Original Article

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Programmatic Management of Drug Resistant Tuberculosis Guidelines for Treatment of Multi Drug Resistant Tuberculosis and Difficulties in its Implementation in Government Medical Colleges of Madhya Pradesh and Role of Pulmonary Medicine Departments

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Abstract

Background: Programmatic management of drug-resistant tuberculosis (DR-TB)" (PMDT) provides for the diagnosis, management and treatment of multi-DR TB (MDR-TB). PMDT aims to cover 100% population by the year 2015, and we thought to assess its possibility.

Methodology: This study has been done by reviewing the relevant data containing PMDT guidelines and scheme of patient care delivery contained therein downloaded from Government of India official website *vis-à-vis'* relevant Medical Council of India (MCI) regulations that were also downloaded from MCI official website.

Results: Madhya Pradesh has 6 Government Medical Colleges (GMC) and except Indore none is equipped to run the MDR-TB ward as per the MCI for running the same. PMDT services have not been started in 3 of the 6 GMC. Deficiency of teaching faculty and senior/junior residents have been observed in 5 out of 6 colleges.

Conclusion: Central TB division, Ministry of Health and Family Welfare of India, State governments as major stakeholders for coordination and implementation of the program but has not included MCI. The main problem is human resource related.

Key words: Extensively drug-resistant tuberculosis, Multi-drug resistant, *Mycobacterium tuberculosis*

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INTRODUCTION

Multi-drug resistant tuberculosis (MDR-TB) is defined as *Mycobacterium* TB (MTB) resistant to isoniazid and rifampicin with or without resistance to other drugs.[1] The data from various studies conducted in India MDR-TB levels of 1-3% in new cases and around 12% in re-treatment cases has been found.[2,3] 2% resistance to rifampicin and 18% resistance to isoniazid either alone or in combination

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with other anti TB drugs was found in a retrospective analysis of various randomized clinical trials conducted by the TB Research Center Chennai.[4] The prevalence of MDR-TB is found to be about 3% in new cases and 12-17% in re-treatment cases.[5]

What is Programmatic Management of DR-TB (PMDT)?

The term PMDT refers to programme based MDR-TB diagnosis, management and treatment. These guidelines also integrate the identification and treatment of more severe forms of drug resistance, such as extensively DR-TB.[6]

Revised National Tuberculosis Control Programme (RNTCP) introduced the PMDT services in the year 2007 after successfully establishing the DOTS services across the country in year 2006, to address the needs MDR-TB patients which is considered as very complex. Internationally, the first WHO endorsed PMDT services were started in year 2000.

PMDT has aimed to follow international standards to treat MDR-TB patients. PMDT guidelines have stressed on efficient and timely identification of patients who require drug susceptibility testing (DST), quality-assured laboratory capacity (smear, culture-DST, rapid molecular test), efficient drug procurement and supply chain management, adherence to difficult-to-take regimens for long periods, prompt identification and management of side-effects, recording and reporting; and human and financial resources. The five components are: (1) Sustained political and administrative commitment, (2) diagnosis of MDR-TB through quality-assured culture and DST, (3) appropriate treatment strategies that utilize second-line drugs under proper management conditions, (4) uninterrupted supply of quality assured second line anti-TB drugs, (5) recording and reporting system designed for PMDT services that enable performance monitoring and evaluation of treatment outcome.

Government of India (GOI) has issued guidelines for running PMDT in India in the form of "guidelines on PMDT in India May 2012". As per the objectives defined in the guidelines, it was aimed that by 2015, nationwide access to MDR-TB diagnosis and treatment for all smear positive.

TB cases registered under RNTCP will be made available. The guidelines further mandates and provides for "DR-TB centers" at Government Medical Colleges (GMC) and patient care is to be delivered through departments of Pulmonary Medicine of respective GMC where TB centers are to be located. Any establishments in medical colleges are governed by Medical Council of India (MCI). It is also of great significance in the context of the things that in order to get MD in TB and respiratory diseases (TBRD) recognized by MCI it is required that the Department of Pulmonary Medicine should have MDR TB treatment facility.[7] Authors being faculty of GMC observed that the aim to cover all population for MDR treatment has not been achieved till the point of study in year 2015 so it was considered to look into the "difficulties in Initiation of PMDT treatment in GMC of Madhya Pradesh and role of Pulmonary Medicine Departments" since under the PMDT ultimate patient care is to be provided by the of Pulmonary Medicine Departments of respective GMC.

