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

## *A Process Document for Differentiated TB Care Management*

*(A comprehensive package of clinical, radiological, and pathological services to reduce preventable morbidity and mortality among TB patients)*

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# Acronyms & Abbreviations

| | |
|---|---|
| BCG | Bacille Calmette-Guerin |
| BMI | Body Mass Index |
| CBC | Complete Blood Count |
| CC | Care Coordinators |
| CGC | Closing the Gap of TB Care Cascade |
| CHC | Community Health Center |
| CXR | Chest X-ray |
| DDR-TBC | District Drug-Resistant Tuberculosis Center |
| DMC | Designated Microscopy Center |
| DRTB | Drug-Resistant Tuberculosis |
| DSTB | Drug Sensitive Tuberculosis |
| DTO | District TB Officer |
| HB | Haemoglobin |
| HIV | Human Immunodeficiency Virus |
| GMERS | Gujarat Medical Education and Research Society |
| IPD | Indoor Patient |
| MO | Medical Officer |
| MUAC | Mid Upper Arm Circumference |
| NPY | Ni-kshay Poshan Yojana |
| NTEP | National Tuberculosis Elimination Program |
| OOPE | Out-of-pocket Expenditure |
| OPD | Outdoor Patient |
| PHC | Primary Health Center |
| PHI | Public Health Institution |
| RBS | Random Blood Sugar |
| SGPT | Serum Glutamic Pyruvic Transaminase |
| STS | Senior Treatment Supervisor |
| TB | Tuberculosis |
| TU | TB Unit |
| UHC | Universal Health Coverage |
| WHP | World Health Partners |

## ABOUT THE CGC PROJECT

Closing the Gaps in TB Care Cascade (CGC) is a four-year project (2020-2024) funded by the United States Agency for International Development (USAID) and led by World Health Partners (WHP). The project is implemented in partnership with the Indian Institute of Public Health Gandhinagar (IIPHG), Everwell Health Solutions, Harvard Medical School, and Leapfrog. CGC is executed in four districts: Ranchi & East Singhbhum (Jharkhand) and Surat & Gandhinagar (Gujarat).

The TB care cascade visualizes various stages of gaps in TB care delivery. These gaps represent patient drop-offs in the ability to access a TB diagnostic test, receive an accurate diagnosis, access TB treatment, adhere to daily medication, and remain TB-free post-treatment. The CGC project monitors care cascades at the district level, aligned with local TB epidemiology and local health systems, guided by principles of access, quality, and equity of TB care.

### About Differentiated TB Care Management Intervention:

Morbidity and mortality during treatment in patients with active TB can occur due to extensive tuberculosis with complications or serious comorbidities such as severe undernutrition, advanced HIV infection, uncontrolled diabetes, substance abuse, mental illness, or immunosuppressive therapy, among others.

To improve treatment outcomes for TB patients, the "Differentiated Care of TB Patients" has been developed. This approach involves assessing every TB patient through basic clinical, laboratory, and radiological evaluations at the time of TB diagnosis. It establishes criteria for risk stratification of TB patients using a scoring system and institutionalizes patient-centered care to mitigate risk factors. This aims to rapidly reduce preventable mortality among TB patients.

# SECTION 1

## 1. BACKGROUND

Tuberculosis (TB) remains a leading cause of death in India, with approximately 480,000 people dying from the illness every year. Reducing TB mortality is one of the goals of the National Strategic Plan for TB (2017-25), aiming for a >=90% reduction in the TB mortality rate by 2025 [1]. Although India contributed to 41% of the global drop in incidence in 2020, it still bears the highest burden of TB cases (26%) globally, according to estimates from the Global TB Report 2020. India has set the target to achieve the End TB Goals by 2025 through robust implementation of National Tuberculosis Elimination Program (NTEP) interventions, surpassing the target outlined in the UN's Sustainable Development Goals.

