Closing the Gaps in the TB Care Cascade (CGC) Project

Strengthening Adherence Monitoring Mechanism for TB Treatment: Field Experiences

Acknowledgment

Disclaimer

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Acronyms & Abbreviations

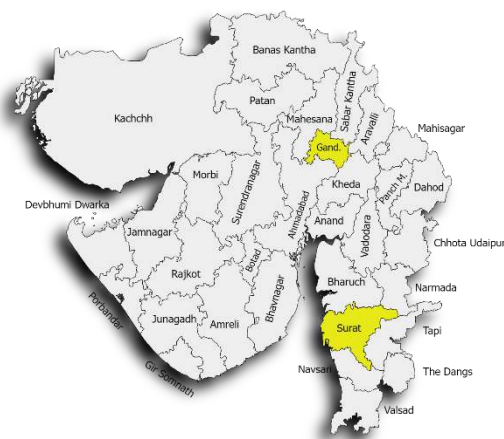|	
CC	Care Coordinators
CGC	Closing the Gap in TB Care Cascade
CHO	Community Health Officer
CXR	Chest X-ray
DAT	Digital Adherence Technology
DBT	Direct Bank Transfer
DMC	Designated Microscopy Centre
DOT	Direct Observed Treatment
DRTB	Drug-Resistant Tuberculosis
DSTB	Drug Sensitive Tuberculosis
DTO	District TB Officer
IDAT	Integrated Digital Adherence Technology
IIPHG	Indian Institute of Public Health, Gandhinagar
MERM	Medication Event and Reminder Monitor
MPHW	Multipurpose Health Worker
NPY	Nikshay Poshan Yojana
NTEP	National Tuberculosis Elimination Program
PHI	Public Health Institution
STS	Senior Treatment Supervisor
TB	Tuberculosis
TFN	Toll-Free Number
TU	TB Unit
UHC	Universal Health Coverage
WHP	World Health Partners

Content

About the CGC project and project Geographies

Closing the Gaps in TB Care Cascade (CGC) is a consortium of organizations led by World Health Partners (WHP), India, along with the Institute of Public Health Gandhinagar and Everwell Health Solutions Pvt. Ltd. To address the gaps effectively, the project designed an implementation and monitoring framework related to the TB care cascade and is demonstrating intervention models. The TB care cascade visualizes various stages of gaps in care delivery. Critical gaps identified include loss of patients due to their ability to access TB diagnostic tests; prescription of an accurate diagnosis; access to TB treatment; adherence to daily medication; and maintaining TB-free status post-the-treatment. The project also addresses cascades for TB sub-populations with DR-TB, comorbidities, and other high risks.

Project Geographies:

State - Jharkhand (Ranchi, East Singhbhum)   *State- Gujarat (Surat, Gandhinagar)*

Project Geographies - Jharkhand & Gujarat

Summary of the TB units and peripheral health institutions under the CGC project, India			
District	Population	TU	PHI/DMC
East Singhbhum	0.6 million	10	19
Ranchi	1.5 million	15	28
Gandhinagar	0.3 million	5	51
Surat	4.4 million	27	144
TU: TB Units, PHI: Peripheral Health institutions, DMC: Designated Microscopy Centre,			

Section 1

1.1 Background and Rationale

1.1.1 Introduction

Tuberculosis (TB) is one of the global public health concerns, as approximately 1.5 million people died from TB in 2020. [1] Treatment and preventive efforts are made on a large scale to combat the disease burden worldwide. Adherence to TB treatment is one of the crucial factors that affect the disease outcome amongst the several factors.

India has the highest burden of Tuberculosis (TB) and Multidrug-resistant (MDR) TB, according to the estimates reported in the Global TB Report 2021. Although the recent data shows a declining trend of TB prevalence, the absolute number of new cases remains high. India has set the target to achieve End TB Goals by 2025 with robust implementation of National Tuberculosis Elimination Program (NTEP) interventions. Around 85% of people who develop TB can be successfully treated with a 6-month drug regimen. Thus, early treatment has the additional benefit of curtailing onward transmission of infections. Since 2000, proper TB treatment has averted more than 60 million deaths. However, many millions have also missed diagnosis and care as access to services still falls short of universal health coverage (UHC). [1] [2]

There is still a sizable global gap between the estimated number of incident cases (10.0 million, range 8.9–11.0 million, in 2019). Out of those, 2.5 million cases are undetected due to underreporting and underdiagnosis. [3] Apart from the disease, social determinants also contribute to the causation of TB and its adverse outcomes. [4] Approximately 14.1 million people have received treatment for TB in 2018 and 2019 globally, against the target of reaching up to 40 million by 2022. Globally, the coverage for TB treatment has increased from 59% (range, 52-67%) in 2015 to 71% (range, 64-79%) in 2019. [1]

In India, almost 95% of the notified TB patients initiated treatment during 2020, with 98% in Jharkhand and 99% in Gujarat. The cure rate for TB patients in India is 61% (72% for Gujarat and 58% for Jharkhand) which may determine multiple factors affecting the treatment and its completion among TB patients. Poor adherence to the treatment could be one of the crucial factors affecting the poor outcome of treatment amongst TB patients. [5]

Once notified, TB patients are followed up by the healthcare providers for routine medical check-ups. The regimen for treating TB patients depends on the number of TB drugs found to be resistant in various investigations carried out at the facility level. TB patients may be required to consume medicines ranging from 6 months to 2 years, depending on their susceptibility to the TB drugs. Patients frequently have irregular adherence to TB treatment during this long period, resulting in

poor treatment outcomes. A patient with more than 10% missed doses will have a 5.7 times higher chance of recurrence of TB disease. In comparison, patients with irregular uptake of medicines will have 2.6 times higher chances of relapse in TB conditions. [6] [7]

Several factors were found to affect the adherence of TB patients, including literacy, transportation mode, time spent for medication refill at a health facility, occupation, financial condition, lack of food, lack of job, psychological factors, lack of social support, alcohol consumption, HIV status, etc. [8] [9]

Several interventions have been implemented by national TB programs to support TB patients in their adherence to treatment for many years. These interventions include social support (e.g. food, financial incentives, and transportation fees), psychological support, home visits (e.g. direct observation of treatment, or DOT), and medication monitoring and staff education. In contrast, other digital health interventions have been recently introduced (such as SMS messages, telephone calls or other reminders, video observation of treatment, or VOT). The interventions should be selected based on assessing individual patients' needs, providers' resources, and conditions for implementation. Various studies reported higher rates of treatment completion and lower rates of loss to follow-up when DOT is provided at the community level; that's why the DOTs and Treatment Supporter concept came into the guideline. [10] It was also seen that Factors like the education status of TB patients, knowledge of health care providers, incentives, psychological interventions, regular monitoring of medication, and use of mobile digital technologies when intervened correctly had shown promising results in the adherence and health condition of TB patients. [11]

1.1.2 Potential of Adherence Monitoring Intervention

Adherence to TB treatment has shown a significant impact on the outcomes of patients. DATs will support TB patients for regular adherence and compliance with minimum effort, time, and transportation barriers. Adherence monitoring had been severely affected due to the absence of clear guidance under NTEP. Inadequate uptake of DATs and suboptimal monitoring of adherence indicators have significantly affected the programmatic outcome. The CGC project undertook comprehensive adherence monitoring intervention to improve the adherence of TB patients and their treatment outcomes.

World Health Partners (WHP) has implemented the "adherence monitoring '' intervention in Gujarat (Gandhinagar, Surat Rural, Surat Municipal Corporations) & Jharkhand (Ranchi, East Singhbhum) and the Indian Institute of Public Health, Gandhinagar (IIPHG) has undertaken the documentation of these interventions to support the scale up. The document explains the process flow during the implementation phase and the lessons learned during the implementation.

