Evaluation of revised national tuberculosis control programme (RNTCP) through treatment activity of pulmonary Tuberculosis and sputum smear conversion of registered TB patients

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Abstract
Introduction: Tuberculosis is a chronic, communicable, infectious disease caused by Mycobacterium tuberculosis bacilli usually affecting lungs primarily resulting in pulmonary tuberculosis.
Objective: to evaluate the Revised National Tuberculosis Control Programme (RNTCP) through to treatment activity of pulmonary Tuberculosis and sputum smear conversion of patients registered for treatment under RNTCP.
Study design: Observational cross-sectional study.
Setting: under District Tuberculosis Centre, Satara involving all the ten Tuberculosis Units (TUs) namely, Umbraj, Satara, Karad, Patan, Vaduj, Koregaon, Wai, Man, Phaltan and Belair.
Participants: Thus fifty (50) slides of sputum smear positive slides for tuberculosis and fifty (50) slides of sputum smear negative slides for tuberculosis were selected randomly.
Sampling: Simple random sampling.
Study period: from 2012 to 2014.
Results: It was found that among pulmonary tuberculosis cases, majority were on Cat-I and the sputum conversion rate among them by 3 months was found >90% in all the tuberculosis units except Bel-Air tuberculosis unit, though the case detection rate is higher in Bel-Air tuberculosis unit the sputum conversion rate was found low in all 3 years. Regarding sputum conversion rate among re-treatment cases the performance of Karad, Vaduj and Dahiwadi, Phaltan, Bel-Air and Wai tuberculosis units was higher in comparison with other tuberculosis units.
Conclusion: Majority of pulmonary tuberculosis cases were on Cat-I treatment and the sputum conversion rate among them has been achieved above the target. Similar with the Cat-II cases except Bel-Air tuberculosis unit where performance of sputum conversion of Cat-I as well as Cat-II is below average.

Keywords: Cat-I, Cat-II, pulmonary tuberculosis, Revised national tuberculosis control programme (RNTCP), Sputum conversion, Tuberculosis units.

Introduction
National Tuberculosis Control Program in India was started in 1962 with the aim to detect cases at the earliest and treatment. The program was implemented in the district through District Tuberculosis Centre (DTC) and the Primary Health Care Institutions with support from state level organizations for coordination and supervision of the program. Despite the existence of National Tuberculosis Control Programme since 1962, tuberculosis remains the leading infectious cause of death in India. Around 2.2 million people are detected to have tuberculosis every year (25% of the global cases) and over 0.5 million die of this disease every year (17% of global tuberculosis deaths). Total population suffering from active disease in India is 14 million of which 3 to 3.5 million are positive for sputum (20% to 25% of total). About one million sputum positive cases are added every year.

India has the largest number of tuberculosis cases in the world, accounting for nearly one fifth of the global burden. Tuberculosis is responsible for 5% of all death worldwide and 9.6% of adult deaths in the 15-59 years old economic productive age groups. The case fatality rate of tuberculosis is high, approximately 50% of untreated cases die of the disease. One out of every three HIV/AIDS (Human Immuno deficiency Virus/ Acquired Immuno deficiency Syndrome) patients has tuberculosis. The latest WHO report on the global status of Multi Drug Resistant (MDR) tuberculosis lists Henan Province, China as a hot spot for its high number of MDR-TB cases. Around 5.3% of new tuberculosis cases in China are Multi Drug Resistant. The key of this strategy is to cure tuberculosis through Directly Observed Treatment at a time and place convenient to the patient. Case finding is passive detection by means of a patient friendly and clinically efficient services based primarily on smear microscopy. Thus the current study is an attempt to evaluate the RNTCP through to treatment activity of pulmonary Tuberculosis and sputum smear conversion patients registered for treatment under RNTCP in Tuberculosis Units of Satara district, Maharashtra.
Materials and Methods
The present record based, observational cross-sectional study was carried out under District Tuberculosis Centre, Satara involving all the ten Tuberculosis Units namely, Umbraj, Satara, Karad, Patan, Vaduj, Koregaon, Wai, Man, Phaltan and Belair. District Tuberculosis Centre is located in the campus of District Hospital, Satara. The functioning of RNTCP under District Tuberculosis Centre at the level of TU’s was studied from 2012 to 2014.

