

# A pilot project: 99DOTS information communication technology-based approach for tuberculosis treatment in Rajkot district

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## ABSTRACT

**Background:** 99DOTS (Directly Observed Treatment, Short course) is a low-cost, mobile phone-based technology that enables real-time remote monitoring of daily intake of treatment, first introduced by the Revised National Tuberculosis Programme under the national programme in 2015 in high-burden antiretroviral therapy (ART) centers. This project was launched for the first time in 2016 in Rajkot district, Gujarat, India, and hence this was an effort to evaluate 99DOTS. **Objectives:** The objective of this study was to evaluate treatment adherence rate and treatment outcome of 99DOTS-information communication technology (ICT)-based approach for tuberculosis (TB) management. **Materials and Methods:** Data from 99DOTS were obtained from February 2016 to September 2017 after obtaining approval from the Institutional Ethical Committee and permission from the head of the department of district TB center (DTC), Rajkot. Data were evaluated for sociodemographic pattern, adherence rate, and treatment outcome. **Results:** A total of total 347 registered patients, 197 (56.77%) patients diagnosed by private practitioners and 150 (43.22%) patients having HIV-TB from ART center were initiated TB treatment under 99DOTS project from nine different talukas of Rajkot district. Mean age of the registered TB patients was  $36 \pm 13.55$  years with predominance of “new cases” ( $n = 275, 79.25\%$ ) and “male” gender ( $n = 257, 74.06\%$ ). The overall treatment adherence rate of 99DOTS was 96.03%, while adherence by “call” was 92.25% and adherence by “manual” was 32.12%. Cure rate was higher in patients with TB only ( $n = 113, 78.47\%$ ) as compared to patients with HIV-TB co-infection ( $n = 46, 67.64\%$ ). Defaulter rate ( $n = 19, 13.19\%$ ) was also higher in patients with TB only, while death rate ( $n = 14, 20.58\%$ ) was higher in patients of TB with HIV co-infection. **Conclusion:** 99DOTS is an effective approach for improving TB medication adherence, thereby increasing the compliance to TB treatment. It will be helpful for easy access of treatment to patients from remote areas, improve notification of patients from private practitioners, and enable differentiated care.

**KEY WORDS:** Antituberculosis treatment, antiretroviral therapy, Directly Observed Therapy, Short course, district tuberculosis center, Revised National Tuberculosis Programme

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## INTRODUCTION

A critical challenge in tuberculosis (TB) treatment is to ensure that patients adhere to the full course of medication.

In India, use of Directly Observed Therapy (DOT) in the public sector has been associated with high treatment

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success. However, DOT introduces challenges for patients who need to undertake frequent travel throughout the course of treatment. It is also challenging for program managers to detect and respond to missed doses in an accurate and timely way.<sup>[1]</sup>

99DOTS (Directly Observed Therapy, Short course) is a low-cost, mobile phone-based technology that enables real-time remote monitoring of daily intake of medication. Research on this novel scheme was carried out by the National Tuberculosis Institute, Bengaluru, in collaboration with St. Johns National Academy of Health Sciences, Bengaluru, and Karma HealthCare.<sup>[2]</sup> 99DOTS introduces anti-TB treatment (ATT) blister pack wrapped in a custom envelop, which includes hidden phone numbers that are visible only when doses are dispensed. This is a novel method and almost foolproof. After taking daily medication, patients will make a free call to the popped-up phone number which is hidden till then, yielding high confidence that the dose was “in-hand” and has been taken. In the event of failure by the patient to call, the senior treatment supervisor (STS) is notified automatically and the STS will follow up with patient and will enter dosage in 99DOTS software. As a very high success rate (of about 99%) is expected by this remote in-built techno-supervision, it is termed as 99DOTS<sup>[3]</sup> [Figure 1] (source: www. 99dots.org).

It was first used under the Revised National Tuberculosis Programme (RNTCP) in 2015 in high-burden antiretroviral therapy (ART) centers for TB-HIV co-infected patients with the use of daily fixed-dose combination medications. In 2016, the RNTCP expanded this ICT-based adherence system to HIV-TB patients at all ART centers in India.<sup>[4]</sup> This 99DOTS pilot project was launched in Rajkot district in February 2016. This study was an effort to evaluate the implementation of pilot project 99DOTS in Rajkot.