This intervention is designed to monitor TB patients on treatment systematically. Real-time adherence monitoring is relatively easy with digital technologies.
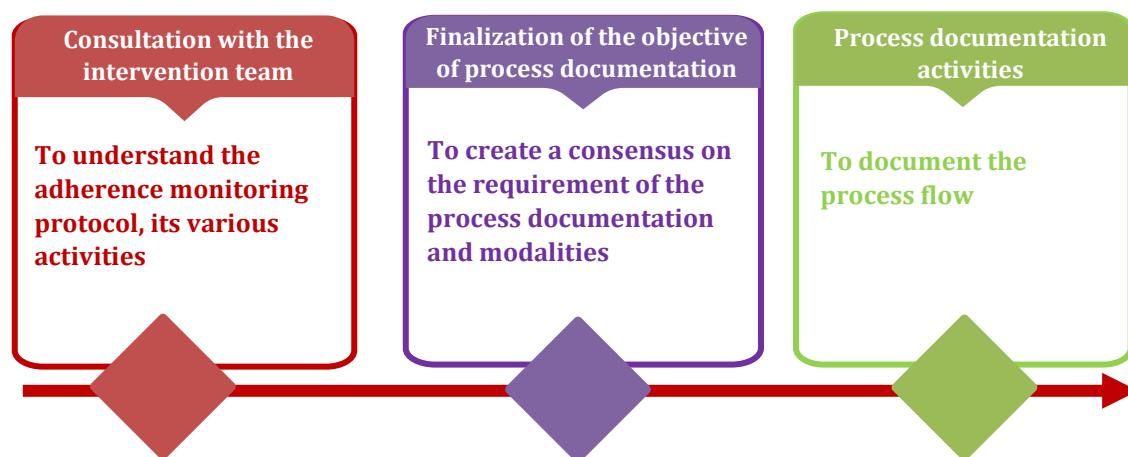
1.2 Objectives

The CGC project demonstrated an adherence monitoring mechanism with the usage of DAT and Nikshay features with the below objectives:

- To develop a "Comprehensive adherence management model" for improved adherence management of TB patients in public and private sectors.
- To generate evidence and learnings to establish a systemic approach for scale-up of the intervention into the National Guidelines.

Activities undertaken to document the flow of the process documentation.

Various activities were undertaken for the documentation of adherence monitoring flow. All the activities are listed below:

Consultation with the intervention team	Finalization of the objective of process documentation	Process documentation activities
To understand the adherence monitoring protocol, its various activities	To create a consensus on the requirement of the process documentation and modalities	To document the process flow

- **Consultation with the intervention team:** The initial consultation was done with all the stakeholders from WHP to understand the adherence monitoring protocol, its various activities, and the involvement of the multiple partners and the existing health system.
- **Finalization of the objective of process documentation:** The consultation was also done with all stakeholders from the WHP team and IIPH Gandhinagar team to create a consensus on the requirement of the process documentation and modalities of the process documentation.
- **Process documentation activities:** Various activities were carried out to document the process flow of the adherence monitoring.

    a. **Secondary evidence generation:** Various literature in research papers and reports on TB and adherence to treatment and efforts to improve adherence had been searched to support the document.

b. **Continued consultation with the intervention team:** The meetings were conducted weekly with thematic Leads. The meeting intended to share the field feedback, inputs, and learnings from the thematic leads, Strategy leads, or any other updates on the protocol or intervention processes.

c. **Primary evidence generation through field visits:** The documentation team from IIPHG visited patients, thematic leads, care coordinators, and the stakeholders from the health system to understand the flow of the process and field-level challenges. Personal interviews with stakeholders were also conducted to understand the intervention's process, challenges, learnings, and monitoring mechanisms.
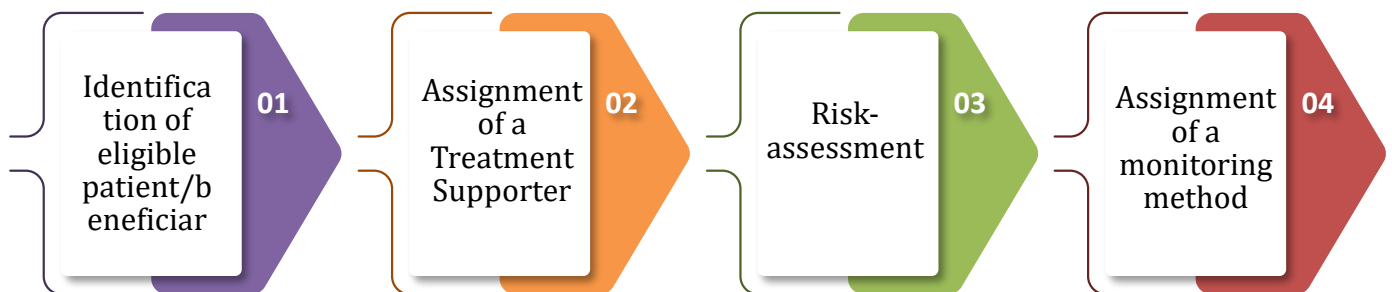
Section 2

2.1 Demonstration of Adherence Monitoring

Adherence monitoring intervention was rolled out in all the four selected geographies of the CGC project, i.e. Gandhinagar and Surat in Gujarat and East Singhbhum and Ranchi in Jharkhand.

The intervention was introduced to establish and strengthen a system of adherence reporting through IDAT introduction complemented by field-level responses by NTEP and the general health system. The key activities were to roll out adherence monitoring methods, conduct extensive training of NTEP staff to sensitize them on adherence metrics and routine monitoring, ensure real-time adherence monitoring, and expand Nikshay access to more users such as CHO and MPHW.

Adherence management workflow starts with the individual eligible for treatment as indicated below (details provided in subsequent sections), followed by continuous monitoring throughout the treatment.

Treatment Initiation:

Identification of eligible patient/beneficiar	01	Assignment of a Treatment Supporter	02	Risk-assessment	03	Assignment of a monitoring method	04

During treatment, patient escalation/de-escalation based on the risk assessment and treatment adherence is carried out till the completion of treatment.

Monitoring through Treatment:

Patient escalation for follow-up	01	Adherence Intervention support	02	Patient outcome assigned & validated	03
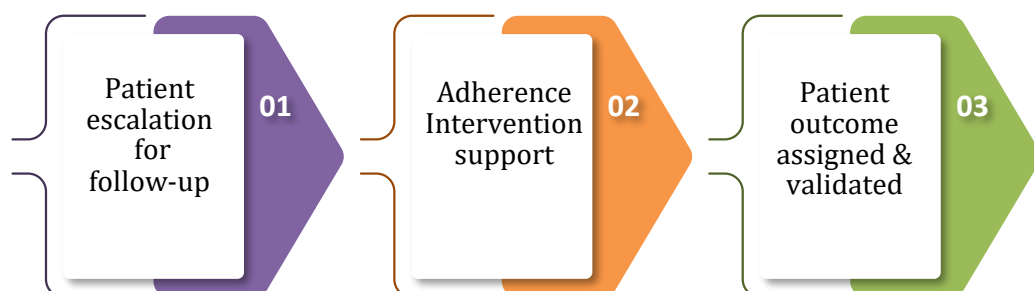
2.1.1 Adherence Monitoring Methods

The introduction of a daily regimen by NTEP has shifted treatment to a more patient-centric model with fewer facility-level visits required by patients and more autonomy over their drug consumption. Daily regimens have also altered the requirements of adherence monitoring, with the availability of newer digital adherence support tools integrated into Nikshay, making it a comprehensive patient management platform.

Various adherence monitoring methods are described below, which provide inputs into Nikshay. Each monitoring method has its potential and limitations.

Any adherence method(s) selected should meet the objective of supporting patients through treatment and not prioritize patient "observation" over patient access to services or quality of care.

a. Directly Observed Treatment (DOT)

Directly observed therapy (DOT) has been the historical standard of care for TB adherence management, whereby patients take their TB medication in the presence of a DOT provider. This method allows for close monitoring of patient adherence but is resource-intensive.

b. Digital Adherence Technologies (DAT)

99DOTS
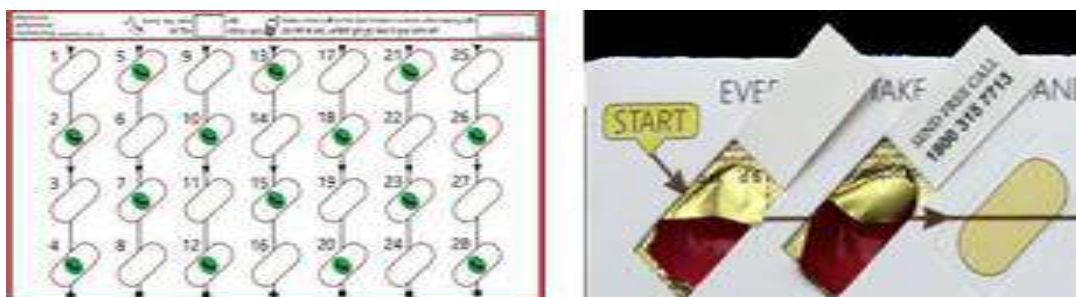
Patients received FDCs packaged in customized envelopes with a series of hidden free call numbers behind the pills. Each time a patient takes a dose of medication, a hidden number is revealed, which is unpredictable. The patient makes a free call to the number, which indicates a dose taken in Nikshay 2.0.

99 DOTS Lite (Sticker and Box)

- 99 DOTS Lite Sticker Model:
  Each TB medicine blister pack is affixed with a sticker containing the toll-free number (TFN). On which patients make a free call daily after taking their medicines. The call is recorded on Nikshay to indicate dose ingestion. Patients can save the number on the phone and call the same

number for the duration of the blister (instead of a new number each day). 99 Sticker models are available for DS-TB patients who have been prescribed FDC.

