ventilation or personal protective equipment, like facemasks worn by the infectious patients, dramatically reduce the possibility of the exposed person to be infected.

INFECTION WITH HIV

Infection with Human immunodeficiency virus brings about a host of changes that assist to tuberculosis infection as well as further development of disease. This has been well exemplified in various studies all over the world.[11,12,13,14,15] A prospective study among injection drug users in New York City demonstrated that HIV is perhaps the most powerful factor yet recognized in the progression of the disease from the pre-existing infection by *M tuberculosis*.[11,12] The risk of progression from latent infection to disease is approximately 5 to 15% per year with a lifetime risk of about 50% if HIV infection is superimposed.[16]

Tuberculosis may spontaneously remit without treatment. If the disease is not treated it will recur in segment of cases. The incidence of tuberculosis increases with age. Several other medical conditions are commonly associated with tuberculosis such as silicosis, where the risk has beeb shown to be 26 times higher to develop tuberculosis.[17] It has also been found to be three times more in diabetics than in the general population,[18] 10-15 times higher in patients with end final stage renal failure and those on hemodialysis and five times higher in male gastrectomy patients. The case notification rates have been

falling at an average of 2% per year for the past decade, which may reflect a real decline in TB incidence.[19]

RISK FACTORS

Generally, persons at high risk for developing Tuberculosis disease falls into two categories

1.Persons who have been recently infected with TB bacteria.

2.Persons with medical conditions that weaken the immune system.[20]

STATUS OF TB BURDEN IN INDIA (2014-2018)

According to the India TB Report 2014,2015,2016-India is the second-most populous country in the world one fourth of the global incident TB cases occur in India annually.[21,22,23]

- In 2012, out of the estimated global incidence of 8.6 million TB cases, 2.3 million were estimated to have occurred in India.[21]
- In 2013, out of the estimated global annual incidence of 9million TB cases, 2.1million were estimated to have occurred in India.[22]
- As per WHO Global TB Report, 2015, out of the estimated global incidence of 9.6million TB cases, 2.2 million were estimated to have occurred in India.[23]

India has highest burden of both TB (Tuberculosis) and MDRTB (Multi drug resistant tuberculosis) based on estimates reported in Global TB Report 2016. An estimated 1.3lakh incident multi-drug resistant TB patients emerge annually in India which includes 79000 MDR-TB patients estimates among notified pulmonary cases. India bears second highest number of estimated HIV associated TB in the world. An estimated 1.1lakh HIV associated TB occurred in 2015 and 37,000 estimated number of patients died among them.[24]

GLOBAL TB REPORT 2016

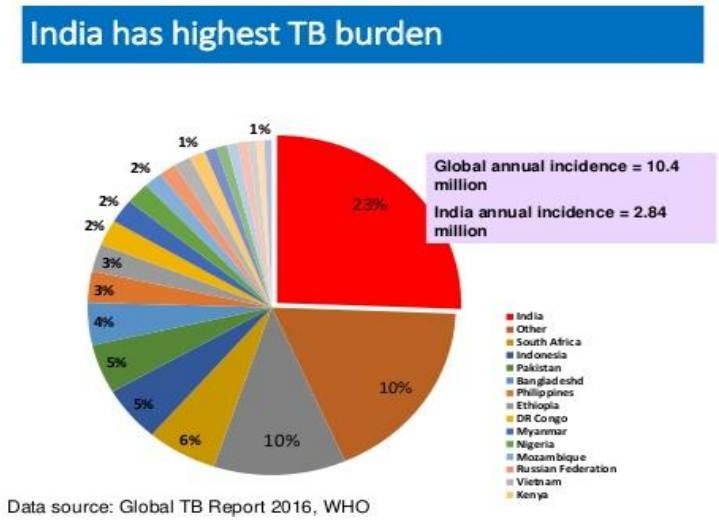

Fig No:-2 Global annual incidence of Tuberculosis adapted from[25]