**MATERIALS AND METHODS**

Data were obtained from 99DOTS from February 2016 to September 2017 after obtaining approval from the

Institutional Ethical Committee and permission from the head of the department of district TB center (DTC), Rajkot. In 99DOTS, two types of patients were registered as follows:

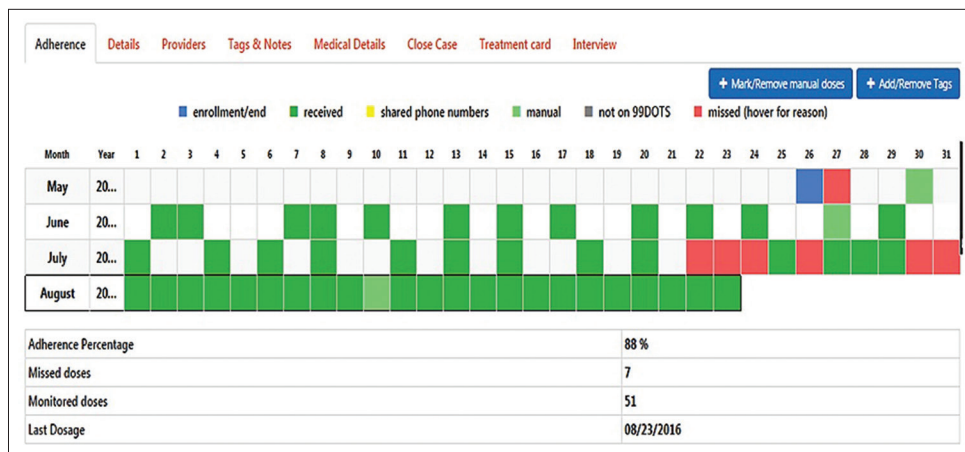
1. TB patients diagnosed by private practitioners who were notified to the DTC and enrolled in 99DOTS program. These patients received standard intermittent ATT blister packs provided by DTC
2. Patients with HIV-TB co-infection who were started on daily ATT as per the RNTCP/National AIDS Control Organization guidelines from ART center and enrolled in 99DOTS program.

Detailed information regarding sociodemographic pattern, treatment outcome, and adherence rate was collected and evaluated. Treatment adherence rate was evaluated which included both adherence by “call” (the blister packs’ list numbers were concealed behind the medicines and this number series is dialed in by the patient to a toll-free helpdesk to register completion of that particular dose of medication) and adherence by “Manual” (if this call from the patient does not come within a stipulated timeframe, then reminders were sent to the patient, which if unheeded was followed up by a visit from the DOT provider or the health worker for necessary support), so the number of doses by reminder or visit were considered as adherence rate by “ manual.”

**RESULTS**

A total of 347 patients were initiated TB treatment under 99DOTS project from nine different talukas of Rajkot district during the study period. Among the 347 patients, 197 (56.77) patients were enrolled under 99DOTS via participation of private practitioners, while 150 (43.22%) patients had HIV-TB co-infection and were started on ATT along with ART from ART centers.

Mean age of registered TB patients was 36 ± 13.55 years with a male predominance. Majority of the patients were new cases and of pulmonary TB and received intermittent



**Figure 1:** Treatment adherence under 99DOTS

treatment. Among the extrapulmonary sites, the most common was lymph nodes (42) followed by pleura (22), abdomen (8), spine (3), and skin (2). Nearly 43.22% of HIV-positive patients had TB and started ATT from an ART center under 99DOTS program [Table 1].

Till the end of September 2017, 212 (61.09%) patients had completed treatment, while the rest were on the treatment.

Adherence rates were calculated in two groups: those who had completed treatment and those who were on treatment at the time of data evaluation (treatment not completed). Overall treatment adherence rate under 99DOTS was 96.03%. Of the total doses, majority of the patients had adherence by both “call” and “manual;” neither patients had 100% adherence by call nor 100% adherence by manual [Table 2].

Cure rate was higher in patients with TB only ( $n = 113$ , 78.47%) as compared to patients with HIV-TB co-infection ( $n = 46$ , 67.64%). Defaulter rate ( $n = 19$ , 13.19%) was also higher in patients with TB only, while death rate ( $n = 14$ , 20.58%) was higher in patients of TB with HIV co-infection [Table 3].

## DISCUSSION

About two-thirds of patients registered under 99DOTS were male. Gender-related factors may impact on notification as well as treatment adherence.<sup>[5]</sup>

Half of the TB patients were registered through private practitioners in this pilot project apart from those covered at ART centers. The project seeks to engage with private practitioners in treating TB patients and providing free-of-cost drugs to patients.<sup>[6]</sup> Over 80% of people with TB first attend the private sector; yet substantial diagnostic delays occur, diagnosis and treatment are of variable quality. This, combined with the absence of drug quality controls, leads to drug resistance. This urgently necessitates enhanced engagement with the largely unorganized and unregulated private sector which accounts for at least half of those treated for TB in India.<sup>[7]</sup> Thus, to build linkages with the private sector and other health-care establishments, the RNTCP has initiated multiple schemes to promote the involvement of private sector. The basic idea behind these schemes is to assist the private partner financially and logistically to improve the quality of work.<sup>[8]</sup> 99DOTS was launched in various parts of India such as Patna in Bihar, Mehsana in Gujarat, Mumbai in Maharashtra, and also in Myanmar in 2016.<sup>[9]</sup> The RNTCP program seeks to implement this strategy across the nation in a phased manner.<sup>[10,11]</sup>