The Sticker is made of vinyl material and has a strong adhesive that makes it resistant to wear and tear and does not lose its stickiness with prolonged storage and use.

o   Single sticker model (East Singhbhum): A single toll-free number (TFN) Sticker was used for all patients in the IP Phase, and a single TFN Sticker was used for all patients in the CP Phase.

o   Unique sticker model (Ranchi): Each blister had a different toll-free number

● 99 DOTS Lite Box Model:

Patients are provided with a plastic container (6*4 inch) to store the monthly stock of the medicine on which a toll-free number is pasted (instead of individual blisters). Patients can save the number on the phone and call the same number for the duration of the blister (instead of a new number each day). Currently applicable for private-sector patients in both state geographies.

MERM Box (Medication Event Reminder Monitor)

MERM box is a digital pillbox with programmed daily audio and visual reminders and dosing instructions. Patients receive drugs in a MERM box (corrugated plastic box). MERM has an electronic module that records the date and time when the box lid is open. Alert mechanisms of MERM include:

- Daily Medication Reminder: Green Light & buzzer as a daily reminder
- Medication Refill Reminder: Yellow light & buzzer to remind patient to go for refills
- Low Battery Alert: Red light to alert the patient of low battery

The open-close lid of the MERM box registers as a dose taken in Nikshay 2.0

MERM DRTB -

Most IDAT technology solutions are inclined towards DS TB requirements, while MERM is a universal solution. However, the standard box size used for DS TB is inadequate; hence the outer box is revised with the same module and mechanism to comply with the DR TB regimen. The Medication Event Reminder Monitor (MERM) is a digital pillbox designed to monitor MDR TB treatment in resource-constrained settings, using relatively affordable technology and drugs provided by the National TB Elimination Programme. This system is designed explicitly with multiple blister-packaged TB medications in DR TB regimens.

Container specification for DR-TB box- The MDR Shorter regimen box will be used uniformly for all 3 DR-TB categories (H-mono, All oral Longer regimen, Shorter regimen).

Label Specifications –

The MERM container provides "billboard" space for pictograms and other instructions regarding dosing, refill, or other patient management issues. Labels: designed for all DR-TB regimens along with Pack back and Pack front labels.

c. Manual updates

- **Nikshay Sampark**

  Nikshay Sampark is the national call centre for TB counseling and adherence monitoring. Counselors make outgoing fortnightly or monthly calls to patients and update adherence information manually in Nikshay adherence calendars. Doses can be updated as "dose taken" or "dose missed."

- **Healthcare workers/Treatment Supporters/Patients**

  Adherence information can also be reported manually by a healthcare worker or treatment supporter, based on an interaction with the patient. Patients may also self-report adherence information through the patient-facing application. Doses can be updated as "dose taken" or "dose missed."

- **TB Aarogya Sathi (Mobile Application)**

  TB Aarogya Sathi is an Android mobile application for patients and citizens. This application enables patients to access adherence details, treatment progress details, DBT details, and several TB-related services in government hospitals. The entire patient history, diagnostic tests, list of medicines in the prescription, and information on treatment adherence are available on the application. Using this mobile application, patients can manually update their treatment adherence and also update their bank details for DBT. In this application, informative content related to TB disease is available for all citizens.

- **Prescription refill monitoring**

  Refill monitoring is a method that estimates patient adherence based on medication possession. It is a complementary modality to routine adherence monitoring (DAT+ non-DAT) and applies to all TB patients.

2.1.2 Selection of Monitoring Method

Various adherence monitoring methods ensure that patients are well-supported during treatment with the least burdensome tools. At treatment initiation or during the first home visit for counseling, the treatment provider or healthcare worker will identify an adherence monitoring method for the patient based on the criteria.

Adherence Monitoring Method	Criteria	Implementation Sites Gujarat	Implementation Sites Jharkhand
99DOTS	• A patient has access to a mobile phone as well as	DS-TB patients have mobile phones	NA

99DOTS Lite	requisite validity of the SIM services. ● Daily, reliable cellular signal available in a home environment. ● A patient does not experience a high stigma (i.e. the patient has not disclosed the diagnosis to the family). Discuss if a patient will be comfortable engaging with technology. ● A patient is initiated on FDCs (for 99DOTS). ● Patient consent/acceptance.	DS-TB patients on private TB drugs (Hub Clinics) and three blocks in Surat Rural.	DS-TB patients have a mobile phone.
MERM Box	● Stigma (i.e. the patient has not disclosed the diagnosis to the family). Discuss if a patient will be comfortable engaging with technology. ● Daily, reliable cellular signal available in a home environment . ● A patient does not frequently travel during treatment (making it difficult to carry a box). ● All DR-TB Patients may be assigned a MERM. ● Patient consent/acceptance.	● All DR-TB patients. ● DS-TB pediatric patients. ● DS-TB patients without a mobile phone.	● All DR-TB patients. ● DS-TB pediatric patients. ● DS-TB patients without a mobile phone.
Manual updates/Call-based monitoring/TB Arogya Sathi	● Patient consent/ acceptance.	Patients not enrolled in any other technology (None).	Patients not enrolled in any other technology (None).

- Within DAT models, MERM devices was prioritized for all the DR-TB patients, pediatric age groups (1-14 years) and patients did not had access to a mobile phone.
- 99 DOTS (for Gujarat)/99 DOTS Lite (for Jharkhand) was the monitoring method for DS-TB patients who had access to a mobile phone.

- 99 DOTS Lite was the adherence technology for patients on private TB drugs in the Hub Centers of SMC, Gujarat.
- Call-based monitoring was the default method for DS-TB patients who were not enrolled in any technology and patients who did not have access to a mobile phone.
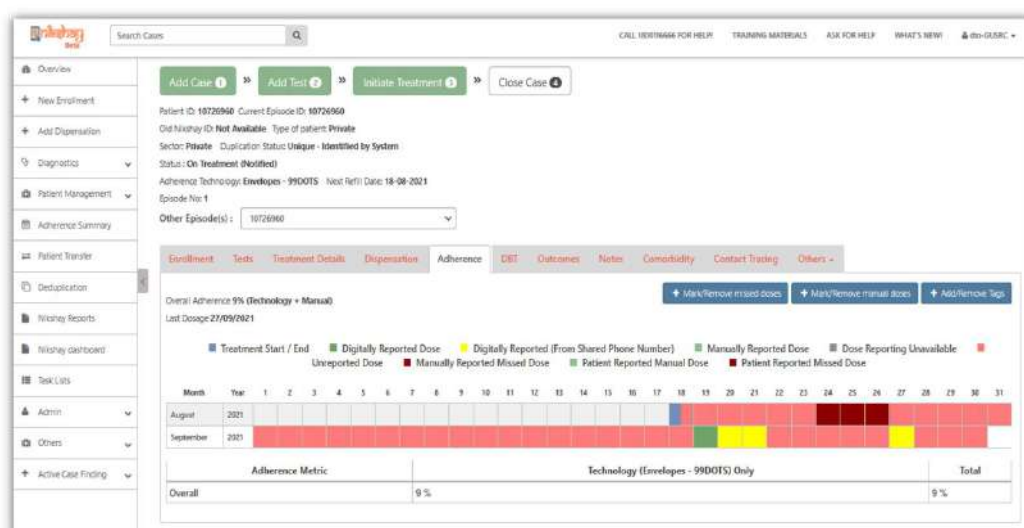
2.1.3   Monitoring through the Nikshay Platform

Adherence to the treatment can be monitored from the various features of the Nikshay. All the features are described below.

a.   Unified Patient Page

The Unified Patient Page helps to monitor the adherence of patients to the medications daily. The different colors display the adherence to the dosage on the Nikshay platform, as shown in the figure below. The significance of various color codes is as follows:

- Blue: Treatment Initiation/Outcome
- Dark Green: Digital Adherence
- Light Green: Manually Confirmed Adherence
- Pink: Unreported Doses
- Dark Red: Manually marked missed dosages
- Yellow: Shared Number
- Green: Calls on a Single Number (Toll-Free)
- X Pink: MERM No Network and Zero battery

Monitoring Adherence of Patient on Nikshay:

Login Nikshay → Click-Patient Management → Click-On Treatment List (Notified) → Search patients by selecting time period → Select adherence calendar to monitor adherence metrics

b. **Follow-up Module:** The follow-up module helps to enter the details of patients by the field staff during the follow-up visit.

Generating Follow-up Register:

Login Nikshay Dashboard → Click-Nikshay Report → Click-Patient Wise List → Click Follow up Register → Download Excel by adding details

Follow-Up Register

c. **Adherence Register:** The adherence register helps monitor patients' adherence (digital and manual) to the TB treatment.