INDIA TB REPORT 2018

Global Report 2018 states that the estimated incidence of TB in India in the year 2017 was 28,00,000 accounting for about a quarter of the world's TB cases. In 2017, India re-estimated its national figures of the burden of Tuberculosis; incorporating information from a wider range of sources and thus is more accurate than previous estimates. The major additional information source is the private sector notification seen throughout the country and in certain project locations with interventions targeted at private sector notification. The following table shows the current statistics of TB and MDR/RR TB (Rifampicin Resistance Tuberculosis) incidence, HIV TB co-morbidity and TB related mortality.[26]

Estimates of TB Burden in India and Global, 2016

Indicator	No	No/Lakhs	Global statistics
Incidence of TB(including HIV)	27,90,000	211	1,04,00,000
Mortality due to TB(Excluding HIV)	4,23,000	32	13,00,000
Incidence of MDRTB/RR	1,47,000	1	6,01,000
Incidence of HIV-TB	87,000	6.6	10,30,000
Mortality due to HIV-TB co-morbidity	12,000	0.92	3,74,000

Table No:-1 Source: Global TB Report 2017 adapted from[26]

GOALS OF NATIONAL STRATEGIC PLAN [26] "DETECT – TREAT – PREVENT –BUILD" (DTPB)

As per 2018 India TB Report, TB incidence in India is declining at about 1-2% per year and to achieve the TB elimination goal by 2025, a decline in TB incidence by about 15-20% annually is required.[26] The requirements for moving towards TB elimination have been integrated into the four strategic pillars of **"Detect – Treat – Prevent –Build" (DTPB).**

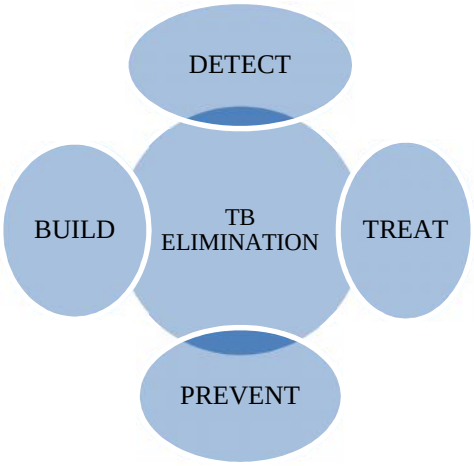

Fig No:-3 "Detect – Treat – Prevent –Build" (DTPB) adapted from[26]

DETECTION

TB needs to be detected by high sensitivity diagnostic tests and methodical screening of high risk population.

a) The following TB tests are currently available Diagnosis Tuberculosis Drug susceptibility test, TB Culture test, TB skin test, TB Interferon Gamma release assay, Sputum smear microscopy, Fluorescent microscopy, Chest X-ray test, Serological tests.Screening for TB and TB infection in high-risk population is also done by Mantoux test, Tuberculin skin test. Multiple puncture devices should not be used to screen high-risk population because they are less specific than the mantoux test.[27,28] For rapid diagnosis of TB, the government has introduced CB-NAAT (Cartridge-based nucleic acid amplification test)/Gene Xpert test machines covering all the country.

b)Scaling-up effective private provider engagement approaches.

c)Reporting of active case findings-Active Case Finding is basically a provider initiated activity with the primary objective of detecting TB cases early by finding symptomatic people in targeted groups and initiating treatment promptly.

TREATMENT - The Indian government has proposed to initiate and sustain all patients on appropriate anti-TB treatment, they seek care, with patient friendly systems and social support. Free TB drugs for all TB cases. New anti-TB drug to be introduced shortly for the treatment of Tuberculosis. Treatment costs have been eliminated by linking eligible TB patients with social welfare schemes including nutritional support.

PREVENTION -The government has proposed prevention by following control measures of air borne infection at health care facilities and address social determinants of TB through intersectoral approach.

BUILD-To build and strengthen enabling policies, empowering institutions, human resources with enhanced capacities, and financial resources to match the plan and scaling up technical assistance at national and state levels. By translating high level political commitment to action through supportive policy and institutional structures.