Despite access to care falling short of Universal Health Coverage (UHC) and millions of people missing in diagnosis and TB treatment care, TB treatment has averted more than 66 million deaths [2]. There is still a significant gap between the estimated number of incident cases (9.9 million, range 8.9–10.9 million, in 2020) and the number of undetected cases (4.1 million) globally due to underreporting and underdiagnosis [1]. Apart from the disease, social determinants and clinical conditions also contribute to the causation of TB and its adverse outcomes [2].

Early death during TB treatment may result from undernutrition, mental illness, alcohol or drug addiction, HIV, diabetes mellitus, chronic lung disease, severe bacterial infections, cancer, bilateral disease on chest X-ray, anemia, malignancy, and other comorbidities (2-6).

In 2021, NTEP developed the technical guidance "Differentiated Care of TB Patients," which evaluates TB patients for clinical parameters at the time of diagnosis to (i) Identify patients with severe disease and a high risk of mortality early in the care pathway. (ii) Provide comprehensive intervention packages that can reduce morbidity and mortality among TB patients, and (iii) Develop a prediction model to identify at-risk patients at diagnosis (7).

Several challenges remain to be addressed, from the conceptualization of the Differentiated Care approach to achieving patient and population-level impact. The validation and resource mapping within the framework of implementation needs more visualization to strengthen the service delivery to TB patients with severe symptoms or comorbidities. The pilot intervention of Differentiated TB Care under the CGC Project has provided a wide range of learnings during the implementation that can guide the states and central policymakers to review the existing guidelines and take necessary evidence-based actions for nationwide implementation.

**Objectives of the Process Documentation of DCM intervention:**

- Examine the implementation framework of the piloted Differentiated Care intervention and corresponding challenges to scaling; provide support for an implementation structure.
- Assess patient-level and provider-level barriers related to the differentiated care approach and identify enablers that support the scaling-up efforts under the NTEP program.

## 2. GEOGRAPHY OF DCM INTERVENTION

The intervention has been implemented at two sites: 1. DTC PHI under Sadar TU of Ranchi District in Jharkhand, and 2. GMERS Medical College under Gandhinagar City TU of Gandhinagar district, Gujarat.
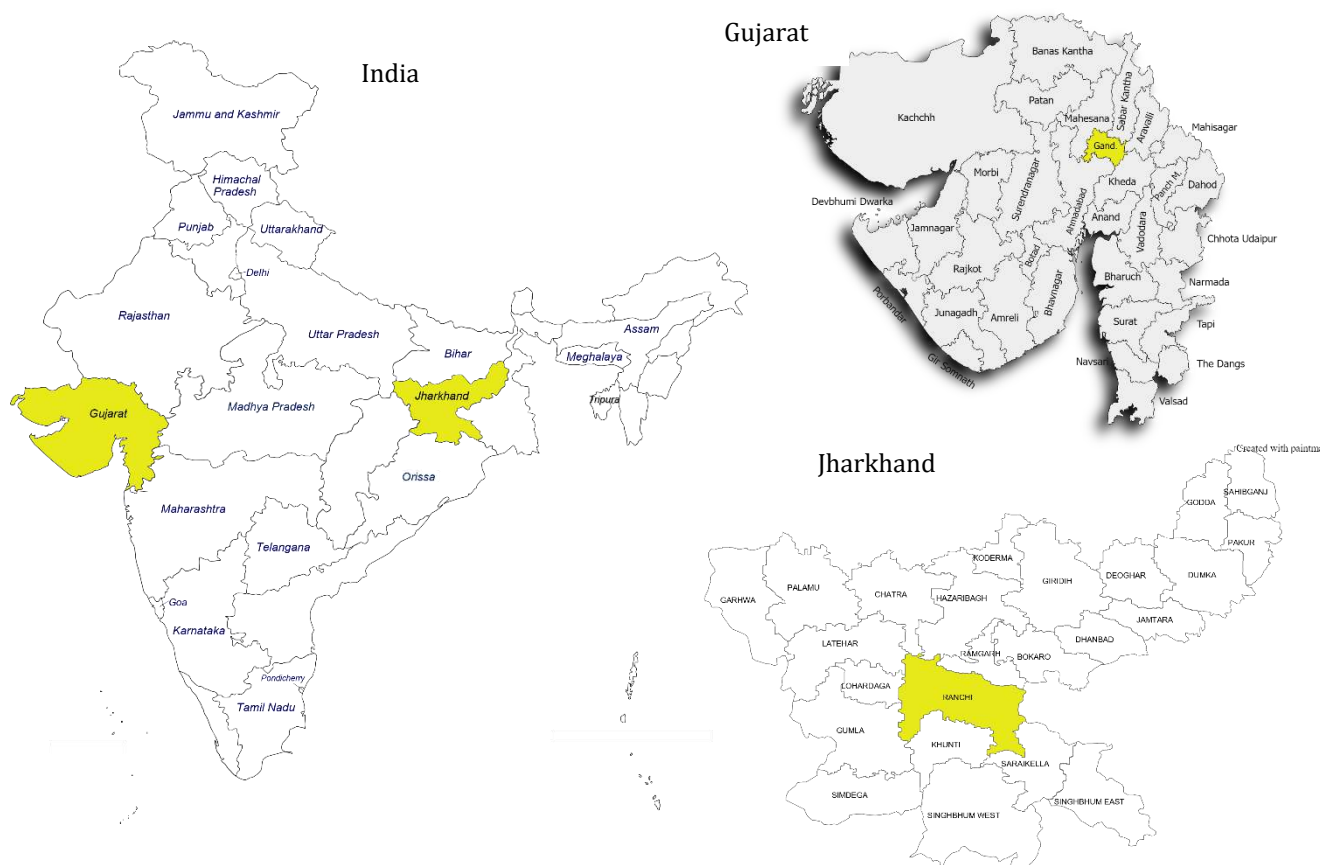