Generating Adherence Register:

Login Nikshay Dashboard → Click-Nikshay Report → Click-Patient Wise List → Click Adherence Register → Download Excel by adding details

Adherence Register

d. **MERM Register: The** MERM Register helps monitor patients' adherence through the MERM box. It monitors the activities of MERM boxes and digitally registers patients' dosages.

Generating MERM Register:

| Login Nikshay Dashboard | → | Click-Nikshay Report | → | Click-Patient Wise List | → | Click MERM Patient Register | → | Download Excel by adding details | → |

MERM Register

e. **Switch Technology Register:** Switch technology register will help monitor various adherence technologies patients use during treatment. It registers how often and with what adherence technology a patient is shifted during TB treatment.

Generating Switch Technology Register:

| Login Nikshay Dashboard | → | Click-Nikshay Report | → | Click-Patient Wise List | → | Click Switch Technology Register | → | Download Excel by adding details | → |

Switch Technology Register

f. **Adherence Dashboard and Summary View under Nikshay: The** Adherence Dashboard will help monitor the adherence of all TB patients, both DAT and Non-DAT, over a period. It gives a complete overview of the usage and performance of all the adherence monitoring methods used for any notification cohort/calendar month with the ability to drill down up to the TU level. It summarizes the number of TB patients assigned to all the adherence monitoring methods and their average commitment. It also helps to identify gaps in adherence of TB patients. The Adherence cascade illustrates gaps in patient engagement based on manual and digital doses.

The Adherence Summary View enables staff at District Level hierarchies and below to view all 'On Treatment Patients' real-time adherence information. The adherence Summary view is designed primarily for treatment supporters and field staff to help monitor their patients' day-to-day adherence metrics and provide them with an option to act on data wherever required.
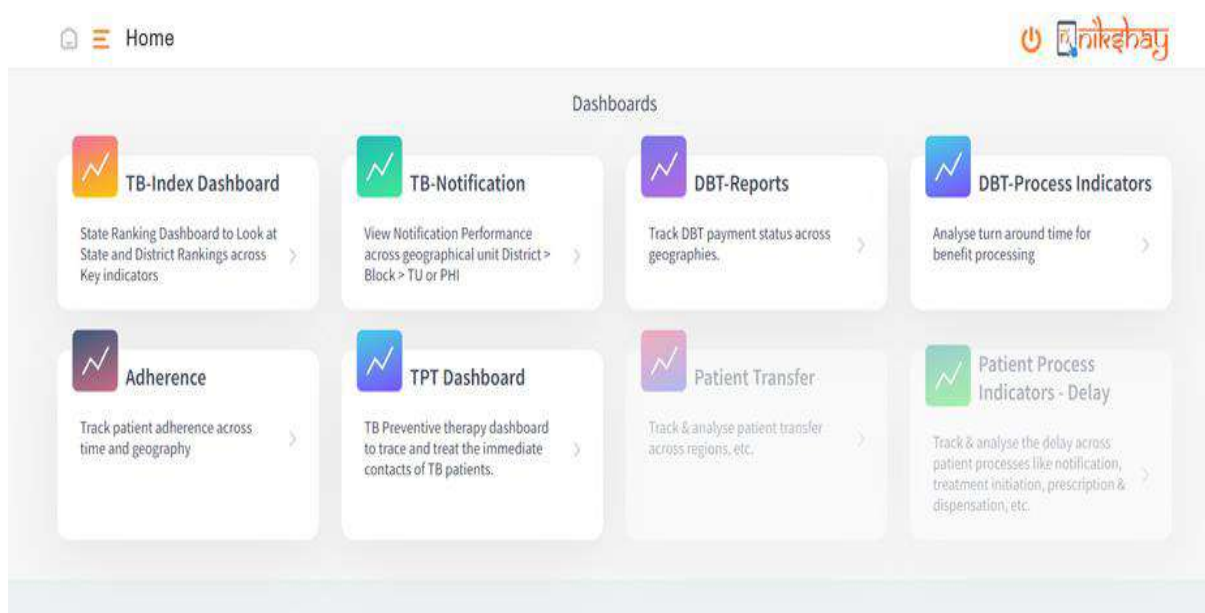
The difference between the adherence dashboard and the adherence summary view is as follows:
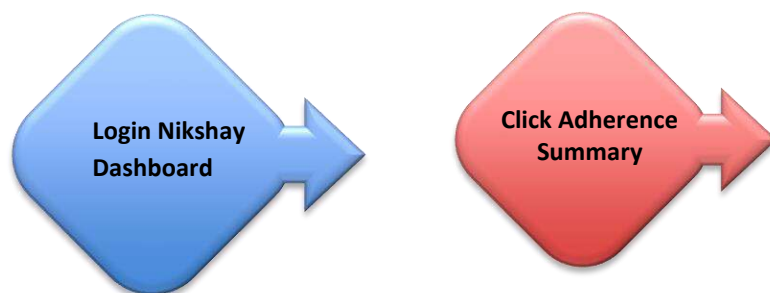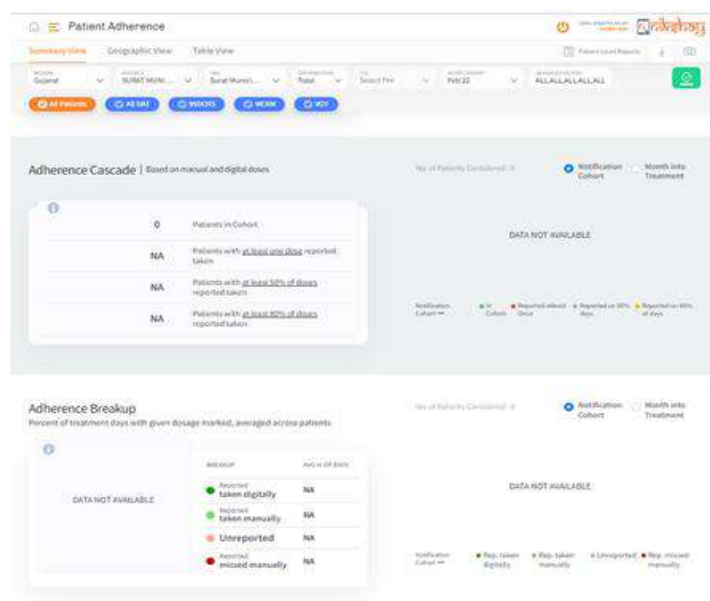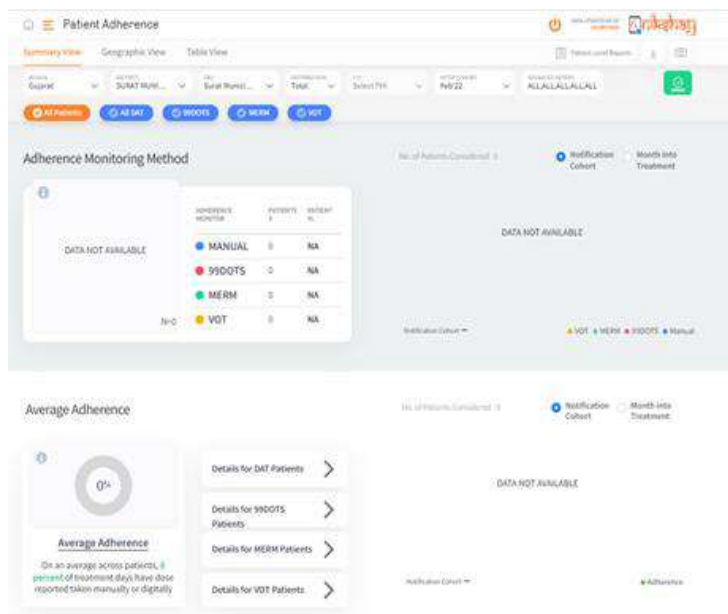
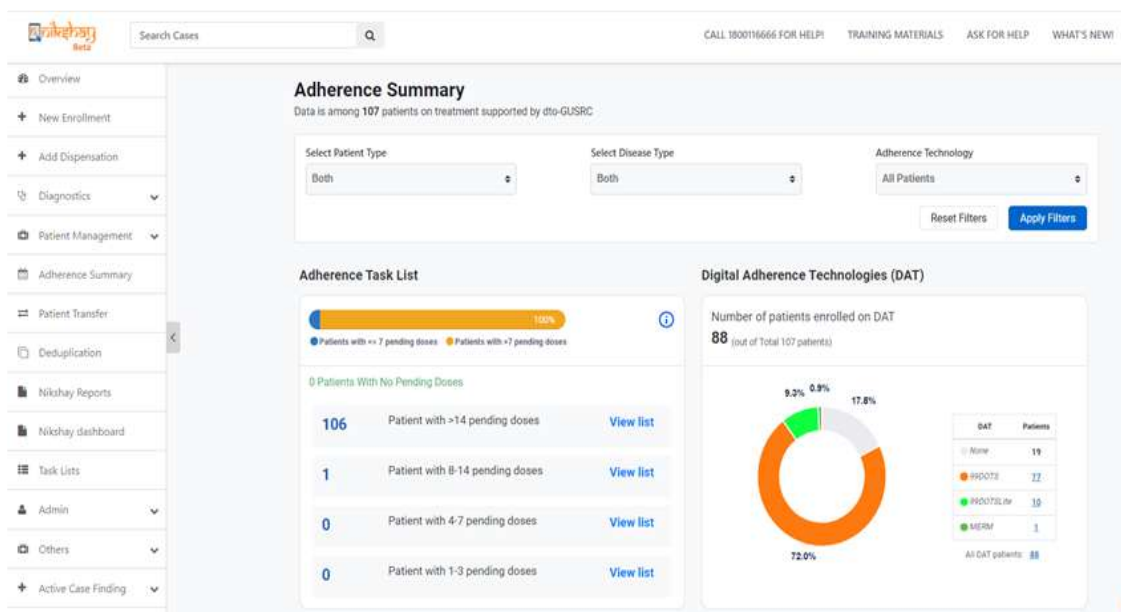|	Adherence Dashboard	Adherence Summary view
Primarily designed for	Administrative staff and decision-makers - CTD, WHO, DTO, STO	Field Staff - Treatment Supporter, STS, TBHV
Type	Analytical	Actionable
Aggregated across	Any level from PHI to National	PHI/TU/District
Data availability	T-1	Real-time
Patients	Current + Historical (on and off treatment)	Current (on treatment)