Data collection
The data collection regarding performance of each Tuberculosis Units was carried out retrospectively by obtaining information regarding case detection activities under RNTCP like staffing pattern, their position and training. Information was obtained pertaining to diagnostic activities. Investigator visited each tuberculosis units and collected information through the laboratory registers, referral registers and treatment registers. To access the functioning of Designated Microscopic Centres (DMC) in the form of microscopic activities like sample collection, slide preparation, procedure, examination of slides, disinfection of collected samples and slides. One DMC was selected randomly from each tuberculosis unit. Thus total 10 DMC were visited to access microscopic activities at DMC level.

Random Blinded Re-Checking (RBRC) of sputum smear positive slides and sputum smear negative slides for tuberculosis was carried out. From each DMC five sputum smear positive slides for tubercle bacilli and five sputum smear negative slides for tubercle bacilli were selected randomly from each DMC. Thus fifty (50) slides of sputum smear positive slides for tuberculosis and fifty (50) slides of sputum smear negative slides for tuberculosis were selected randomly. All the selected slides were re-examined by the laboratory technician of respective Designated Microscopic Centre in the presence of Medical Officer and Investigator. Investigator was observing the procedure of slide preparation, method of disinfection and method of slide examination by laboratory technician. The verification of obtained results were carried out in comparison with the original results by the Medical Officer in the presence of Investigator.

Performance indicators:
For the evaluation of Revised National Tuberculosis Control Programme following indicators pertaining to treatment activity and sputum smear conversion were calculated:

1. Proportion of Pulmonary tuberculosis cases on treatment.
2. Proportion of Extrapulmonary tuberculosis cases on treatment.
3. Sputum smear conversion rate for Cat-I.
4. Sputum smear conversion rate for Cat-II.

Ethical issues
1. Written permission from District Tuberculosis Officer was obtained. 2. Verbal permission from Medical Officer of each Tuberculosis Units was obtained. 3. Individual informed verbal consent was obtained telephonically from each patient before initiating interview.

Statistical analysis
Data was entered in Excel and Tuberculosis Units wise proportions and performance indicators pertaining to treatment activity and sputum smear conversion were calculated for years 2012, 2013 and 2014.

Results
At district tuberculosis centre in 2012, out of total tuberculosis cases 2875 (84%) were pulmonary tuberculosis cases. Total 2503 pulmonary tuberculosis cases were on treatment at various sub-district level under district tuberculosis centre, of which 1951 (77.9%) were on Cat-I and 552 (22.1%) were on Cat-II. It was observed that overall pulmonary tuberculosis patients on Cat-I showed 91.8% sputum conversion rate at the end of 3months, whereas 65.8% sputum conversion rate at the end of 3months was found among Cat-II patients.

Out of all pulmonary tuberculosis cases on treatment maximum (>80%) proportion of Cat-I cases were seen registered at Belair, Dahiwadi, Vaduj, Koregaon and Umbraj tuberculosis units. However in Karad TU (67%) and Satara TU (69%) Cat-I cases were registered less in comparison with other TU’s. On the contrary higher proportion of Cat-II patients were found registered in Karad (33%) and Satara (31%) tuberculosis units. These high rates of patients on Cat-II at Karad and Satara might be due to these two TU’s are linked with tertiary care centres.