## 3. PROCESS DOCUMENTATION OF THE DCM INTERVENTION

The process documentation was undertaken to map each step of the DCM approach in the pilot health facilities, ensuring an examination of the intervention through a pre-defined process. The literature review was the initial step, followed by the documentation of the process of implementation. The following activities were carried out for this purpose:

- **Consultation with the intervention team:** The initial consultation was conducted with all stakeholders from WHP to understand the intervention protocol, create a

consensus on the need for process documentation, establish modalities for the process documentation, and finalize the outline of the documentation process.

- **Literature Review**: Various literature, including research papers and reports on mental health issues and substance use among TB patients, and their effects on treatment outcomes, were searched to support the document.

- **Continued fortnightly meetings with the intervention team**: Regular meetings were conducted with the concerned thematic leads every 15 days. The meetings were intended to discuss any updates or changes in the protocol or the interventions. They were also meant to share field feedback, inputs, and learnings from the thematic leads.

- **Primary evidence generation through field visits**: The documentation team from IIPHG visited patients and care coordinators to understand the intervention process flow, field-level challenges, learnings, and monitoring mechanisms.
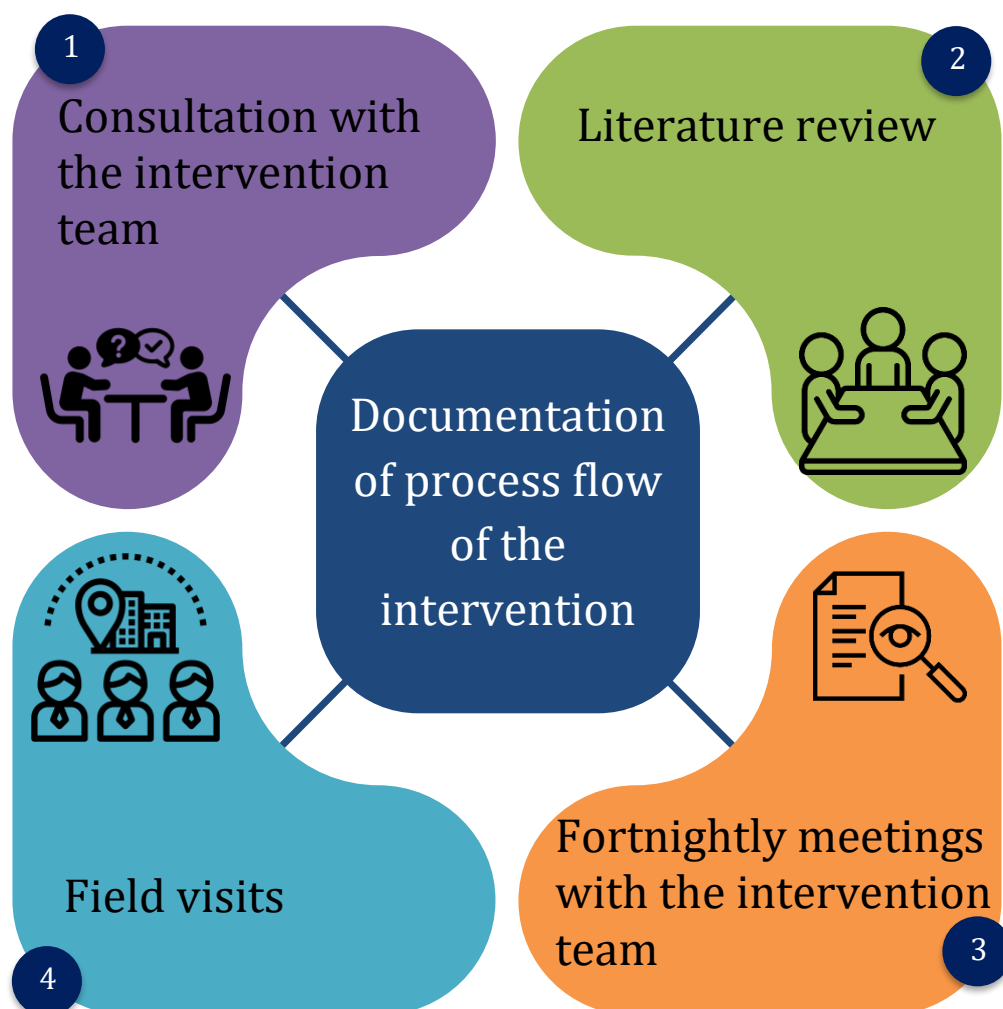
# SECTION 2

## 4. LITERATURE REVIEW - DIFFERENTIATED CARE APPROACH

Globally, the top five attributable risk factors for new TB cases are undernutrition, alcohol abuse, smoking, diabetes, and HIV. Severe undernutrition is the most common comorbidity in TB patients and is often severe and life-threatening.

Nearly 50% of Indian adult men and women with TB weigh less than 43 kg and 38 kg, respectively. Assessment of comorbidities and other risk factors, such as uncontrolled diabetes, substance abuse, advanced HIV stage, severe kidney disease, silicosis, organ transplant, malignancy, COVID-19, and mental health, helps prioritize TB patients for intensified care and treatment support. Morbidity and mortality in TB patients mostly occur due to the severity of TB with complications or serious comorbidities. This optimization of treatment outcomes reduces the chances of an unfavourable condition during the treatment phase, resulting in various consequences [3].

In 2020, 95% of patients-initiated TB treatment; 98% in Jharkhand and 99% in Gujarat. The cure rate for TB patients in India is 61% (72% for Gujarat and 58% for Jharkhand), influenced by various factors.