PMDT delivers patient care through state level state PMDT Committee and district level DR-TB Centers which as per guidelines preferably be established in tertiary care hospitals and medical colleges. State PMDT Committee are responsible for developing a plan of action for implementation, expansion, maintenance, supervision, monitoring and quality enhancement of PMDT services in the respective state.

Composition of DR-TB Centers as per PMDT at GMC under RNTCP

Provisions to be made by institute selected as DR-TB center

PMDT guidelines suggest that the treatment is decentralized, but the complicated clinical care that is required to manage a case of MDR-TB case needs services of experts from various clinical disciplines. Ensuring availability of this clinical expert resource group is the essentially DR-TB center. The job of DR-TB centers is to initiate treatment, follow-up case management, and manage complications. One DR-TB center is expected per 10 million populations roughly. PMDT plans to scale up DR-TB centers nationwide in a phased manner. The selected DR-TB center in addition to being (1) a tertiary care center, has to provide, (2) separate Ward for males and females, (3) all routine services required under PMDT like beds, investigations and ancillary drugs for management of adverse drug reactions (ADRs) to be provided free of cost to the patient, (4) availability of relevant specialties like Pulmonologist, Physician, Psychiatrist, Dermatologist and Gynecologist etc. (5) formation of DR-TB Centre Committee, (6) National Training of All Doctors Included in DR-TB Centre Committee including Chairperson, (7) compliance of National Air Borne Infection Control Guidelines, (8) routine clinical laboratory investigation facility to be made available for pretreatment evaluation and monitoring of all patients, (9) provision of ancillary drugs as per DR-TB Centre Committee's advice, (10) management of ADRs as per PMDT guidelines, (11) doctors and Nursing staff should be available from the Institute, (12) records and reports to be maintained for PMDT, (13) quarterly reports to be submitted electronically.

Provision to be made by PMDT under RNTCP

1. Remuneration of Senior Medical Officer and statistical assistant - DR-TB Centre
2. Training, formats and registers for PMDT
3. Second line anti TB drugs
4. Computer and internet facility.

Funds

Funds for up-gradation of chosen DR-TB center site as per PMDT guidelines: An amount up-to INR 1.5 million may be availed to renovate and incorporate airborne infection control measures.

Locations

All proposed DR-TB Centre must be established in a GMC Hospital under PNDT.

Coordination

To run a national program, coordination of activities at all levels from all perspectives is critical. Central TB Division (CTD), Ministry of Health and Family Welfare (MOHFW), GOI are the principal stakeholders. The CTD is considered the central coordinating body. PMDT under RNTCP is flexible to build partnerships with all relevant health care providers as per the need. PMDT activities if required, may be tailored to fit into the respective state and district levels infrastructure. Depending upon the existing infrastructure, the exact organizational structure of the RNTCP PMDT services may vary between the different settings.

METHODOLOGY

Patients' Consent and Ethical Clearance

The article is theoretical and did not require contact with the patient at any point in time hence no question of patients consent or ethical clearance from the Institute was not required.

The relevant data for this study have been downloaded from GOI official website regarding PMDT guidelines and scheme of patient care delivery contained therein and review of the same has been made and relevant MCI regulations that were also downloaded from MCI official website have also been reviewed *vis-à-vis'*. Faculty members or district TB officers from each GMC of MP or district where DR-TB centers are proposed or have been started were consulted to know about the facilities as per GOI guidelines for running DRTB centers at their chosen site in their respective GMC.

Scope of the Present Study

Scope of the present study is kept limited to assess the difficulty in starting DRTB centers in GMC on account of status of Pulmonary Medicine Departments in respective GMC and their role in delivering PMDT services and does not include the assessment of other State, District, Field and DST lab related aspects as envisaged in PMDT guidelines.