National TB Elimination Board with revision in the current administrative set up at the national level and matching structures at state level. Restructuring RNTCP management

structure and implementation arrangement: Substantially augmented HR and HR reforms and TB surveillance network in the country. Align and harmonize partners activities with programme needs to prevent duplication.[26]

NATIONAL STRATEGIC PLAN FOR TB ELIMINATION 2017-2025(NSP)[26]

The goal to achieve TB elimination by 2025 in India has been envisaged by our honorable Prime Minister, Mr. Narendra Modi.NSP will help in giving direction and hey initiatives that the Ministry of Health and Family Welfare will undertake from 2017-2025 for working towards achieving the goal of eliminating TB by 2025.

GOAL OF NSP: TB Free India with zero deaths, disease and poverty due to TB.

OBJECTIVES OF NSP:

1.Find all Drug Sensitive TB and Drug Resistant TB cases
2.Initiate and sustain all patients on appropriate anti-TB treatment
3.Prevent the emergence of TB in susceptible populations.
4.Build and strengthen enabling policies, empowered institutions, additional human resources with enhanced capacities, and provide adequate financial resources.

KEY STRATEGIES

1.Private sector engagement
2.Active Case finding
3.Drug resistant TB case management
4.Addressing social determinants including nutrition
5.Robust Surveillance system
6.Community engagement&Multi-sectoral approach

EXPECTED OUTCOME

The National Strategic Plan is aiming to achieve elimination of TB, by 2025. During plan period, targets for TB are
1.80% reduction in TB incidence (i.e. reduction from 211 per lakh to 43 per lakh)
2.90% reduction in TB mortality (i.e. reduction from 32 per lakh to 3 per lakh)
3.0% patient having catastrophic expenditure due to TB.

NATIONAL STRATEGIES IMPLEMENTED,2018

RNTCP LABORATORY NETWORK -The RNTCP Programme has put in a number of patient centric systems such as ICT(Information and communication technology) based adherence monitoring, increasing the breadth of treatment and social support options available to people affected with TB, expanded laboratory capacity and policy for detecting drug resistance. The program is currently scaling up its policy of universal DST(Drug susceptibility testing) where by all cases diagnosed with TB will receive a minimum of Rifampicin and Isoniazid resistance testing. The government has introduced more than 1135 CB-NAAT (Cartridge-based nucleic acid amplification test)/Gene Xpert test machines covering all the districts of the country for rapid diagnosis of TB across the country. TB diagnosis was offered through more than 14,000 designated microscopy centers. For decentralized molecular testing for TB and simultaneous detection of Rifampicin resistance CBNAAT (Cartridge-based nucleic acid amplification test) facilities have been established at District levels.

DRUG SENSITIVE TB: Direct sputum smear microscopy done by Ziehl-Neelsen acid- fast staining/Fluorescence microscopy are the primary case detection tool in RNTCP for patients with TB infection**.**

DRUG RESISTANT TB: DR TB Patients at risk as defined by the programme Multi-Drug Resistant TB, are diagnosed using WHO endorsed rapid diagnostics(WRD) like Cartridge Based Nucleic Acid Amplification Test(CBNAAT)/ Line probe assay(LPA).

RNTCP LABORATORY NETWORK

The RNTCP laboratory network is composed of a three tier system with

- National level Reference Laboratories(NRLs)
- State level Intermediate Reference Laboratories(IRLs)
- Peripheral level laboratories as Designated Microscopy Centers(DMCs)

Laboratories are equipped with either all three diagnostic technologies or single or any combination of these technologies by depending upon the availability of necessary infrastructure and resources.

LABORATORY CERTIFICATION STATUS

The following laboratories have been certified by RNTCP (Revised National Tuberculosis Control programme):

1.48laboratories-To perform Solid Culture & DST (Drug susceptibility testing)
2.45laboratories-To perform DST (Drug susceptibility testing) for first line drugs using liquid culture system
3.38laboratories-To perform DST (Drug susceptibility testing) for second line anti TB drugs
4.56laboratories-To provide First Line LPA (Line probe assay) Services.
5.50laboratories-To provide Second Line LPA (Line probe assay) technology

LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)

A Laboratory Information Management system was developed with support from FIND (Foundation for Innovative New Diagnostics). Implementation of LIMS will ensure providing accurate & timely information to the patient.