Generating Adherence Dashboard and Adherence Summary View:

Login Nikshay Dashboard → **Click-Nikshay Dashboard** → **Click Adherence**

Adherence Dashboard

Login Nikshay Dashboard

Click Adherence Summary

Adherence Summary View

2.1.4 Adherence Monitoring Task List

Adherence Task List: A task list for the patients with missed doses during the last 1 to 15 days is generated under Nikshay. It helps to prioritize the follow-up of the patients. Reasons for the missed doses by the patients may vary as per the geographic conditions and the patient's convenience. Appropriate actions from the health cadres during this specific time interval may target the patient's issues and put him back on treatment. Regular monitoring of the task list thus helps to keep the patients adhering to the medicine for a more extended period.

Generating Adherence Monitoring Task List:

Login Nikshay Dashboard → Click Task Lists → Click on list of Missed Doses

Missed Dose Task List

MERM Battery Level and Refill Due Task List: The MERM battery level task list signifies the battery level of the patients. All the patients below 25% are notified under this task list to take further follow-up of such patients and advise them to charge their MERM box battery. Refill refill-due task list is generated when a patient has left with the medicines for two days. Patients are followed up for further refilling of MERM boxes to continue the treatment without missed doses.

Generating MERM Battery Level and Refill Due task List from Nikshay:

MERM Battery Level Tsk List

Refill Due Task List

2.1.5 Patient-wise list sharing with DTC

The patient-wise list is shared with the DTC by the WHP for the district-level monitoring of the DAT activity. The patient-wise list is shared weekly with the DTC for further follow-up by health staff. The weekly list-sharing and follow-up mechanism encourages staff to regularly follow up with the patients until they actively utilize the task list available on Nikshay. The phase-wise monitoring mechanism is detailed below:

Criteria for weekly patient wise list sharing with DTC

Phase 2
Less than 80% doses in last 30 days

Phase 1
Less than 50% doses in last 30 days

Phase 3
Transition to Nikshay Task-lists

Expected Outcomes

Cumulative adherence is more than 70%

Cumulative adherence is more than 80%

Cumulative adherence is more than 90%
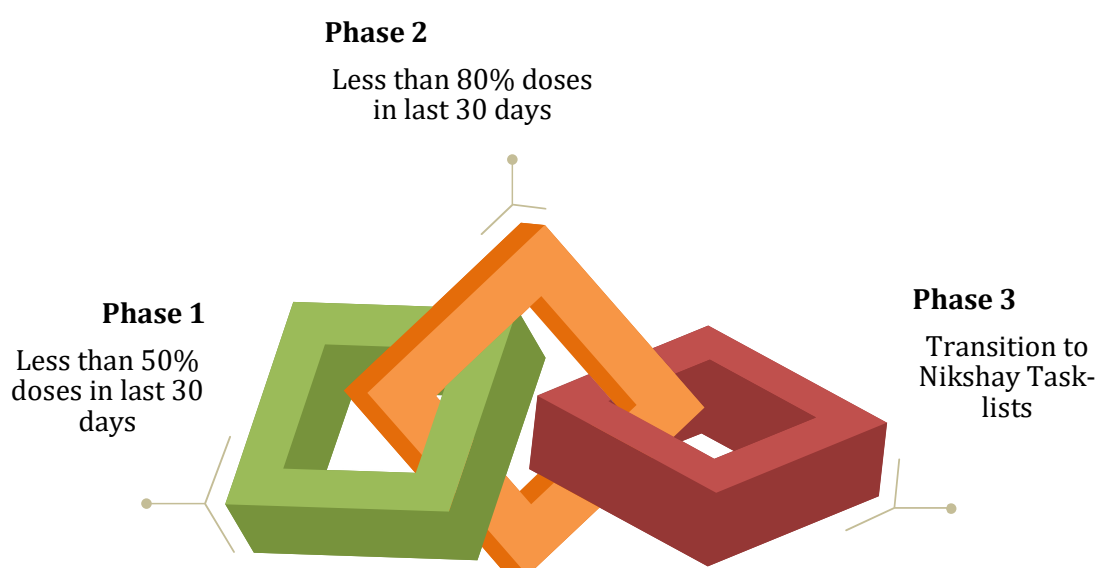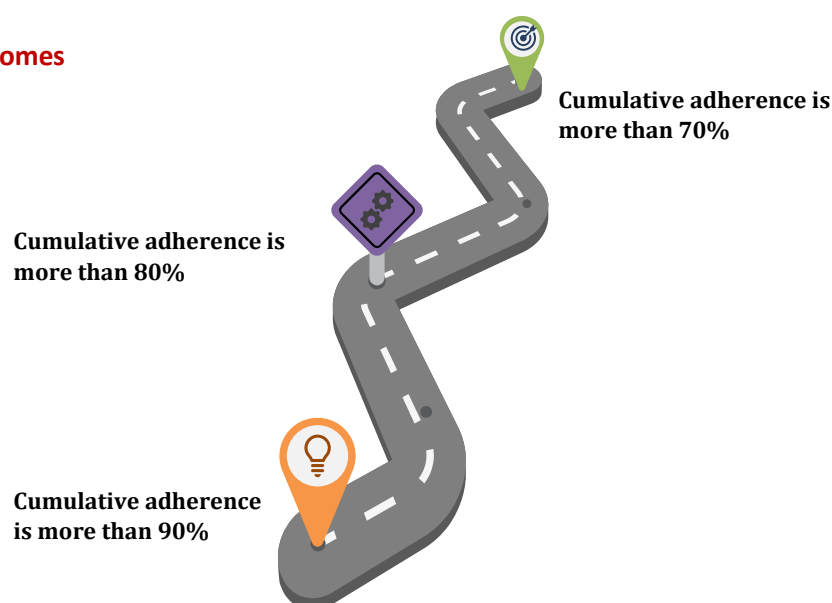
2.1.6 Dispensation Module

A Dispensation Module has been introduced into Nikshay to add details of the product and quantity of drugs provided to the patients. It has a few more features like providing the prescription to patients by printing it, copying the previous prescription, logging details for returned drugs, and a timely dispensation of drugs through linkages with the 'Refill Due Task List'.

Nikshay provides an option to restrict manual dosage updating in the absence of complete dispensation entry under the "Type of monitoring method". District and facility staff can indirectly monitor particular patients' adherence to TB treatment by restricting manual doses from being added under the dispensation module. The dispensation module has been replaced with the prescription module under the Nikshay platform due to the following issues in the prescription module.

- Lack of linkages with the following drug refill date
- Lack of any provision for printing and providing the prescription details to the patient
- Lack of any differentiation between drug prescribed, supplied, and started dosage for the same
- No options to return the issued drugs
- No linkages between medication prescribed and adherence.

Module for the dispensation is available on Nikshay under the options 'On Treatment' and 'Outcome Assigned.'