Regarding sputum conversion rate more than 90% sputum conversion was reported by all TU’s except Bel Air where sputum conversion rate among Cat-I patients was found 86.3%. Sputum conversion rate among Cat-II patients was achieved higher by the TU’s Dhawadi (81%), Vaduj (80.8%), Karad (80%), Umbraj (75%), Belair (67.5%) and Patan (65%). Table 1

| TB Units | Total TB | PTB | Ref for Treatment | PTB (on treatment) | CAT I | CAT II | Sp con Cat I | Sp Con Cat II |
|----------|----------|-----|------------------|-------------------|-------|--------|-------------|-------------|
| Umbraj   | 265      | 220 | 7                | 213               | 172(80.6) | 41(19.2) | 91.8        | 75          |
| Satara   | 610      | 484 | 177              | 307               | 212(69) | 95(31)  | 91.4        | 41.8        |
| Karad    | 524      | 467 | 134              | 333               | 223(67) | 110(33) | 91.4        | 80          |
| Patan    | 331      | 302 | 4                | 298               | 231(77.5) | 67(22.5) | 94.2        | 65.6        |
| Vaduj    | 244      | 216 | 5                | 211               | 176(83.4) | 35(16.6) | 94.1        | 80.8        |
At district tuberculosis centre in 2013, out of total tuberculosis cases 3000 (83.5%) were pulmonary tuberculosis cases. Total 2640 pulmonary tuberculosis cases were on treatment at various sub-district level under district tuberculosis centre, of which 2090 (79.2%) were on Cat-I and 550 (20.8%) were on Cat-II. It was observed that overall pulmonary tuberculosis patients on Cat-I showed 91.2% sputum conversion rate at the end of 3months, whereas 61% sputum conversion rate at the end of 3months was found among Cat-II patients.

Out of all pulmonary tuberculosis cases on treatment maximum (>80%) proportion of Cat-I cases were seen registered at, Dahiwadi, Satara and Koregaon tuberculosis units. However in all other TU’s, the Cat-I cases registered were more than 70%. In case of Cat-II cases, higher proportion of Cat-II patients were found registered in Karad (25.4%), Patan (24%), Vaduj (23.3%) tuberculosis units.

Regarding sputum conversion rate more than 90% sputum conversion was reported by all TU’s except Belair where sputum conversion rate among Cat-I patients was found 82.2%. Sputum conversion rate among Cat-II patients was achieved higher by the TU’s Phaltan (91.3%), Belair (77.1%), Patan (70%), Koregaon (64.3%), Karad (62.1%) and Wai (60%).

Table 2: Treatment activities of pulmonary tuberculosis at sub-district level for the year 2013

| TB Units | Total TB detected | PTB | Ref. for Treatment | PTB (On treatment) | CATI | CATII | Sp con Cat I | Sp con Cat II |
|----------|-------------------|-----|-------------------|-------------------|------|-------|-------------|-------------|
| Umbraj   | 256               | 195 | 9                 | 186               | 147(79)| 39(21)| 94.5        | 56.3        |
| Satara   | 609               | 485 | 125               | 360               | 290(80.5)| 70(19.4)| 91.9        | 48.4        |
| Karad    | 532               | 470 | 135               | 335               | 250(74.6)| 85(25.4)| 91.1        | 62.1        |
| Patan    | 368               | 334 | 9                 | 325               | 247(76)| 78(24)| 90.5        | 70          |
| Vaduj    | 256               | 225 | 6                 | 219               | 168(76.7)| 51(23.3)| 93.5        | 45          |
| Koregaon | 237               | 201 | 0                 | 201               | 161(80.1)| 40(19.9)| 91.5        | 64.3        |
| Wai      | 276               | 223 | 34                | 190               | 149(78.4)| 41(21.6)| 90.6        | 60          |
| Dahiwadi | 193               | 169 | 1                 | 168               | 157(93.4)| 11(6.5)| 94          | 36.8        |
| Phaltan  | 316               | 266 | 11                | 255               | 201(78.8)| 45(17.6)| 92.5        | 91.3        |
| Bel Air  | 549               | 432 | 31                | 401               | 311(77.5)| 90(22.4)| 82.2        | 77.1        |

At district tuberculosis centre in 2014, out of total tuberculosis cases 2589 (818%) were pulmonary tuberculosis cases. Total 2253 pulmonary tuberculosis cases were on treatment at various sub-district level under district tuberculosis centre, of which 1754 (77.8%) were on Cat-I and 499 (22.1%) were on Cat-II. It was observed that overall pulmonary tuberculosis patients on Cat-I showed 90.2% sputum conversion rate at the end of 3months, whereas 67% sputum conversion rate at the end of 3months was found among Cat-II patients.

