

Decentralization of Treatment Services for Drug Resistant Tuberculosis – A Patient Friendly Strategy from Telangana Region of India**Chakrapani Chatla*¹, Jyoti Jaju¹, Shanta Achanta¹, Suryaprakash Chakramahanty², Prabakaran Jayaraman¹, Jayakrishna Kurada¹, Ramadevi Sangepu³, Sreenivas Achuthan Nair¹, Malik Parmar¹**¹World Health Organization, India Country Office, New Delhi, India, ²State TB Officer – Telangana State, DM&HS Campus, Koti, Hyderabad, Telangana State, India, ³Drug Resistant TB Centre, Government General and Chest Hospital, Warangal, Telangana State, India**Date of Submission** : 01-12-2017**Date of online Publication** : 07-01-2018**Date of Acceptance** : 23-12-2017**Date of Print Publication** : 31-03-2018***Author for correspondence: Dr. Chakrapani Chatla**, WHO-RNTCP State Consultant, Hyderabad, Telangana State, India. Email: chatlachakri@gmail.com**Abstract**

Context: Drug Resistant Tuberculosis (DR-TB) is a major public health challenge in India. In 2016, WHO estimates 79,000 DR-TB cases among the notified pulmonary TB cases emerging annually in India. Revised National Tuberculosis Control Program had initiated treatment services under Programmatic Management of DR-TB through designated DR-TB Centres for each ~10 million population with 20-30 bedded infection control complaint wards manned by a clinical committee of specialists and trained staff to provide the in-patient care for the initial 2 weeks of treatment. The utilization of services at the DR-TB Centre in Hyderabad, Telangana State serving 10 districts, was observed to be sub-optimal mainly due to long distances to be travelled by the patients. Delay in treatment initiation, loss of wages due to travel and travel cost are major challenges in early initiation of the treatment. **Aim:** In this report, we present a patient friendly approach initiated in Telangana State to address these gaps. **Material and Methods:** As a strategic intervention to address these issues, the state TB cell of Telangana developed decentralized district level DR-TB Centres for each ~2 million population with 4-8 bedded ward in each of the 10 districts. These were linked to the DR-TB Centre at Hyderabad that would serve as a nodal-centre for referrals of difficult cases, mentoring and monitoring the quality of the treatment services. **Results:** The proportion of patients initiated on treatment for DR-TB increased from 69% before decentralization in 2010 (123/178) to 89% (727/817) in 2015 after decentralization ($\chi^2 p < 0.05$). Monitoring of patients who were not initiated on treatment and validation of data at regular intervals was additional yield of the decentralization approach followed in the region. **Conclusions:** The approach implemented suggest that decentralization of DR-TB treatment services help in early initiation of treatment and also builds confidence in the patients in availing treatment besides supporting the state in preparedness for incremental diagnosis through newer diagnostic tools.

Key-words: Decentralization, Drug Resistant TB, Treatment, Integration, Telangana.**Introduction**

Tuberculosis (TB) is caused by *Mycobacterium tuberculosis* (MTb) which most often affects lungs. TB is treatable and curable disease with complete, consistent and appropriate drug regimen. Drug Resistant Tuberculosis (DR-TB) occurs when patients fail to complete the first line anti TB treatment or newly acquire DR-TB from another person with DR-TB. Resistance to antimicrobials in bacteria is not a new phenomenon and has been a well-established fact in *Mycobacterium tuberculosis* also. According to Annual TB Report 2017,

there would be an estimated 1.3 lakh incident multi-drug resistant TB patients emerge annually in India which includes 79000 MDR-TB Patients estimated among notified pulmonary cases^[1].