Adding Dispensation Details on Nikshay:

1

Login Nikshay Dashboard → Add Dispensation → Search Episode ID or Dispensation ID → Add Dispensation details for the patient

2

Login Nikshay → Click-Patient Management → Click-On Treatment List (Notified) → Search patients by selecting time → Select Patient from the list → Click on Dispensation Tab → Add Dispensation details for the patients

Patient Details

Episode ID	10731767
Type Of Patient	IndiaTbPrivate
Status	DIAGNOSED_ON_TREATMENT
Adherence technology	99DOTSLite
Type of Regimen	DSTB

No data to show

+ Add Dispensation

Generating Dispensation Report and Register:

| Login Nikshay Dashboard | Click-Nikshay Report | Click-Patient Wise List | Click Dispensation Register | Download Excel by adding details |

Dispensation Register

Login
Nikshay
Dashboard → Click-Nikshay
Report → Click Report → Click
Dispensation
Report → Download
Excel by
adding details

Dispensation Report

2.1.7 Role of various staff members

a. **Healthcare workers** (STS/TB-HV/Treatment Coordinators/ASHA/ANM/MPW Male/ other assigned healthcare staff responsible for patient adherence monitoring) will have the following responsibilities:

- Conduct a home visit within one week of treatment initiation for patient counseling on TB (with counseling checklist)
- Facilitate the assignment of a treatment supporter (family member/caregiver/ community volunteer)
- Assess patients for risk factors with appropriate tagging in Nikshay
- Ensure patient is enrolled and engaged in appropriate adherence monitoring method with consent; switch monitoring method if engagement is low
- Troubleshoot technical challenges with DATs or Nikshay
- Diligently monitor task lists daily and follow up for adherence interventions
- Update Nikshay adherence calendars and prescription information with completeness and accuracy
- Assign treatment outcomes to patients with accuracy

b. **Senior staff**

The senior cadre of staff (MO, MO-DTC, DR-TB Supervisor, DTO, treating provider, PPM coordinator) will have the following responsibilities:

- Monitoring the quality of risk assessment and adherence interventions administered by healthcare workers
- Oversee training and refresher training for healthcare workers based on identified gaps in the assignment of monitoring methods, risk management, and adherence interventions
- Routine review of adherence metrics and dashboards with monthly review meetings

2.1.8 Training of NTEP Staff

a. **Training**

During every monthly review meeting at the district level, all the NTEP staff were sensitized to the new features of adherence monitoring in Nikshay. Besides the initial orientation, staff members were sensitized during every review meeting and communicate more recent updates. The training was provided by experts from the districts and the thematic leads of the adherence monitoring intervention from WHP.

In Jharkhand, a separate training session was conducted for the CHOs.

The NTEP staff were trained on each adherence monitoring activity and the related Nikshay features. The training sessions were provided using demonstrations, field observations, issues in the field, or unfair practices.

b. Launch Events for MERM and Training

The training was organized with WHP (CGC project) joint efforts and NTEP staff to orient about MERM. The training sessions included a brief overview of the CGC project, a brief of MERM technology for adherence, monitoring in Nikshay, and a review of adherence indicators.

- In Surat rural, training was conducted on 26th October 2021. A total of 50 participants attended the training, including WHP and NTEP staff, Taluka Health Officers, and the Medical Officer of the DR-TB ward.
- In Gandhinagar, training was conducted on 28th June 2021. A total of 50 participants attended the training, including WHP, IIPHG, NTEP staff, and esteemed members from STDC. The event also witnessed the presence of Dr Makwana (State Tuberculosis Officer Gujarat).
- In Jharkhand, the DR-TB MERM box launch event was organized on 8th September 2021 in the presence of MD NHM, Jharkhand. A total of 30 stakeholders attended the event.
- In Jharkhand, 99 DOTs lite and DS MERM boxes were launched by MD NHM on the eve of World TB Day, i.e. 24th March 2021.

2.2 Consultation with CTD

A series of consultations were carried out with the CTD to implement the adherence monitoring activity effectively.

2.2.1 Adherence Roadmap

A meeting was organized with the CTD and other stakeholders for efficient adherence management. The meeting was scheduled to discuss the plan to rejuvenate adherence management monitoring at the state/district level, review the Nikshay feature to facilitate the establishment monitoring matrix, identify priority activities, and timelines, and review mechanisms at the CTD level and evaluate adherence monitoring. Establishing a formal mechanism for adherence monitoring was suggested to reach the peripheral health staff for follow-up and retrieval action. Identifying three to five comprehensive indicators and prioritizing them for adherence monitoring at various levels was also recommended.

2.2.2 DR-TB MERM Box

A consultative meeting was conducted with the CTD to plan the DR-TB MERM box implementation under the CGC project on 5th May 2021. While conducting the DR-TB MERM box implementation feasibility team faced particular challenges; hence the meeting was conducted to fix the implementation plan. During the meeting, discussion and deliberation were carried out on the box specification (like placing the DR-TB drugs in the drug-specific slot, arranging the separator aligned

to the drug label color bar size for each drug in the regimen), and other implementation aspects. A few of the important suggestions and recommendations provided by the CTD are listed below:

- Increase the serrations in the template that holds the separators to increase the number/size of slots to accommodate drugs for the highest category of weight band in each of the DR-TB regimens
- Patients residing in low mobile network areas should be counseled on the network issues and how they can be addressed
- Already available resources such as the Aarogya Saathi Application and Call Centre can be leveraged to improve adherence to technology implementation, monitoring, and reporting.

Section 3

3.1 99 DOTS Lite Evaluation Report

99 DOTS Lite was introduced to address the challenges associated with 99 DOTS. From April '21 to March '22, over 1500 patients were enrolled on 99 DOTS Lite. Based on the encouraging findings, states have already initiated scaling this intervention to additional districts using state resources.

However, the provision to map patients on 99 DOTS Lite is currently unavailable within the Niskhay app of CTD. STO Jharkhand has requested CTD to consider implementing this feature in Nikshay.

In 2022, Surat district implemented the 99 DOTS Lite provision for 2500 private sector patients. A joint interim evaluation conducted by WHP and Everwell, in coordination with state teams, has been submitted to CTD. This report, along with the request from STO Jharkhand to incorporate the 99 DOTS Lite feature into the Nikshay app, aims to further scale up this initiative.

Key findings of the evaluation report highlighted procurement-related issues in 99 DOTS, such as the uniform form factor not fitting all requirements and a lengthy government process. Supply chain challenges included the absence of checks ensuring the compatibility of shipped 99 DOTS envelopes with existing forms. Operational issues like high per-patient costs and envelope shortages were also identified.

Comparatively, the evaluation revealed that 99 DOTS Lite is compatible with various drug packaging types, independent of the manufacturer, and supports non-FDCs and pediatric drugs. This versatility enables broader coverage. Moreover, 99 DOTS Lite encounters fewer procurement challenges, operates independently of centralized processes and allows for rapid, local supply replenishment due to its decentralized and cost-effective model. Operational challenges are minimized as affixing stickers is easier and requires minimal storage space. Patients expressed a preference for 99 DOTS Lite as they could easily spot the number on the blister while taking medication, serving as a reminder to make the required call, and found it more convenient overall.

3.2 TB Aarogya Sathi Feedback Study

A study was conducted to gather feedback on the TB Aarogya Sathi application. Virtual interviews were conducted with 20 active TB patients currently using the application, using a semi-structured interview guide. Additionally, feedback was obtained from super users of TB Aarogya Sathi. The interviews aimed to gauge the application's usefulness, the effectiveness of its walkthrough, the benefits of the DBT Bank edit function, the significance of self-reported adherence, and collect general feedback or suggestions. A detailed report has been prepared and submitted to CTD.

Key findings from the study indicated that 60% of approached users responded to the interview, while the remainder cited unavailability of time or lack of interest as reasons for refusal. Most users found the dietary section informative and appreciated the instructional videos, which emphasized the importance of regular medication intake and provided insights into available social support schemes for patients. Although the initial phase lacked local language support, the application is now accessible in several local languages. However, over 60% of patients were unaware of the walkthrough feature, and only 50% were familiar with the self-adherence reporting feature. Users provided suggestions to enhance user-friendliness:

- Using the mobile number as the login ID for easier access, as some users faced difficulty accessing their Nikshay ID.
- Addressing application slowness, especially when marking self-reported doses.
- Providing more effective contact details for obtaining the required information, as many users had trouble getting the information they needed when contacting the provided number.

Section 4

4.1 Scale-Up of the Intervention

4.1.1 Scale Up within the Districts (Gujarat)

In Gujarat, in 2022, MERM Box for DR-TB patients scaled up in another six districts (i.e. Banaskantha, Bharuch, Dahod, Jamnagar, Narmada, and Rajkot). A total of 327 devices have been supplied to date. As of 22nd July 2022, 150 patients are currently using MERM BOX. Approximately 200 staff members were trained till July 2022.