Observations

Model of PMDT care includes services to be delivered at state, district, DR-TB center, field and culture and DST lab levels where coordination is required for integration and smooth functioning. Relevant observations made are given below in the form of tables. Table 1 depicts about the various tasks under PMDT and the corresponding levels for coordination and completion. Table 2 depicts the present status of MD TBRD seats and PMDT facilities in GMC of MP. Table 3 shows status of MD TBRD seats and MD general medicine seats in private and GMC of MP. Table 4 shows human resource (HR) status about staff requirement and deficiency as per MCI norms to run Medical College Department and PMDT Ward.

DISCUSSIONS

Status of Pulmonary Medicine Departments

The National PMDT guidelines state that it can be started in either Department of Pulmonary Medicine or Department of Medicine where the Department of Pulmonary Medicine does not exists. The Department of Public Health and Family Welfare (PHFW) of state Government of MP which controls the PMDT services in the state, has stressed to choose the former. The shortage of faculty in the TBRD specialty is known to all. The principal reason for the shortage is non-availability of MD TBRD courses in the government colleges. Despite being more than 50 years having passed since the inception of the colleges all medical colleges (except the one at Sagar, which was started in year 2008) none of the 6 GMC offer MD TBRD course. All GMC except Indore all have HR shortage. GMC at Indore offers DTCD course for 2 seats. Department of Pulmonary Medicine from the functional point is still non-existent as it is evolving in all the colleges except Indore and does not have adequate number of faculty at all medical colleges as per MCI norms. Similarly, there is a shortage of any junior resident (JR)/senior resident (SR) at all medical colleges except Indore. Due to this reason local residents do not have the opportunity to study the specialty and it is natural that faculty and SR seats will remain vacant. No MD TBRD teaching facility, no MD pass outs forms a vicious cycle that is difficult to break. The reason for the shortage of SR remains the same as the qualification to be appointed as SR is the same, i.e., MD in the concerned specialty. The shortage of JR is again mostly due to the same reason, i.e., no post-graduate teaching facility because students pursuing MD course are

Table 1: Various tasks under PMDT and the corresponding levels for coordination and completion

Level	Sub-level	Task	Required HR to be made available by state or GMC
State drug store	State TB society	Prepare and ship drug boxes to districts	State
District	District TB society	Identify suspects, refer specimens	State
	District TB society	Coordinate diagnostic results	State
	District TB society	Refer new/difficult cases to DR-TB center	State
	District TB society	Coordinate care and drug flow to field	State
	District TB society	Maintain records, monitor and supervise	State
DR-TB Center	Dean/Medical Superintendent	Maintain ward and AIC measures	GMC
	Department of Pulmonary Medicine	Pre-treatment evaluation	GMC
	Department of Pulmonary Medicine	Start M/XDR TB treatment	GMC
	Department of Pulmonary Medicine	Consult for complications	GMC
	Department of Pulmonary Medicine	Maintain records	State
Field	PHC, CHC government Dispensaries clinics etc.	Identify suspects, refer specimens	State
		Communicate results to patients	State
		Support, supervise, manage MDR cases	State
		Manage minor adverse effects	State
		Collect and refer follow-up specimens	State
Culture and DST lab	Accredited labs for DST under PMDT	Receive diagnostic/follow-up specimens	State
	Accredited labs for DST under PMDT	Provide rapid results to district Field, and DR-TB Center	State
	Accredited labs for DST under PMDT	Maintain records	State
	Accredited labs for DST under PMDT	Quality assurance of results	State
	Accredited labs for DST under PMDT	Prepare and ship drug boxes to district	State

State: State Government, GMC: Government Medical College PHC: Primary Health Center, CHC: Community Health Center, PMDT: Programmatic management of drug resistant tuberculosis, HR: Human resource, DST: Drug susceptibility testing, DR-TB: Drug resistant tuberculosis, MDR: Multi drug resistant, XDR TB: Extensively drug resistant tuberculosis, TB: Tuberculosis