After successfully establishing the DOTS (Directly Observed Short Course) services across the country in 2006, Revised National Tuberculosis Control Programme (RNTCP) of India has introduced the Programmatic Management of Drug Resistant TB (PMDT) services in 2007 to address the needs of this group of patients and is

now rapidly scaling up services across the country while also expanding services towards universal access^[2]. Under RNTCP, the patients are categorized to be DR-TB patients when the sputum or an extra pulmonary sample of the patient is confirmed microbiologically for MTb and the bacteria are resistant to the most potent first line anti TB drugs such as Rifampicin (Rif) with or without Isoniazid (INH). As part of PMDT, RNTCP in Telangana State initiated Drug Sensitivity Testing (DST) for Rifampicin and Isoniazid in December 2008 and a DR-TB Treatment Centre in Hyderabad in December 2008.

The current, RNTCP PMDT vision is to provide early and rapid diagnosis and prompt initiation of effective treatment to all DR-TB patients, integrated into RNTCP. However under PMDT, RNTCP envisages 7-10 days of in-patient treatment in the DR-TB Centre for the DR-TB patients during which the Pre-Treatment Evaluation (PTE) of the patient for various parameters such as Liver function tests, Renal function tests, Hemogram and other important baselines physiological functions are performed so that the treatment can be tailor made / altered based on the results of physiological and biochemical tests. The PTE period is also utilized effectively in providing counselling about the duration, mode of treatment for DR-TB and the potential side effects of the drugs, follow-up visits needed, importance of adherence to the drug regimen and precautions to be taken towards reducing transmission of the disease to other members in the family. Once discharged from the DR-TB Centre the patient will be provided with ambulatory treatment in domiciliary fashion with a designated treatment regimen by RNTCP for 2 years which includes Flouro-quinolones and aminoglycosides as mainstay drugs. According to RNTCP a DR-TB Centre can be established for a geographic area covering population of minimum 10 million^[2]. One such DR-TB Centre was established in Government General and Chest Hospital in Hyderabad city of Telangana State in 2008 December with separate female and male wards having proper airborne infection control measures in place. Telangana Region of India had a population of ~30 million in 2008 with 10 revenue districts and 1 additional TB district. In late 2012, an additional DR-TB Centre was initiated at Government General and Chest Hospital, Hanamkonda in Warangal district of Telangana region according to the guidelines.

On the above of all, for the patient to travel to a DR-TB centre which is far from his/her residence and stay for 7-10 days for PTE would make the initiation of DR-TB treatment even more challenging. At that point of time, there was not much experience of decentralized DR-TB treatment services in India, through there was a plan for RNTCP to progress towards decentralized care.

In this situation, the State TB Cell of Telangana, India developed and implemented the innovative strategy of decentralized provision of DR-TB treatment services at the district level while ensuring maintenance of quality of

care. In this report, we analysed the impact of this innovative decentralization strategy on initiation of treatment at DR-TB treatment Centres under programmatic settings.

Material and Methods

The scenario of diagnosis of DR-TB and utilization of the treatment services at the DR-TB Centre at Hyderabad was assessed through a situational analysis followed by discussion with various key administrators of RNTCP in Telangana State. The approaches designed by the team were submitted for administrative commitment and approval to MD-NHM (Managing Director–National Health Mission) and Principal Secretary–Health, Medical & Family Welfare (PS) of the then state of Andhra Pradesh in which Telangana region was a part. In 2-3 focussed meetings held in the presence of PS, the approaches to deal with the issue were finalized and named as “**decentralized provision of DR-TB treatment services**” as part of regular health system in collaboration with RNTCP. This plan had envisaged having a DR-TB Centre in every district and as many link wards as possible in all the districts for effective and early treatment initiation. It also laid out a clear monitoring plan to cross check the quality of implementation in these district level DR-TB Centres and sub-district level link wards. These approaches needed some bold decisions by the state health system towards supporting some infrastructure needs and provision of human resources as the then guidelines of RNTCP had some limitations in terms of establishing number of DR-TB Centres in proportion to population and limited number of contractual staff provided under the program.