In order to achieve the goal of TB elimination in India by counseling the patients and family members on all aspects of TB and also Mass public campaign about preventive and curative aspects of TB.

ACTIVE CASE FINDING: TB Notification incentives Direct Benefit Transfer (DBT), AADHAR and NIKSHAY for direct cash benefits to patients .The government has started implementation of active case findings from 16-01-2018 for tuberculosis in 50 districts across 18 states. 2nd phase of Active case finding started across 26states/UTs covering 100 priority districts. The government is implementing incentives of Rs.1000 will for notification of TB patients. This will be given at Rs.500 at notification and of services and Rs.500 for reporting treatment outcome. The incentives will be provided upon notification in the TB reporting software i.e.Nikshay through a smooth and transparent manner. Linkages for provisions of free drugs and diagnostics to private sector patients either through social marketing approach or reimbursements Direct Benefit Transfer Linking Bank Account, AADHAR and NIKSHAY for direct cash benefits to patients: The programme adopted a DBT mechanism for transfer of monetary support and

incentives to patients. This will ensure the funds to rightful recipients in a timely manner. Participation from the private sector has nearly half the patients seeks treatment from the private sector. Efforts have to be made to integrate the private sector through mandatory notification of TB by all health care professionals. Notifying TB patients will enable the programme to offer health support and will also boost the active case findings. National Tuberculosis Control Programme is working in synergy with RNTCP for implementation of collaborative team work. The programme is also collaborating with pharmacovigilance programme of India to systemically identify, detect and manage the adverse effect of anti-TB drugs. The programme is continuously working to engage with the private sector.

POLICY FOR TREATMENT

To enhance treatment adherence, Fixed Dose Course(FDC) in daily regimen, new anti-TB drug Bedaquiline has already been introduced for drug resistant TB patients and the drug Delamanid will also be introduced shortly. NIKSHAY- a web based solution for monitoring TB patients will provide patient information to Central Tuberculosis Division and other social service schemes. Approval of bold and arduous National strategic plan is one of the landmark achievement of 2017 for the elimination of Tuberculosis. Elimination is a framework to provide guidance for the activities of stakeholders including the National and State governments, Developmental Partners, Civil Society Organizations, International Agencies, Research Institutions, Private sector and many others whose work is relevant to TB elimination in India. This would mean release of guidelines on PMDT (Programmatic management of drug resistant tuberculosis) in India; National TOT (Training of trainers)

CONCLUSION

The paper concludes that India is the one of the highest Tuberculosis burden countries but the incidence of disease is gradually decreasing year by year. As per 2018, India TB Report, TB incidence in India is declining at about 1-2% per year and to achieve the TB elimination goal by 2025, a decline in TB incidence by about 15-20% annually is required. However, late diagnosis of the disease, non-adherence or non-completion of treatment, co-morbidities, drug resistant TB and inter and intra-state difference in health system response are some of the challenges reported According to NSP (National Strategic Plan),early diagnosis of TB , active case findings and treatment will help in bringing down the disease burden in upcoming years. Some of the newer initiatives like NIKSHAY, DBT(Direct Benefit transfer), ACF(Active case finding) and the anti-TB drugs like Bedaquiline, Delamanid introduced for DRTB(Drug resistant Tuberculosis) patients should remarkably show significant results. NIKSHAY is instrumental in linking with the case based system of surveillance with Drugs Logistics Management, Public financial management (PFMS) etc. Novel diagnostic tools like 1135 CBNAAT/Gene Xpert machines covering all the districts of the country have been introduced for the rapid diagnosis of TB. All these initiatives can lead to early case detection , treatment, adherence and better outcome. The multi sectoral support will also help in addressing the challenges and achieving the goal TB elimination by 2025. All the above initiatives and strategies proposed by the government if implemented and monitored strictly can help in achievement of the goal of eradication of TB by year 2025.

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