Table 2: Status of PMDT facilities in government medical colleges of MP

GMC	MD TBRD/ DTCD available (yes/no)	PMDT started (yes/no) year	PMDT running organization-PHFWD or GMC	Pretreatment Evaluation facility	Emergency Management	Expert Clinical Resource	Manpower HR-Doctors available at MC as per MCI norms	Manpower HR-SR available at GMC as per MCI norms	Manpower HR-JR available at GMC as per MCI norms
Indore	DTCD	Yes	PHFW	Yes	Yes	Yes	Yes	Yes	Yes
Gwalior	No	No	NA	No	No	No	No	No	No
Bhopal	No	Yes	PHFW	Yes	Yes	Yes	No	No	No
Jabalpur	No	No	NA	No	No	No	No	No	No
Rewa	No	No	NA	No	No	No	No	No	No
Sagar	No	Yes	PHFW	Yes	Yes	No	No	No	No

PMDT: Programmatic management of drug resistant tuberculosis, MD TBRD: Doctor of medicine in tuberculosis and respiratory diseases, DTCD: Diploma in and chest diseases, PHFW: Public Health and Family Welfare Department, HR: Human resource, SR: Senior resident, JR: Junior resident, GMC: Government Medical College, MCI: Medical Council of India

Table 3: Status of MD TBRD and MD General Medicine seat in Private/Trust and GMC of MP

College	Private/ trust/ government	Place	Year of inception	Number of TBRD seats per year	Number of MCI recognized MD general medicine seats
Index Medical College Indore	Trust	Indore	2007	2	7
Peoples College of Medical Sciences and Research Centre	Trust	Bhopal	2005	2	4
Ruxmaniben Deepchand Gardi Medical College	Trust	Ujjain	2001	3	8
Sri Aurobindo Medical College and Post Graduate Institute	Trust	Indore	2003	3	8
MG Medical College	Government	Indore	1948	0	12
NSCB Medical College	Government	Jabalpur	1955	0	12
Gaj Raja Medical College	Government	Gwalior	1946	0	10
S S Medical College	Government	Rewa	1963	0	8
Government Medical College	Government	Sagar	2008	0	0
Gandhi Medical College	Government	Bhopal	1955	0	14

MD: Doctor of Medicine, TBRD: Tuberculosis and respiratory diseases, MCI: Medical Council of India, GMC: Government Medical Colleges

Table 4: HR status about Staff Requirement and deficiency as per MCI norms to run Medical College Department and PMDT ward

Staff required	For Pulmonary Medicine (First unit as Per MCI Norms)	For PMDT ward (Second unit as Per MCI Norms)	Total staff required for both Pulmonary Medicine and PMDT wards	Available/ Sanctioned posts	Filled posts	Vacant posts	Deficiency	Level at which Action is required
Professor	1	0	1	1	0	1	1	State Government's Medical Education Department
Associate Professor	1	1	2	2	1	1	1	-do-
Assistant Professor	1	2	3	3	2	1	1	-do-
Senior Resident	3	3	6	1	0	1	6	Dean of the medical college service can.
Junior Resident	3	3	6	3	0		6	Dean of the medical college service can.
TBHV	2	0	2	2	0	2	2	State Govt. College through PEB
Social worker TB	1	1	1	1	0	1	1	-do-
LT	1	0	1	1	0	1	1	-do-
Senior Medical Officer	0	1	1	Provision to be made by State Govt. as per PMDT norms	0	1	1	State government through its Department of PHFW/District TB Society
Statistical Assistant	0	1	1	-do-	0	1	1	-do-
Counselor	0	1	1	-do-	0	1	1	-do-

HR: Human resource, PEB: Professional Examination Board (a body of state government entrusted to make recruitments), PHFW: Public Health and Family Welfare, PMDT: Programmatic management of drug resistant tuberculosis, MCI: Medical Council of India

considered as JR by MCI. The four private medical college of MP, which have been started after the year 2001 are able to meet MCI norms and offer 10 MD TBRD seats per year.[8] They also absorb most of their product as SR or faculty immediately after passing out as the demand of a MD TBRD is pretty high due to MCI regulations and which are same for both private and medical colleges. A few of the products return to their native states who do not hail from MP. This difference in status of Private and GMC in TBRD specialty is staggering and calls for better understanding of the issue, coordination and implementation at all levels especially the Department of Health and Medical Education of State Governments, MCI, MOHFW, GOI and better planning should be done to decide desirability and feasibility for opening of a particular MD course keeping in view the health needs of the that respective state and country. JRs can be appointed on the basis of MBBS qualification but such seats are temporarily filled by those aspirants who either have to serve a rural area service bond. The rural area service bond candidates get an exemption from going to the rural area if they are employed as JR in a GMC. After completion of 1-year tenure, which is equal to the bond period they leave. Most of such JR aspirants join the posts just to avoid going into the rural area and keep preparing for the postgraduate entrance examination. As per government policy if they are selected for PG courses, they again get an exemption from the rural area service bond. Long procedural delay at various levels of administration is an important issue. For example, faculty posts are filled at the state level, and principal secretary and director medical education are the appointing authorities. Publishing wants, calling for applications, interviews and selection take a lot of time, and suitable candidates who have freshly passed MD TBRD find better employment somewhere else.