The approach developed towards the innovative strategy is shown below and had following key components:

1. **Structured reorganization of DR-TB treatment services** with specific functions at each level:
 - a. Nodal DR-TB Centre
 - b. District DR-TB Centre
 - c. Link DR-TB Ward
2. **Ongoing Administrative commitment:** This was specially envisaged to handle the issues/ challenges faced during the rollout of the approach. For example: Issues related to space for wards, human resources and task sharing, funds for repairs, modifications and beautification etc. and issues related to administrative commitment at district level.
3. **A time bound expansion plan:** A phase wise expansion was made which envisaged that every potential District DR-TB Centre will begin functioning as Link DR-TB ward and gradually progress as DR-TB Centre under the direct support and mentoring from the Nodal DR-TB Centre as well as technical and administrative support from state level RNTCP team.

A structured framework for the approach has been developed and agreed upon by all stakeholders (*Figure 1.*). Responsibilities of each focal point in the approach are laid out in *Table 1.*

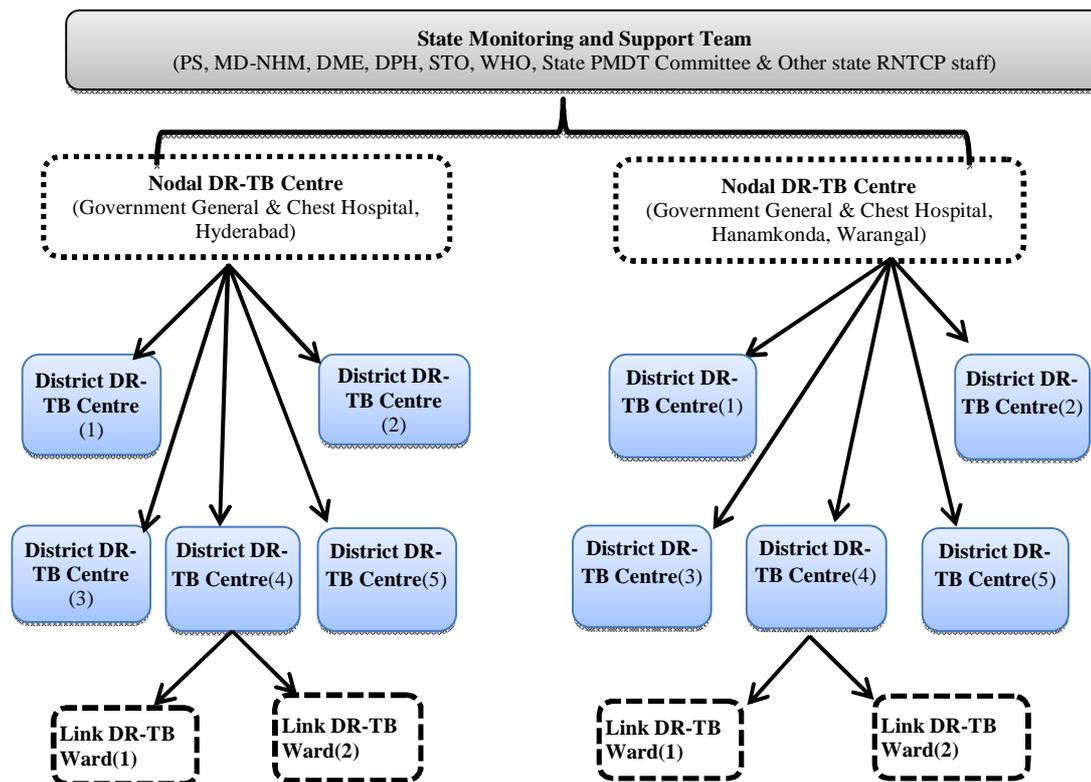
Table 1: Responsibilities at various layers in the decentralization Approach.