A cohort study in South India in 2018 on risk factors contributing to unfavourable outcomes among TB patients showed a significantly higher risk of death (AOR: 4.19; 95% CI: 2.47-7.11) and an unfavourable outcome (AOR 2.21; 95% CI: 1.56-3.12) among TB patients with more than one risk or one risk (AOR: 3.28; 95% CI: 2.11-5.10 for death; AOR 1.71; 95% CI: 1.29-2.26 for an unfavourable outcome) compared to TB patients with no identified risk. Additionally, the odds of death and unfavourable outcomes were higher among males with lower education status, undernutrition (initial weight below the national median), co-existing HIV disease, previous history of treatment, drug-resistant TB, and regular alcohol use. Age > 60 years for TB patients was associated with the odds of death [3].

A cohort study in Malaysia from 2014 to 2017 on determinants of unsuccessful outcomes and mortality among tuberculosis patients showed an association of various social and clinical factors (older age, males, foreign nationality, urban dwellers, lower education levels, passive detection of TB cases, absence of Bacilli Calmette-Guerin (BCG) scar, underlying diabetes mellitus, smoking, extrapulmonary TB, history of previous TB treatment, advanced chest radiography findings, and human immunodeficiency virus (HIV) infection) with unfavorable TB treatment outcomes and deaths [4].

To prevent morbidity and mortality associated with TB, it is necessary to have risk stratification and screening for various comorbidities among patients diagnosed with TB. This will help in providing appropriate care and treatment for TB patients. Assessment of vital indicators among TB patients will also stratify the patients and help take appropriate actions
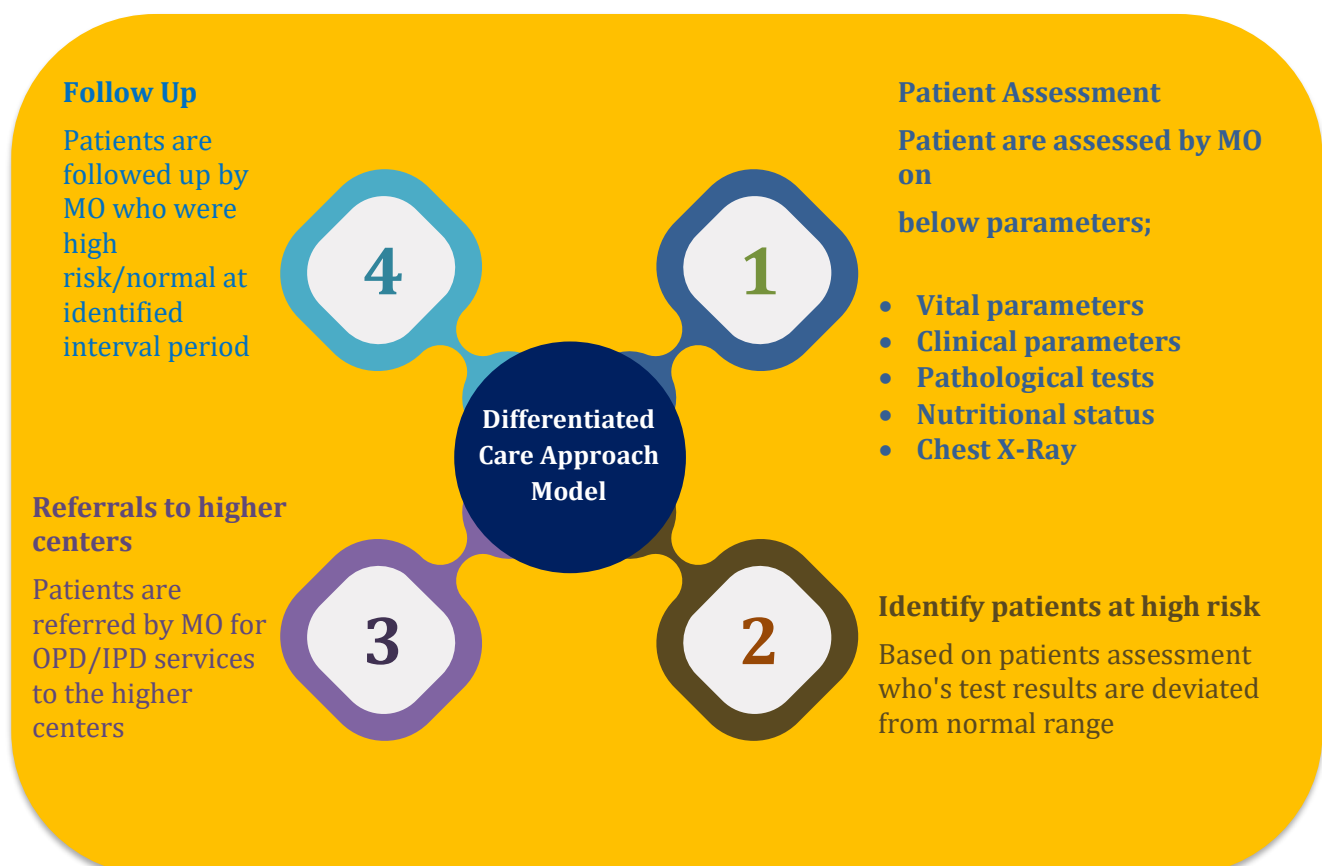
in admitting and treating patients at the facility or community level, resulting in a favorable outcome [5] [6].