Treatment adherence rate was good (96%) in completed treatment patients. The World Health Organization (WHO) estimates that even in developed countries, less than half of chronic disease patients take medication as directed. This problem is especially dire in the case of TB, where

**Table 1 Socio demographic parameters of patients registered under 99DOTS**

Socio demographic parameters	N=347(%)
Age Mean±SD (Years)	36±13.5
<40 years	232 (66.85%)
>40 years	115 (33.14%)
Gender	
Male	257 (74.06%)
Female	90 (25.93%)
Patient enrolment	
Via private practitioner	197 (56.77%)
Via ART centre	150 (43.22%)
Type of TB patients	
New (cat-1)	275 (79.25%)
Previously treated (cat-2)	68 (19.59%)
Not mentioned	4 (1.15)
Site of tuberculosis	
Pulmonary	114 (33.23)
Extra pulmonary	104 (30.32)
Not mentioned	129 (37.17)
Co morbidities*	
HIV	11 (3.17)
Diabetes -type 2	150 (31.70)

\*162 cases out of 343 had co morbidity

**Table 2: Treatment adherence rate under 99DOTs**

Adherence rate	Treatment completed group	Ongoing treatment group
Overall adherence rate	96.03%	74.60%
*Average adherence rate by call	92.25%	63.79%
Average adherence rate by manual	32.12%	18.83%

\*This table depicts average value of average adherence rate of each patient

**Table 3 Treatment outcomes of TB patients notified under 99DOTS**

Treatment outcome	Tuberculosis, n=144(%)	Tuberculosis and HIV, n=68(%)	Total (n=212)
Cure & treatment completed)	113 (78.47)	46 (67.64)	159 (75.0)
Defaulter	19 (13.19)	7 (10.29)	26 (12.26)
Death	2 (01.38)	14 (20.58)	16 (7.54)
Transfer out	4 (02.77)	0	4 (1.8)
Treatment regimen changed	6 (04.16)	1 (01.47)	7 (3.30)

nonadherence to medication contributed to an estimated 490,000 drug-resistant cases in 2016 globally.<sup>[12]</sup> To boost adherence, countries such as India have long embraced DOTS, where patients travel to clinics to take doses under the direct observation of a care provider. DOTS has seen great success in achieving good cure rate, but it has various limitations. Reasons for nonadherence to DOTS were recognized in WHO's End TB strategy<sup>[13,14]</sup> and these factors greatly limit its reach and effectiveness.<sup>[15]</sup> Since successful treatment relies on proper adherence and monitoring, enhancing adherence is important to safeguard both individual and public health. Ensuring adherence is therefore a key component of WHO's post-2015 global TB strategy – the “End TB Strategy.”<sup>[16]</sup>

Once the 99DOTS platform gets this real-time adherence information, it can be used in multiple ways. Program staff can login into www. 99dots.org from their computer/mobile (using Nikshay username and password) to see the patient

adherence. Customized SMS reminders are also sent to patients and government health-care staff (e.g., TB-health visitor and STS) to alert missed doses and trigger additional counseling. The platform empowers staff with daily information about their patients' adherence and allows them to use differentiated care to counsel those patients who need it the most. Similarly, patients are empowered to take their medication independently and receive immediate outreach if they start to waver in adherence. 99DOTS is also being integrated with Nikshay so that patient adherence can also be visualized in them.<sup>[7]</sup> A successful creation and deployment acceptance of adherence system has more positive feedback effect on attracting patients from private sectors.<sup>[17]</sup>

## CONCLUSION

99DOTS will be a cheaper approach for improving TB medication adherence, thereby increasing compliance to anti-TB treatment. Compared to the current standard of care, 99DOTS offers two key benefits. First, it reduces patients' burden: instead of traveling to a center for every dose, patients can provide evidence of dosing from the comfort of their home. In addition, 99DOTS enables differentiated care: instead of mandating that all patients receive frequent counseling, adherent patients can proceed with less supervision, while limited program resources are focused on cases that need the most attention.

### Challenges for 99DOTS:

- Data entries regarding type of patients (new/previously treated, pulmonary/extrapulmonary) and relevant follow-up investigations were not mentioned in 99DOTS which are essential for the analysis of outcome
- There are some challenges to overcome such as systematically recording treatment outcome of patients whose diagnosis is changed after treatment notification and purchasing drug from outside despite being provided by the RNTCP (UATB Care book)
- An approach for adverse drug reaction those occur during treatment and its management will be questionable.

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## Conflicts of interest

There are no conflicts of interest.

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