Layer	Responsibility
State TB Cell	<ul style="list-style-type: none"> To ensure the implementation of decentralization plan of DR TB treatment services with the support of State Monitoring and Support team (SMST), established District DR-TB Centres with airborne infection control compliant wards capable of independently managing DR-TB patients. To ensure availability of necessary funds, human resources (HR) and trainings in line with RNTCP PMDT guidelines To identify administrative bottlenecks in the decentralization process and discuss with the SMST. To ensure the provision of technical and administrative support from state health society for enabling policy decisions and resources not explicitly spelt out in RNTCP guidelines to implement the decentralization plan.
Nodal DR-TB Centre	<ul style="list-style-type: none"> To provide technical and mentoring support to District DR-TB Centres for ensuring quality of care. To act as a higher reference Centre to provide clinical care for the DR-TB cases with complication or extensive disease referred from District DR-TB Centres To ensure management and documentation of adverse drug reaction issues identified in the field and liaise with pharmacovigilance program. To review and validate the data of all the records and reports from District DR-TB Centres on monthly basis.
District DR-TB Centre	<ul style="list-style-type: none"> To ensure availability of HR at District DR-TB Centre from the general health system, in coordination with District TB Officer as exclusive staff were not made available under RNTCP at District DR-TB Centre Level. To monitor treatment initiation status of all patients diagnosed with DR-TB from the district based on the reports from Culture & Drug Sensitivity Testing (C&DST) labs. To ensure all the patients get early initiation of treatment. To ensure provision of all laboratory tests are made available for the patients as per PMDT guidelines. To ensure MoU (Memorandum of Agreement) is made with private laboratories for those laboratory tests which are not available within the health facility. To ensure wards are maintained cleanly, hygienic and in compliance with Airborne Infection Control Guidelines. To ensure Pre Treatment Evaluation (PTE) is complete and the patients gets thorough counselling about the drug regimen, duration of treatment, potential adverse drug reactions and the process to be followed till the completion of treatment. To ensure sputum sample is sent to C&DST lab for baseline second line drug resistance analysis at linked National Reference Laboratory under RNTCP. To support all the Link DR-TB Wards attached for quality of treatment services. To complete the registration process for all patients according to PMDT guidelines. To provide registration number for patients from Link DR-TB Wards upon reviewing PTE lab reports shared by Link DR-TB Ward. To attend the review and data sharing meeting called by Nodal DR-TB Centre/ State TB cell and share all the data as needed. To ensure Food, Accommodation, Ancillary drugs needed for the patients are borne by Hospital without charging extra to the patient. To refer the patients on treatment for complications or adverse drug reactions who need clinical intervention at higher Centres to attached Nodal DR-TB Centre.

Link DR-TB Ward	<ul style="list-style-type: none"> To provide separate male and female wards either in government or private facility where all the speciality clinical services are available as per PMDT guidelines. To ensure availability of human resources at Link DR-TB Ward from the general health system, in coordination with District TB Officer (in case of government facility) or Hospital Administration (in case of private sector) as exclusive staff were not made available under RNTCP at Link DR-TB Ward Level To ensure the PTE lab reports are made available to patients free of cost (even in the Link DR-TB Wards in Private sector). To share the PTE lab reports to attached District DR-TB Centre for the review by District PMDT Committee. To record the PMDT TB registration number provided by the District DR-TB Centre and document the patient details of treatment etc. as per PMDT guidelines. To attend the review or data sharing meeting called by District DR-TB Centre and share all the data as needed. RNTCP (DTC) will identify a point person from the RNTCP to provide technical support on continuous basis (ex: DTO/ MO DTC/ MO-MC) etc. To ensure Food, Accommodation, Ancillary drugs needed for the patients are borne by Hospital without charging extra to the patient. To refer the patients on treatment for complications or adverse drug reactions who need clinical intervention at higher Centres to attached District DR-TB Centre or to Nodal DR-TB Centre.
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The gradual expansion of the DR-TB Treatment Centres and Link Wards needed a comprehensive strategy and sticking to the plan over a period of time (*Figure 2*). The first DR-TB Centre for Telangana Region at Government General & Chest Hospital (GGCH), Hyderabad was established in December 2008. The DR-TB Centre (DRTBC) catered to the 34 million population of Telangana Region and around 4 million population of Kurnool district from Rayalaseema region of the state. The bed occupancy was almost full with a waiting time of average 7-10 days in general and >1 month in extreme cases. A position of Senior Medical Officer – DR-TB (SMO) and a Statistical Assistant (SA) were recruited under RNTCP. A counsellor was later placed by Lepira Society, a Non-Governmental Organization (NGO) without any funding by the program as the counselling was a highly felt need (*Figure 2-A*). In 3Q2012, the second DR-TB Centre was started at GGCH, Kakatiya Medical College, in Warangal. Warangal DRTBC catered to 6 districts of Northern Telangana with 15 million population. The DRTBC at GGCH, Hyderabad continued to serve 5 districts of Telangana region and Kurnool district of Rayalaseema region. A SMO was recruited under RNTCP for Warangal DRTBC. Counsellor & SA posts were not available for Warangal DRTBC. A Link DR-TB Ward was initiated in RIMS (*Figure 2-B*), Adilabad catering to two districts – Adilabad and Nizamabad. On 30/3/2013, in the DR-TB Committee (DRTBCC) meeting conducted under the chairmanship of In-charge director of RIMS (Rajiv Gandhi Institute of Medical Sciences), Adilabad, it was decided to allot the unused old building belonging to NPCB (National