Out of all pulmonary tuberculosis cases on treatment maximum (>80%) proportion of Cat-I cases were seen registered at all tuberculosis units. However in Karad TU (73.7%) and Wai TU (72.2%) Cat-I cases were registered less in comparison with other TU’s. On the contrary higher proportion of Cat-II patients were found registered in Karad (26.3%) and Satara (25.9%) tuberculosis units. These high rates of patients on Cat-II at Karad and Satara might be due to these two TU’s are linked with tertiary care centres.

Regarding sputum conversion rate for Cat-I, more than 90.2% sputum conversion was reported at DTC, but less than 90% was reported by Belair (80.8%), Satara, Wai (88.6%) and patan (89.4%) Sputum conversion rate among Cat-II patients was achieved higher by the TU’s Dhawadi (81.3%), Koregaon (78.3%), Belair (77.1%), Phaltan (75%), Umbraj (64%), Vaduj (60.9%), and Patan (60%).

Table 3: Treatment activities of pulmonary tuberculosis at sub-district level for the year 2014.

| TB Units | Total TB detected | PTB | Ref. for Treatment | PTB (On treatment) | CATI | CATII | Sp con Cat I | Sp Con Cat II |
|----------|-------------------|-----|-------------------|-------------------|------|-------|-------------|-------------|
| Umbraj   | 258               | 202 | 7                 | 195               | 154(79)| 41(21)| 95.5        | 64          |
Sputum conversion rate for Cat-I cases was above 90% in all the years for tuberculosis units, Umbraj, Karad, Vaduj, Koregaon, Dahiwadi and Phaltan. Whereas the sputum conversion rate was found decreased in 2014 in comparison with year 2012 and 2013 in TU’s Satara, Patan, Wai and Belair. In Belair sputum conversion rate was consistently on lower side than other TU’s since 2012 to 2014. Fig. 1.

Sputum conversion rate for Cat-II cases was above 60% in all the years at district tuberculosis centre. In year 2012 the sputum conversion rate was maximum seen at Dahiwadi and Vaduj TU’s, with least at Satara TU. The sputum conversion rate for Cat-II patients at Dahiwadi TU was much high in year 2012(81%) compared to year 2013 (36.8%) the same finding are observed at Vaduj TU. Whereas the sputum conversion rate for Cat-II at Satara TU remained constantly below 50% throughout the years. Fig. 2.

Discussion
In 2012 out of 3427 tuberculosis cases detected at the level of District Tuberculosis Centre 84% (2875) were pulmonary tuberculosis cases. Out of these cases 13.4% cases were referred to other Tuberculosis Units within the District Tuberculosis Centre, Satara and 2503 cases were pulmonary tuberculosis cases registered for treatment. Among these 2503 patients almost 78% were on Cat-I and 27% were on Cat-II. Majority of tuberculosis units had the patients on Cat-I (>80%), whereas Cat-II patients were registered in high proportion by Satara and Karad Tuberculosis Units (31% and 33% respectively). In 2013 total pulmonary tuberculosis cases 83.5% (3000) of which 12% were referred for treatment to other Tuberculosis Units within the district and 88% (2640) were kept on treatment. Out of 2640 pulmonary tuberculosis cases on treatment,79% were on Cat-I. Dahiwadi Tuberculosis Unit has reported maximum cases on Cat-I (93.4%), whereas high proportion of Cat-II cases were registered for treatment in tuberculosis units Karad (25.4%) and Patan (24%). In 2014 similar to 2012 almost 13% of pulmonary tuberculosis cases were referred within the district for treatment and 87% were kept within the tuberculosis units for treatment. Out of 2253 pulmonary tuberculosis cases on treatment almost 80% were on Cat-I. Similar to the findings of 2013, Dahiwadi TU reported highest cases of Cat-I patients (90.8%) followed by Bel-Air TU (81.8%). Category-II cases on treatment was reported highest by Wai (27.7%), Karad (26.3%) and Satara (25.9%) Tuberculosis Units. It was seen that the Cat-II pulmonary tuberculosis cases on treatment was reported higher from the Tuberculosis Units who have been attached to tertiary care centres where specialized health care personnel’s were available. Many studies have reported high proportion of pulmonary tuberculosis cases on Cat-I similar to the present study from 81% to 95.5%. A Mishra et al.3 and Abhijit M et al.4, A L.DaCosta et al.5 have reported the patients on DOT, non DOT category though the non DOT category is phased out. This non DOT category was not found in any of Tuberculosis Units of present study area nor reported by the reference studies.