4.1.2 Scale Up within the Districts (Jharkhand)

In Jharkhand, in 2022, MERM Box for DR-TB patients was already in use in CGC intervention districts, and WHP-HQ decided to scale up this intervention in 6 high case load districts. So the same was discussed with STO, Jharkhand, and after consultation with the WHO Consultant, he suggested scaling this intervention in Dhanbad, Bokaro, Sahibganj, West Singhbhum, Palamu, and Deogarh. These districts contribute 36% of all the DR TB case load of Jharkhand. A letter from STO to DTOs of all the above-mentioned districts was issued on 29th December 2021.

After approval of scale-up WHP in consultation with districts, planned an orientation of all NTEP staff on adherence management. In most of the places, training was also attended by DTOs and Civil surgeons.

Training Plan- Jharkhand

Districts	Date of Training	No. of. Participants
Dhanbad	19th January 2022	14
Bokaro	20th January 2022	27
Palamu	22nd January 2022	15
West Singhbhum	24th January 2022	20
Deogarh	27th January 2022	23
Sahibganj	10th February 2022	15

Adherence Data of Scale-up Districts - Jharkhand

Districts	No DR TB Patients	No DR TB Patients on MERM	Adherence
Bokaro	25	11	60%
Deogarh	17	7	67%
Dhanbad	36	6	59%
Palamu	18	4	54%
West Singhbhum	19	5	71%
Sahibganj	18	6	37%

4.1.3   Scale Up and Technical Support to NTEP Himachal Pradesh

DR-TB MERM was introduced in Himachal Pradesh as part of the TB adherence management initiative (TB-TAM) under the CGC project and rolled out in February 2022. To date, a total of 57 DR-TB patients enrolled on the MERM Box, and 100 devices have been supplied.

4.2   DAT Enhancement

4.2.1 Search by IEMI feature

Now users can search only an IMEI number and view all the information associated with it.
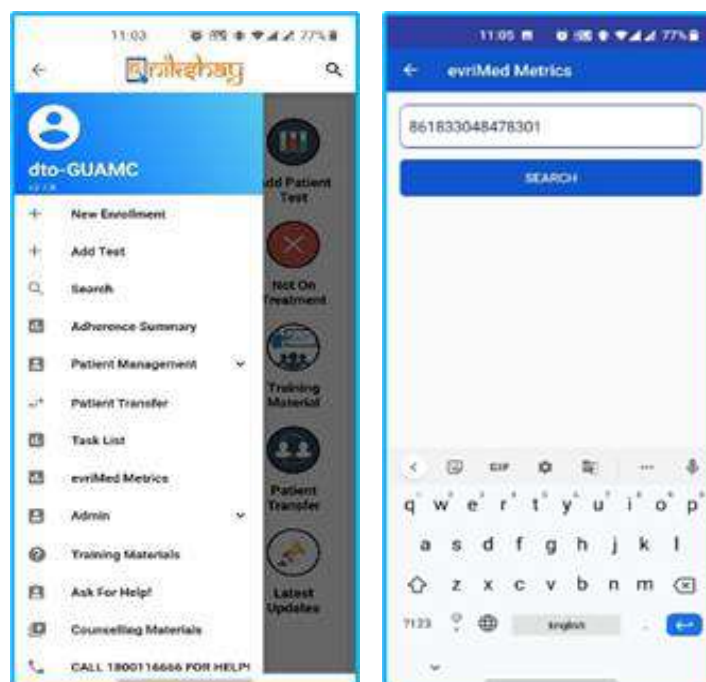
2.3.2   No dose reported task list

2.3.3 A new task list has been added to the Nikshay. This task list contains the list of all the patients whose dose is not reported either digitally or manually for the current day.

2.3.4 Adherence Summary View -App

The staff widely used the Adherence Summary Graph that was available earlier on the Nikshay App to monitor the daily adherence of all patients. It had been removed some time back, resulting in a lack of real-time monitoring of adherence data at the field level. For the field-level staff, it was quite challenging to check the adherence calendar of every patient. Hence to resolve this, the Adherence Summary view is designed primarily for treatment supporters and field staff to help them monitor the day-to-day adherence metrics for their patients and provide them with an option to act on this data wherever required.

4.3 Troubleshooting DATs

- The onboarding toolkit was developed and shared for the smooth onboarding of new sites.
- Troubleshooting support is provided on an ongoing basis.
- Formatting issues resulting in the adherence string being downloaded as a scientific notation were fixed. This can help the team in finer analysis of the adherence pattern of patients. An issue resulting in the battery percentage of MERM devices not being visible has been fixed to improve the monitoring of patients on MERM.
- To increase the adoption of the TB Aarogya Sathi app and to provide actionable data for the program staff to monitor uptake among patients, a report providing the users with the uptake of the TB Aarogya Sathi app was made available on Nikshay Reports.
- The MERM Battery % column, which was missing in the MERM Task Link was rectified
- The Adherence Calendar for MERM Patients disappears on assigning outcomes; this issue has been rectified
- A bug displaying all IMEIs in the IMEI dropdown was resolved to only display the IMEIs tagged to the ID logged into Nikshay.
- A Bug that resulted in Adherence reminder SMS not being sent timely was resolved.
- A bug that resulted in an Adherence Calendar for DAT patients, not loading was resolved.
- The MERM module was unavailable for allocation after de-allocation from a previous patient.
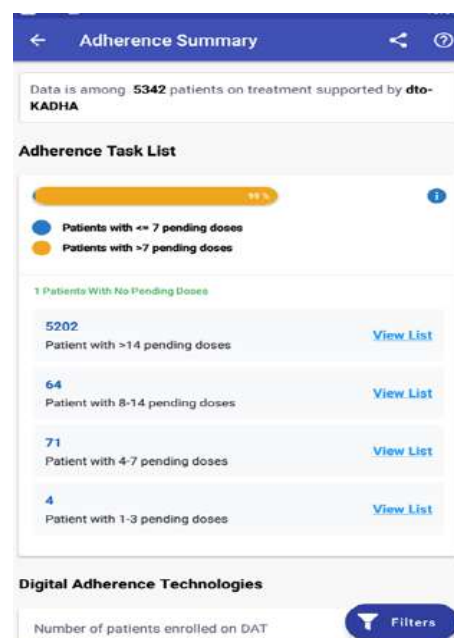
Section 5

5.1 Results and Progress

As of July 2022, a total of 851 patients for the MERM Box and 3407 patients for the 99DOTS Lite were enrolled. These efforts have improved real-time reporting of treatment adherence under the NTEP. The system-strengthening approach has improved DAT coverage, patient-reported DAT signals, and overall adherence.

Total no. of patients enrolled as of 20th July 2022

Adherence monitoring method	Gujarat	Jharkhand	Himachal Pradesh	Total
99 DOTS lite	2063	2423	-	4486
MERM Box	480	371	57	908

After implementing the adherence monitoring mechanism with the usage of DAT and Nikshay features, there is an increase in digital adherence and the cumulative average adherence of the patients. There is an improvement in the reporting of the dosages within the Akshay. Hence there is a reduction in the proportion of unreported dosages. Additionally, there is an increase in reported missed doses (manually). This increased reporting to aid the NTEP staff in real-time monitoring of adherence.

5.2 Process Documentation Flow

Different activities were carried out at different stages to document the entire process flow of the adherence monitoring intervention.

To document how the intervention is implemented in the field, Team IIPHG conducted field visits to a few patients and stakeholders and observed the entire process of the implementation. Critical observations, findings, and suggestions from the various staff are mentioned below as challenges and learnings.

5.2.1 Challenges Faced

During the implementation of adherence monitoring, it was observed that the patients and the system providers faced various challenges. All these challenges are described below in detail.

Adherence Monitoring Methods

1. **Demand Side Challenges**

   a. **99 DOTS lite**

   Many staff members observed and reported that patients on the calling method often do not call after taking medications due to behavioral or financial issues.

- In rural areas, they frequently change their mobile numbers. So, instead of calling from a registered number, they call from different numbers.
- Often, registered mobile numbers are of patients' family members, relatives, or neighbors, so they cannot call daily.
- Usually, they regularly call in the initial phase and then they eventually stop calling, thinking that they took medicine now it does not matter whether they call or not.
- Sometimes patients complain that they are taking medicines regularly, so why do they have to call?

b. **99 DOTS (in addition to the above challenges)**

- Often patients do not have a balance in the registered number, so they are not able to call on the given free call number.

c. **MERM Box**

Patients' perception: For patients, it is not convenient to carry the box while traveling to other places, considering the large size of the boxes and the stigma associated with it. They believe that if they carry the box, people who don't know he/she is taking medicines will also come to know.

Social stigma still exists in some communities, which causes a hindrance in the adherence monitoring process as they take the medicines but do not want others to know the same.