Figure 1: Framework of decentralization of PMDT Treatment services

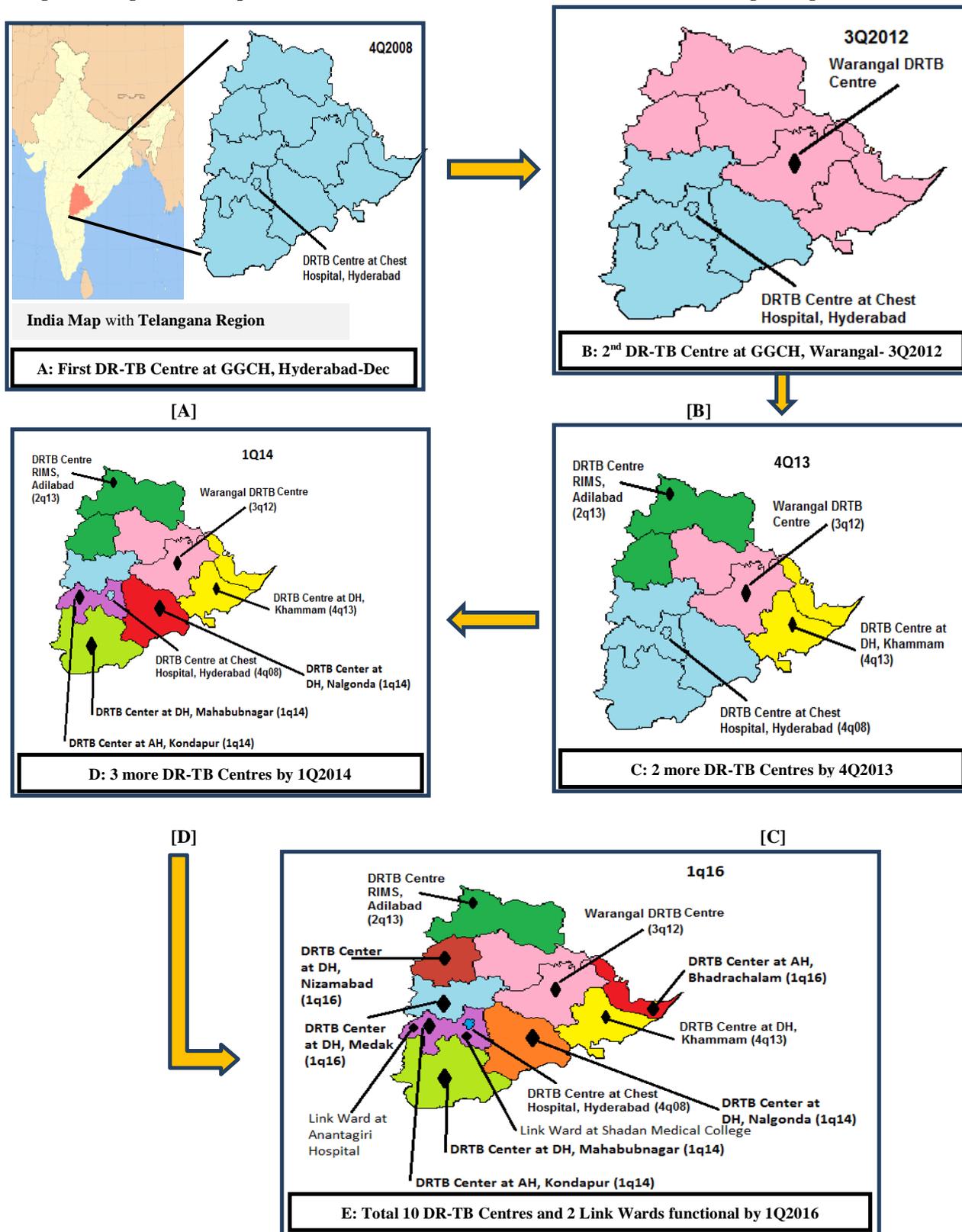


Program for Controlling Blindness) for the DRTB Ward. Advocacy Meeting held on 15/4/2013 at Conference Hall, Secretariat under the chairmanship of Principal Secretary – Health. On 18/5/2013, a Link DR-TB Ward in RIMS for DR-TB patients was started as an attached ward to the Warangal DRTBC. As the services were satisfactory, the Link Ward at Adilabad was upgraded to DRTBC status from June 2013 (Figure 2-C). No additional staffs were provided from RNTCP. RNTCP supported with partial funding in renovating the building along with HDS (Hospital Development Society) funds of RIMS, Adilabad. A Link DR-TB Ward was initiated in District Hospital Khammam catering to two districts – Khammam and Bhadrachalam. DRTBCC was formed on 22/5/2013. Patients were admitted still the linkage continuing with DRTBC, Warangal. As the services were satisfactory, the Link Ward was upgraded to DRTBC status from October 2013. No additional staffs were provided from RNTCP. District Collector approved the funding for establishing Link Ward in DH from the HDS funds on 20/7/2013. Link DR-TB Wards were started and DRTBCCs formed in 3 more districts on the following dates: DH, Nalgonda on 5/10/2013, AH Kondapur, Rangareddy on 6/11/2013, DH, Mahabubnagar on 16/12/2013. The Link Wards were upgraded to DRTBC status from 1/1/2014 (Figure 2-D). No additional staff were provided from RNTCP. Renovations necessary for the Wards were raised from HDS funds with partial support from RNTCP. Link DR-TB Wards were started and DRTBCCs started in 5 more districts on the following dates: AH, Bhadrachalam on 10/9/2013, DH, Nizamabad