The Interdepartmental and Intradepartmental Coordination

As per the scheme of PMDT ward the facility provided by program through national health mission via Department of PHFW is includes provision of drugs to treat MDR TB, Indian national rupees 1.5 million for renovation work of PMDT ward at the chosen site to adhere to Air Borne Infection Control Guidelines and provision of one medical officer one statistical assistant and one counselor. Other facilities are to be provided by the medical college. Permission to renovate, provision of man power of doctors falls in the domain of principal secretary and director of medical education. PMDT under RNTCP requires a ward to be opened in a GMC. Pulmonary Medicine related tasks under PMDT requires a vice chairperson of DR-TB Committee (Head of the Department of Pulmonary is considered fit for it) and a senior doctor from the department to function as nodal officer for the DR-TB Centre. Provision of JR and SR falls in the domain of dean and provision of nursing and ancillary drugs and pathological and radiological services in the domain of medical superintendent, so to ensure smooth delivery of all services required under PMDT, coordination

becomes indispensable. MCI is the body which governs the medical education and running of affiliated hospitals and has prescribed standard norms for opening a clinical wards and compliance of the same is mandatory for all medical colleges in India. In order to get a Department of Pulmonary Medicine recognized for the purpose of running MD TBRD course MCI, in its regulation has made it mandatory for PMDT services to treat MDR TB to be available in a medical college. MCI provides relaxation for appointing faculty for super-specialty courses like DM and MCH where they are to be inducted for the first time but does not provide any for broad specialty course like MD TBRD.[9] This comes across as an anomaly in states like MP where none of GMC offers the MD course in TBRD specialty. PMDT has identified CTD, MOHFW GOI and State governments as major stake holders for coordination and implementation of the program but has not included MCI so the efforts must be made to include MCI as the stake holder. Including MCI as stake holder and developing a comprehensive view may be helpful as ultimately PMDT under RNTCP depend upon the GMC and their Pulmonary Medicine/TBRD Departments to serve as the clinical expert resource and if the same is not strengthened then the success of the program will remain questionable.

CONCLUSION

PMDT under RNTCP requires a ward to be opened in a GMC. MCI is the body which governs the medical education and running of affiliated hospitals and has prescribed standard norms for opening a clinical wards and compliance of the same is mandatory for all medical colleges in India. PMDT has identified CTD, MOHFW GOI and State governments as major stake holders for coordination and implementation of the program but has not included MCI. The main problem is HR related as it is difficult to meet MCI norms in making recruitment on relevant posts. None of the six GMC offers MD in TBRD which is the root cause of non-availability of teaching faculty and SRs. Opening MD courses in TBRD in every GMC is the only long-term solution to deal with the HR problem. All key decision makers from the Government Departments of PHFW/National Health Mission and Department of Medical Education starting from Principal Secretaries Directors, Dean Medical Superintendents of Medical College Hospitals and Head of the Departments of Medicine and Pulmonary Medicine should form a team and sit together and develop a time-bound action plan. Until the time Pulmonary Medicine Specialty and its Departments in GMC do not grow sufficiently the Department of Medicine should be made responsible to deliver PMDT services and run indoor MDR TB ward with the help of available clinical resource of its own and also the Department of Pulmonary Medicine. The role playing of each stake holder should be clearly defined and made accountable. MCI and GOI must be involved in the meetings and action plan development. Coordination needs to be improved between Department of PHFW/National Health Mission and Department of Medical Education and between district health authorities and medical college bodies. A clear cut guideline about the method and modus of coordination between two agencies may be developed. Decision making and implementation should be time bound and made accountable.

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