Sputum conversion rate for the patients on Cat-I was found declined from 91.8% in 2012 to 90.2% in 2014. Sputum conversion rate was reported >90% by all the Tuberculosis Units except Bel-Air TU in 2012 and 2013. The overall decline might be due to decrease in sputum

| Category | 2012 | 2013 | 2014 |
|----------|------|------|------|
| Satara   | 565  | 468  | 159  |
| Karad    | 417  | 345  | 98   |
| Patan    | 311  | 269  | 5    |
| Vaduj    | 180  | 149  | 0    |
| Koregaon | 226  | 171  | 7    |
| Wai      | 205  | 167  | 0    |
| Dahiwadi | 163  | 142  | 0    |
| Phaltan  | 295  | 225  | 13   |
| Bel Air  | 544  | 451  | 40   |
| DTC      | 3164 | 2589 | 336  |

*figures in parenthesis are percentages*
conversion rate among Cat-I pulmonary tuberculosis cases in Satara, Patan and Wai Tuberculosis Units. However all the Tuberculosis Units of current study except Bel-Air have achieved targets given for three months sputum conversion for Cat-I (≥90%) as per Revised National Tuberculosis Control Programme (RNTCP) guidelines. Almost similar rate sputum conversion by three months of Cat-I pulmonary tuberculosis cases was reported by Bawri S et al. Simmi Tiwari et al reported achievement below average (84%) and . S Biso, et al also found poor conversion rate (74%) among new sputum positive cases.

Sputum conversion rate by three months of re-treatment cases was found minimum of 41.8% (Karad TU) to maximum of 81% (Dahiwadi TU) in 2012. In 2013 very low level of sputum conversion among Cat-II patients was reported by Dahiwadi Tuberculosis Unit (36.8%) in contrast to sputum conversion rate in 2012 (81%) and in 2014 (76.5%) in the same Tuberculosis Unit. It was found that Karad TU have reported consistently low level of sputum conversion rate among re-treatment cases during all the three years. Whereas Phaltan and Koregaon Tuberculosis Unit have shown consistent improvement in sputum conversion rate among re-treatment cases. A Mishra et al reported 56% of sputum conversion rate among re-treatment cases and Md Shamim Akhtar et al have reported very low level of sputum conversion rate among re-treatment cases, in contrast to these studies Gurpreet K et al reported highest sputum conversion rate among Cat-II patients. The consistent low level of sputum conversion rate among Cat-II patients in Karad tuberculosis unit may be due to majority of patients were on Cat-II and who might have got infected with drug resistant tuberculosis cases (MDR-TB) and referred to the tertiary care centre where medical college is located.

**Conclusion**

Majority of pulmonary tuberculosis cases were on Cat-I treatment and the sputum conversion rate among them has been achieved above the target. Similar with the Cat-II cases except Bel-Air tuberculosis unit where performance of sputum conversion of Cat-I as well as Cat-II is below average that has also reflected on the cure rate, treatment completion rate and success rate below average and death and transferred out rate is much higher in Bel-Air tuberculosis unit in comparison with other tuberculosis units.

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**Conflict of Interest**

None.

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None.

**Ethical Approval**

Permission for the study was obtained from the College authorities prior to commencement.

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