(Govt. MC) on 24/4/2014, AH, Anantagiri, Rangareddy District on 17/10/2014, Shadan Medical College (pvt.) on 19/12/2014, DH, Sangareddy, Medak in October 2015. The Link Wards were upgraded to DRTBC status from 1/4/2016 at Bhadrachalam, Medak and Nizamabad. However the Link Wards at Shadan Medical College and Anantagiri Hospital are planned to continue as Link Wards. Renovations necessary for the Wards were raised from HDS funds. No additional staff were provided from RNTCP. More Link DR-TB Wards are planned in the following: Kamineni Medical College, Narketpally (pvt.), SV Medical College, Mahabubnagar (pvt.). However the Link Wards at Shadan Medical College and Anantagiri Hospital are planned to continue as Link Wards (Figure 2-E).

The cohorts included for the analysis were all the patients diagnosed with DR-TB under programmatic settings in Telangana Region from 1st December 2008 till 31st December 2015. The data necessary for the analysis was collected through the PMDT TB Registers, Culture & DST Lab Registers, and data generated from e-SMARTS (a software monitoring tool developed for PMDT in Hyderabad), quarterly PMDT reports generated at district, state and DR-TB Centre level. All the analysis was conducted utilizing MS-Excel. Chi-Square analysis was performed to compare categorical variables. Since, the data generated was part of national programme and was analysed within the programmatic units, confidentiality was maintained under programmatic settings.