A study conducted in Gujarat in 2021 on "Screening adults with tuberculosis for severe illness at notification: program experience from Gujarat, India" shows a significant number of deaths occurring early in treatment due to delays in undergoing a comprehensive assessment of severely ill patients aged >15, considering the existing diagnostic and clinical capacity gaps in the peripheral health institutes (PHIs) [7].

## 5. PROCESS DOCUMENTATION OF INTERVENTION

The intervention was designed with sequential steps to apply the differentiated care approach to TB patients. Initial consultations with pulmonologists, public health experts, and state officials suggested identifying facilities for its pilot demonstration, and based on learnings, expansion could be planned. The intervention took place at selected Peripheral Health Institutes (PHIs) and followed major processes such as initial assessment, risk stratification, referral, and follow-up mechanisms established within the project's geography.

Information regarding assessment results, laboratory and radiological findings, and the patient's status was recorded on a digital platform for detailed analysis. The WHP project team, composed of thematic leads and care coordinators, provided supplementary support to the PHIs at stages.



**Follow Up**

Patients are followed up by MO who were high risk/normal at identified interval period

**4**

**Referrals to higher centers**

Patients are referred by MO for OPD/IPD services to the higher centers

**3**

**Differentiated Care Approach Model**

**Patient Assessment**

Patient are assessed by MO on

below parameters;

- **Vital parameters**
- **Clinical parameters**
- **Pathological tests**
- **Nutritional status**
- **Chest X-Ray**

**1**

**2**

**Identify patients at high risk**

Based on patients assessment who's test results are deviated from normal range

## A. INITIAL ASSESSMENT

- TB patients underwent an initial assessment to identify their health status, including general conditions, laboratory and radiological findings, severity of symptoms due to TB, and comorbidity status if any. The initial assessment provided supporting criteria for the risk stratification of TB patients, which is crucial for comprehensive clinical care.

- The selected Peripheral Health Institutes (PHIs) had a mixed intervention structure where the project team and healthcare providers coordinated the tasks for implementation during the assessment. The Medical Officer of the PHI evaluated patients for icterus, pedal edema, and general condition, and recommended laboratory tests along with chest X-ray. At the time of diagnosis (Annexure -2), all Drug-Sensitive Tuberculosis (DSTB) patients (both Pulmonary TB and Extra-Pulmonary TB) were enlisted for the initial assessment, while Drug-Resistant Tuberculosis (DRTB) patients underwent pre-treatment evaluations based on the Programmatic Management of Drug-Resistant TB (PMDT) guidelines.