2. System Side challenges

a. **99 DOTS/ 99 DOTS lite**

Selection of the patients: It is very difficult for migrants and homeless people to decide on the adherence monitoring method. They do not have access to mobile phones, and boxes cannot be provided, considering they may not be able to maintain them.

Counseling and orientation: Patients were oriented about the IDAT method. But still, there is a scope for improvement. A clear message and communication are required. Messages like- calling is free of cost, and calling from the registered number only needs to be communicated. In one of the cases, it was found that the patient called only the first time when she had taken medicine as per her understanding because she was not informed that she had to call every day after taking medicine. Also, no one followed up until she went to the TU for the next month's dose. It was also observed that the patients were counseled that they must call after taking medicines but not counseled that they do not have to call if they did not take medicine, which is equally important to reduce false reporting.

Supply Chain Issues (99 DOTS): The 99 DOTS envelopes from the central location (SDS) are supplied to the districts. Then the district sends it to TU and PHI. Sleeving envelopes (if the envelope is a right fit) are undertaken at the PHI level at the time of drug distribution to

patients. If the person is not trained to sleeve the envelope or the envelopes are not the right fit, then the envelope and the medication are handed over to the patient. There are no checks in place throughout the supply chain to ensure that the 99DOTS envelopes shipped will be compatible with the existing form factors at various stages

b. MERM Box

Selection of the patients: Selection of the patients for the MERM box is not challenging. However, it is challenging to cover all the eligible patients for the MERM box as very few boxes are available, and the notification rate is high.

Counseling and orientation: A clear message and communication are required. Messages like charging indication, duration of MERM box, and they only have to open the box when they want to take medicine need to be communicated

End treatment retrieval: If patients were not counseled properly at the time of enrollment, then the staff needs to put a lot of effort into retrieving the used boxes. Patients were unable to maintain the boxes properly, or the condition of retrieved boxes was not so good; hence, the reusability of such boxes is sometimes questionable.

Scale Up in other districts: During the scale-up of the project in other districts, the following challenges were faced.

- Capacity to use among District Staff
- Lack of Review and Follow-up of FLWs
- Difficulties in Follow-up of Patients (Transfer outs, patient counseling at the time of it, retrieval actions, etc.)
- Despite having enough boxes in scale-up districts, patients are not being assigned to MERM.
- DPS take this MERM as an additional responsibility in their job.

All Adherence Monitoring Method

Monitoring adherence data: One of the biggest challenges in any adherence monitoring method is false positive reporting. Many staff reported that patients tend to call or open the box even if they did not take medicine, so their adherence was marked digitally on the Nikshay when they did not take the dosage. However, they cannot manually modify the adherence for the digitally drawn dosages even after verification.

Difficulty in distinguishing an individual patient's adherence when more than one patient has the same registered mobile number to report adherence. At the field level, it was observed that the ground-level staff, especially MPHW, had no clarity on the updation of the dosage manually after physical verification if there was any discrepancy.

Monitoring of task lists: During the field visits, it was observed that very few staff members use the task list frequently. It was also observed that the MPHW involved in the adherence monitoring process had very limited knowledge of the various features available in the Nikshay for adherence monitoring.

Building interest of private sector staff: Adherence management and deployment of DATs is still a challenge in the Private sector. Continuous interaction with the PPSA agency is required to improve coverage and engagement.

3. **Technical Issues**

   a. **99 DOTS and 99 DOTS lite**
   - Patients often called the provided number, but the dosage was not reported in the Nikshay even after the call got connected and received a thank you message.
   - 99 DOTS only: The size of the envelopes is not appropriate many of the times (not suitable for pediatric FDC, DR TB drugs, and patients initiated on drugs other than FDC).
   b. **MERM Box**
   - Technical issues related to network and battery (Very few compared to previous boxes).
   - Boxes are not folded properly; hence, there is an issue in the updation of the adherence data in the Nikshay.
   - MERM DR-TB: Alarm sounds don't get activated if the device is opened within 4 hours of the set alarm time. This may create confusion among patients concerning device functionality.

Dispensation Module

- It is very time-consuming and increases the workload of the respective staff. They have to enter the same data in multiple platforms like Nikshay Aushadhi and manual stock registers, which ultimately leads to delays in entering data.
- Especially in the rural areas, pharmacists did not receive the extensive orientation of the module, and hence they have very limited knowledge about all the features of the module.

Technical issues:

- It takes more time to open due to frequent updates in the application.
- Users sometimes faced some issues in saving the entries; entries were not saved or, even if saved, did not show after some time, so they had to re-enter all the data.
- Edit option not available; if they enter the wrong data by mistake, they have to return the dispensation and again have to enter it.
- The copy and paste option is unavailable in the Nikshay application, so they must type every time.
- While returning the dispensation, the actual entry got deleted.

○ Weight band needs to be entered manually sometimes, and sometimes it comes automatically.

5.2.3 Learning and Way Forward

- Acceptance:

  99 DOTS Lite: The acceptance of 99 DOTS Lite is good and more accepted than 99 DOTS due to its easiness in operations at both the system and demand sides.

  MERM: The acceptance of MERM is among eligible TB patients of MERM interventions and from the system side, it provides adherence feedback in ni-kshay with support to manual monitoring of dosages.

  Patients have not shown any concern about any method as they have not been given an option. However, on inquiring further, they preferred MERM boxes over the calling method as they do not have to call.

- User-friendliness:

  99 DOTS Lite: 99 DOTS Lite is more user-friendly and easier than 99 DOTS as one can save the number and then only have to dial that number. The number is already visible as affixed on the blister or the box, while in 99 DOTS number is not visible; one has to reveal the number from the envelope.

  MERM Box: Out of all the available options MERM box is the best option as it is very easy to use, and there are fewer chances of errors from the patient side.

- Maintaining counseling standards: Proper counseling of the patients plays an important role in adherence.

  ○ Initial counseling of TB patients on adherence was found to be sub-par, which leads to low self-reported adherence for some patients.

  ○ Patients should be counseled adequately when they have to call and when they do not have to call to avoid false reporting and misinterpretation of the information provided.

- TB champions are identified in many areas but not actively involved in the adherence monitoring process. They should be actively engaged to improve the acceptance of these technologies and adherence among the community.

- During the previous assessment, it was observed that few patients altered the dosage without any consultation. Instead of taking three tablets at a time, they took one tablet three times a day which ultimately suggests that the patient was not fully compliant with the dosage. In that case, it would be great to record the no. of times the box opened in a single day so such patients can be counselled to improve their overall adherence.

- The physical follow-up of each patient is more important.

- In Jharkhand, the monitoring part needs to be strengthened from the system side as, in many cases, it was found that no one has visited or called during treatment except CGC field staff. So, to make this a sustainable intervention, government personnel need to be sensitized and accountable.

- Most of the interviewed NTEP staff suggested that available general health system staff should be involved to improve adherence. Specifically, medical officers should be engaged as the community emphasizes the advice provided by the doctors. At the same time, other staff can be engaged in the monitoring process.
- One of the suggestions from the staff is that the free call number for the 99 DOTS/lite should be made completely free or any alternate option can be explored. Many patients could not call due to a zero balance in the registered number.
- Treatment outcomes of such patients should be measured or documented to know the effect of adherence monitoring technologies.

5.2.4 Recommendations

- **Behaviour change communication**: More directed efforts should be made to improve the community's knowledge and awareness, leading to behavior change and increased adherence.
- **Capacity enhancement**: To ensure the quality staff members from the general health system involved in the adherence monitoring process (Especially MPHW, ASHA, and PHC Pharmacist) should be trained thoroughly and more frequently.
- **Engagement of general health system staff**: It was emphasised by many stakeholders that general health system staff should be engaged more actively for better outcomes. Intersectoral coordination should be established.
- **Dispensation module**: Integration between the dispensation module and Nikshay Aushadhi should be done to avoid duplication of work and to ensure the timely updation of the data. There is a need to create a field-testing schedule before integration into Nikshay.
- **Self-reporting by patients**: If a patient manually reports the dosage using the Arogya Sathi application, then in the Nikshay, it shows a light green color, which is similar to the manually reported dosage by the staff. The color should be different so that it can be easily identified that the patient reported it manually using the digital technique.
- **Utilisation of other digital platforms**: Arogya Sathi, Nikshay Sampark, and Nikshay Setu should be utilized to improve the treatment adherence and capacity of the staff.
- **Continuous Concurrent review**: Regular monitoring is required from the NTEP Staff to improve patients' overall coverage and adherence. Required emphasis was not given to the adherence component during the monthly meetings at the PHI level. Along with these, periodic supervision and monitoring mechanisms should be established.

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Annexures

Field Photographs

a.   **MERM Box (DR-TB Patient)**