Improving Adherence through Tuberculosis Medication Regimen using Tuberculosis Monitoring Encouragement Adherence Drive (TMEAD) Intervention in Nasik City of Maharashtra

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Policy Brief

Summary

The digital adherence technologies (DAT) may have the potential to facilitate medication adherence and monitor adherence remotely. Tuberculosis Monitoring Encouragement Adherence Drive (TMEAD) is one of such modern DATs being piloted in one of the districts (Nasik) in Maharashtra from April 2020 to December 2021. This study had enrolled 400 DSTB patients, 200 each in the intervention and control arm. The study reported overall treatment adherence at 94% among those who completed treatment. Patient reported high levels of treatment adherence in the intervention group (99%) as compared to the Control group (90%). Adherence assessed through analysing trace of Rifampicin in urine sample for intervention arm was 84% compared to control arm (80%). Per beneficiary (discounted) cost for TMEAD was INR 6,573. Incremental cost effectiveness ratio of the intervention is INR 11,599 which shows the intervention is highly cost-effective. This study concludes that, TMEAD could be an opportunistic DATs considering the above adherence, cost factors and could complement the national strategy of TB elimination by improving adherence to the treatment regimen in India.

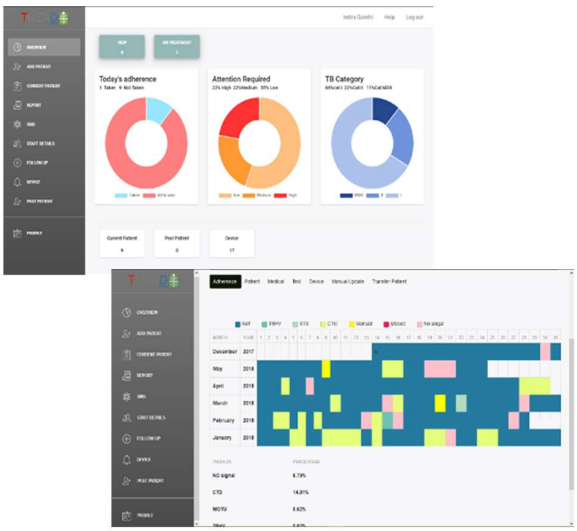

Figure 1: Daily Regime Monitoring and Real Time Tracking

Introduction

As per WHO report 2018, Tuberculosis (TB) is amongst the top 10 leading causes of mortality globally. India has a huge burden of TB accounting for roughly a quarter of the total global burden. Medication adherence is one of the critical challenges to TB elimination in India. Poor medication adherence is associated with an increased risk of death, disea se relapse, and the development of drug resistance. Digital adherence technologies holds promise in treatment adherence. With an understanding of existing challenges of DATs, a Tuberculosis Monitoring Encouragement Adherence Drive (TMEAD) was piloted by a start-up in Maharashtra.

About TMEAD

TMEAD was designed and developed by SenseDose Technologies, a start-up venture supported through India Health Fund, an initiative of TATA Trust. TMEAD helps monitor and ensure patient compliance. It also creates a detailed, automated adherence dashboard of all patients for health workers and policymakers toprioritize their resources towards patient adherence

Figure 2: TMEAD Device

Policy Implications and Novelty

- Evaluation of patient and health worker behaviours and beliefs following implementation of TMEAD will be essential in optimising its acceptability and clinical impact.
- This study shows innovative approaches to adherence, promotion by creating interventions to enhance treatment adherence can improve treatment outcomes.
- TMEAD can complement the national strategy of TB elimination by improving adherence to the treatment regimen.

Aim of the Study

The study aims to assess the adherence (self-reported/digital/clinical) and cost effectiveness of the new DATs i.e. TMEAD, compared to the standard of care for the drug-sensitive tuberculosis (DSTB) patients residing in the urban geography of Nasik City in Maharashtra, India.

Policy Implications and Novelty

Primary objective of the study is to measure treatment adherence (self-reported/digital) of the TMEAD as compared to the standard of care.

Secondary objectives:

- To validate the adherence (clinical) through urine rifampicin levels
- To estimate the cost-effectiveness of the TMEAD as compared to the standard of care for the DSTB patients

Methods

The study was undertaken prospectively at Nasik districts of Maharashtra during 2020-21. The target population for the study were All newly diagnosed TB patients at selected TU as per the NTEP protocols. For Intervention 3TU and control 2TU.Based on an assumption of an increase in the adherence to TB treatment from 80% (as cited from available literature to 95% (as desired under NTEP guideline) with 95% CI and 80% power and 20% of Drop Out / Non-response / Attrition, the sample size in each of the arm was 200.

During the study period, TMEAD was use as a reminder for adherence to treatment in intervention arm and standard of care was followed for control arm.

The study was mixed-method which involved Quantitative Method for longitudinal follow up of the patients assigned in each arms and Qualitative Methods by interviews with key informant and In-depth interview of the family members and DOTS supporters to document the acceptance of technology and challenges if any. Adherence was also assessed by analysing trace of rifampicin in urine among 20% of patients enrolled from both arms.