Figure 2: Diagrammatic depiction of Phase wise decentralization of PMDT Services in Telangana region



Results

The decentralization process implemented by RNTCP in Telangana State has resulted in increase of number of DR-TB Centres from 1 to 10 and the Link DR-TB Wards from None to 2. The approach also facilitated initiation of Link DR-TB wards in private sector which is very essential for End TB Strategy. The treatment initiation among those diagnosed with DR-TB under RNTCP has increased significantly over time due to decentralization of treatment services (Figure 3 & Table 2).

[E]

It can also be observed that the treatment initiation from 2008 to 2010 decreased from 81% to 69% (Figure 3). This decrease is mainly due to 3 reasons. One, the diagnosis of DR-TB cases increased from 47 in 2008 to 126 in 2009 and 178 in 2010 while the DR-TB treatment centre catering to these patients was only one located at GGCH, Hyderabad. The other reason being non-acceptance for treatment by the patients as DR-TB was a relatively newer diagnosis and the confidence of patients

on the treatment protocols was not strong enough during the initial days of PMDT. The third reason being the distance to be travelled to get admitted into the only available DR-TB treatment centre in Hyderabad from long distances. As the expansion of DR-TB centres took place, all these factors could be negated to a major extent which reflected in increase in treatment uptake in later course of PMDT (Figure 3).

Table 2: Chi-Square Analysis of Patients initiated on treatment versus not initiated over time

Cohort	Initiated on Treatment	Not Treated	Total	Chi-Square Value	P-Value
2008	38 (80.9%)	9 (19.1%)	47		
2015	727 (89.0%)	90 (11.0%)	817	2.8976	0.088711
2009	95 (75.4%)	31 (24.6%)	126		
2015	727 (89.0%)	90 (11.0%)	817	18.0182	0.000022
2010	123 (69.1%)	55 (30.9%)	178		
2015	727 (89.0%)	90 (11.0%)	817	46.4131	<0.05

Figure 3: Treatment initiation among the DR-TB diagnosed from 2008 – 2015

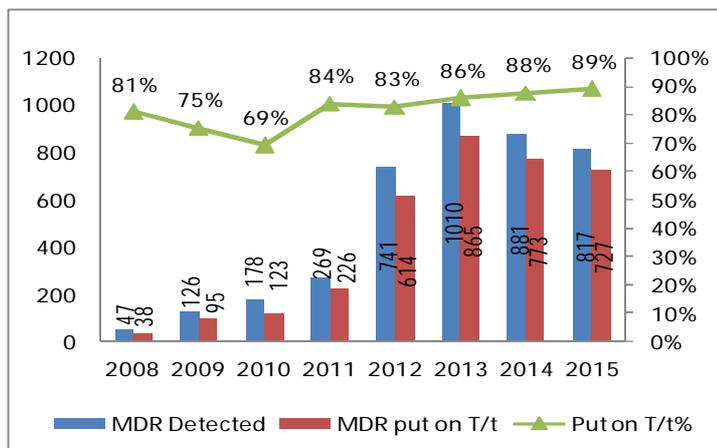
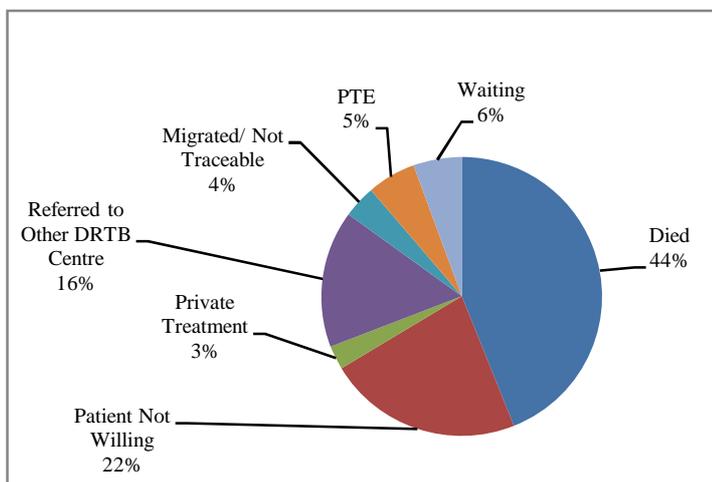


Figure 4: Among the non-treated DR-TB from 2008 – 2015, reasons for not initiation of treatment



When analysed for the reasons for non-initiation of treatment it was observed that 44% of the patients were severely ill by the time of diagnosis with DR-TB and thus died due to DR-TB even before initiation of treatment (Figure 4).