Health-related quality of life (HRQoL) was assessed using the EQ-5D-5L tool at baseline and follow-up.

Transition probabilities were derived from primary as well as secondary literature. Time horizon of the study was one year and 3% discounting was applied. One-way sensitivity analysis was carried out by varying model parameters to estimate uncertainty in all parameters.

Conceptual framework for Decision tree model

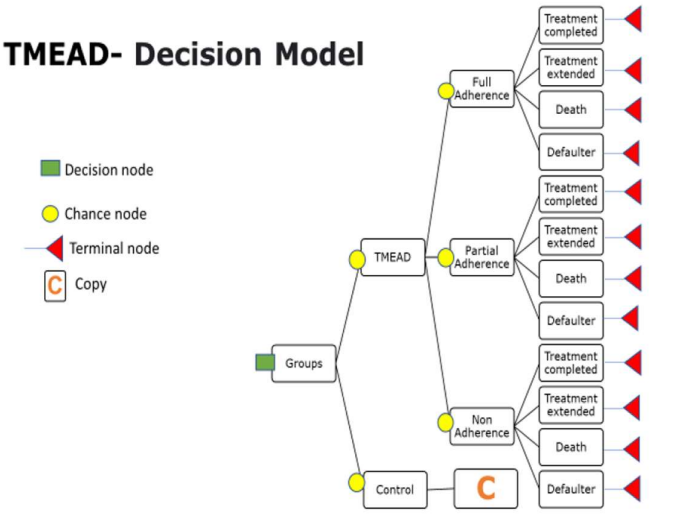

Figure 3: Decision tree model

Results

Overall adherence was 94% among those who completed treatment. Adherence in the intervention arm was 99% compared to 90% in the control arm. The average adherence reported by TMEAD devices was 88.2% in intervention group. Point adherence among those who are on treatment was 97.4% with higher adherence reported in the intervention arm (98.7%) compared to 95.24% in control arm. The adherence reported by urine rifampicin analysis was 76% in the intervention arm and 72% in the control arm.

Outcomes	Intervention	Control
Cost (in INR) per patient treated as per modelling	6573	4764
Difference in Cost (in INR)	2042.17	
Difference in QALYs	0.176	
ICER	11,599.46	

Table 1: Incremental Cost-Effectiveness Ratio (ICER)

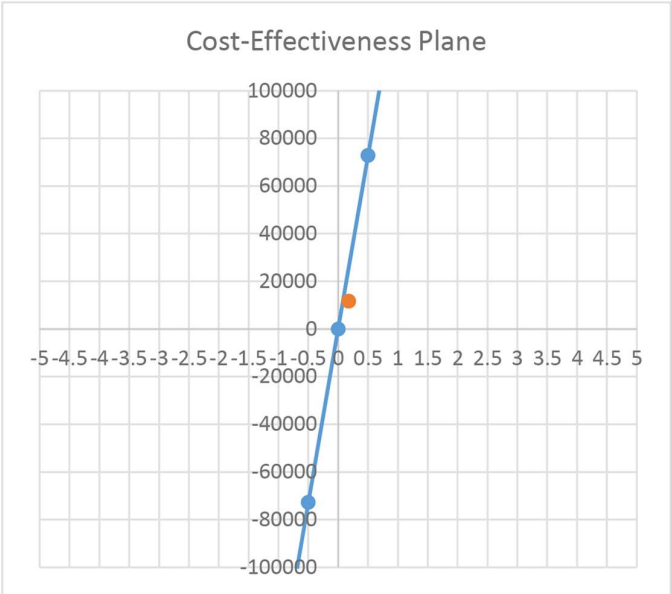

Figure 4 illustrates cost-effectiveness plane. Orange dot indicates ICER value which falls in the North East quadrant. It means intervention is costly than comparator but highly effective.

The tornado diagram of one-way sensitivity analysis shows that ICER value is slightly changed when the input parameters were changed in multiple indicators. The cost of control arm, the cost for full adherence in the treatment completed group, QALYs among the full adherent patients in both intervention and control arm, the cost for defaulters among partial adherent to control arm were key parameters that influence the model.

Budget impact analysis shows that in-order to scale up the TMEAD intervention for DSTB to the entire state of Maharashtra, the burden on the exchequer will be to the tune of 55 crores. This is just 0.02% of Maharashtra's annual health budget of 3232 crores. Further, it is important to remember that the intervention was found to be cost-effective from a health system perspective.

Conclusion

This study revealed that patient-reported treatment adherence was high in TMEAD as compared to standard therapy of care for the DSTB patients and the intervention is cost-effective. This study shows innovative approaches to adherence, promotion by creating interventions to enhance treatment adherence can improve treatment outcomes. TMEAD can complement the national strategy of TB elimination by improving adherence to the treatment regimen.

Acknowledgement

This study was supported through India Health Fund - A Tata Trust Initiative.

DHR provided a supplementary grant for urine rifampicin analysis.