Discussion

Drug Resistant TB is one of the major challenges being faced in India. The decentralized approach for providing treatment services for DR-TB under PMDT (Programmatic Management of Drug Resistant TB) in India have shown very good and promising results in increasing number of cases put on DR-TB regimen under programmatic conditions. Antimicrobial resistance among patients with various infectious diseases in general and in Tuberculosis patients specifically has become a major challenge to the public health services in India and in Telangana State. With nearly 60-70% of health care access being accessed from private sector in states like Telangana, it is more important to become aware of the challenges posed to the society and in turn to the health care of future generations to come by irrational, incomplete, insufficient usage of antimicrobial agents.

Impediments towards universal access to DR-TB treatment are many, ranging from insufficient donor funding to poor laboratory diagnostic capacity and health system challenges, including the need to encourage ambulatory care models^[3]. In our settings it was observed that smooth fund flow could be achieved by decentralization coupled with administrative commitment, though there are no quantitative measurements for this change. However, it was clearly felt by the hospital staff that it was easy to mobilize funds for few DR-TB patients in each of the DR-TB Centres compared to mobilizing funds for all the patients in 1 or 2 initial Nodal DR-TB Centres as the case load was high and the funds consumed by the Nodal DR-TB Centres were high in view of the hospital administrators. After decentralizing the proportion spent in each DR-TB Centre was less compared to the overall spending of the hospital and thus could easily get approval for various investigations, medicines or other needs such as food for patients and attendants etc. without a feeling of burden on the administrators.

Several large scale DR-TB programmes have demonstrated that decentralization will improve access to care and management without compromising treatment outcomes^[4-7], including programmes that have task shifted initiation of DR-tuberculosis treatment to trained nurses and paramedical staff^[8]. Decentralisation has been a crucial strategy for expanding access to treatment for HIV and has been associated with better patient outcomes than with hospital-managed care, mainly due to improved retention^[9,10]; there is a broad consensus that to improve early health-seeking behaviour, promote adherence to medication, and minimise defaulting, HIV care is best

provided as close as possible to the patient's home and community. These lessons for patient support are clearly applicable to DR-tuberculosis because default rates from care commonly exceed 20%^[11]. In most high-burden settings, the DR-TB epidemic is driven primarily by direct transmission of DR-TB strains. Therefore, efforts to reduce transmission should be directed at diagnosing and treating as many cases as possible and as early as possible^[12].

Our analysis also demonstrates that decentralized DR-TB treatment Centres at district level could be an intervention that has benefits for the patients in terms of prompt treatment initiation for almost 90-95% of lab confirmed DR-TB patients in lesser time, travel distance and cost for treatment initiation. This also can benefit the health system due to its low cost, further integration and enhanced ownership by harnessing district hospital services.

Limitations: Our study had limitations in terms of detailed data related to reasons for non-initiation of treatment before the decentralization leading to inability to compare the reasons before and after decentralization. Lack of data on financial implications on patients or health system before and after decentralization was an issue in analysis cost-effectiveness of the approach.

Conclusions: We conclude by recommending decentralization of DR-TB treatment centres at least upto district level in every district of India as a cost effective intervention to enable prompt initiation of appropriate treatment of lab confirmed DR-TB patients and reducing delay in initiation of treatment. Decentralization also helps in meeting the growing demand for treatment expected with the expansion of rapid molecular test and the move towards universal DST over the next few years thus in turn reducing the chain of transmission effectively.

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