- Project staff/Healthcare providers were assigned to measure height, weight, Mid-Upper Arm Circumference (MUAC), Oxygen Saturation, respiratory rate, blood pressure, pulse rate, and temperature when patients were confirmed with TB. Project staff/Healthcare providers would then refer patients for chest X-rays either at Peripheral Health Institutes (PHIs) or to linked X-ray facilities engaged under the CGC i-SMART project intervention.

- The mapping of public and private facilities was part of the initial assessment, ensuring that prescribed laboratory tests were available. Project staff or health care providers sent patients to the nearest health facility where the required laboratory investigations were accessible. These investigations were provided free of cost to the patients. Facilities engaged under the Free Diagnostics Initiative and impanelled under the "Pradhan Mantri Jan Arogya Yojana under Ayushman Bharat" were mapped, while chest X-ray facilities engaged under the CGC project were utilized.

### Assessment of DS TB patients with active pulmonary/ Extra Pulmonary TB

**Vitals & Nutritional**
Pulse Rate, Respiratory Rate, Oxygen Saturation (SPO2), Blood Pressure, Temperature, Height, Weight, MUAC

**Clinical**
General Condition, Icterus, Peripheral Oedema

**Pathological**
HB, WBC (TC), HIV, Diabetes, S. Bilirubin, SGPT, S.Create

**Radiological**
Chest X ray – X ray facility linkages with CGC ismart Intervention
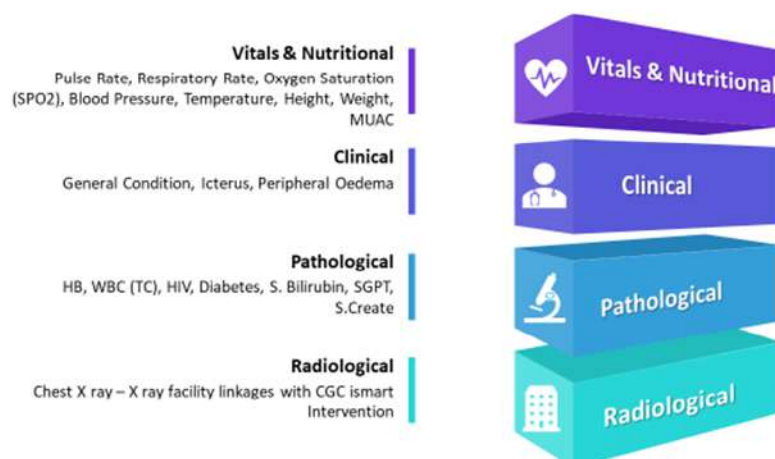
Patients are undergone for DCM at the time of diagnosis/ before treatment initiation

- The WHP team provided the required equipment to measure height, weight, SPO2, blood pressure, and temperature to identified health facilities in both states under this intervention.
- To prevent patients from dropping out of specified investigations, Project staff and health system staff followed up with patients twice weekly for two weeks starting from the date of TB diagnosis/treatment initiation. The results of these investigations were captured in physical form and/or through the Commcare application.



Assessment/Data collection Tool: Scoring Based

## B. RISK STRATIFICATION OF PATIENTS FOR REFERRALS:

- According to the assessment criteria-based score, the medical and paramedical staff at the Peripheral Health Institutes (PHIs) categorized patients' risks. It was determined by the Medical Officer whether a patient needed in-patient care, critical care management, or outpatient management. The reasons for such referrals for outpatient (OPD) or inpatient (IPD) care were documented in physical form and/or the Commcare application. Annexure 2 comprises a tool for basic clinical, laboratory, and radiological investigations of TB patients and referral criteria from primary/secondary care to tertiary care.
- For a patient with Drug-Resistant TB (DR-TB), pre-treatment evaluation remained the same as per the Programmatic Management of Drug-Resistant TB (PMDT) guidelines of the National Tuberculosis Elimination Program (NTEP).
- The criteria and scoring values were different from the guidelines by the Government of India. A few parameters, including SGPT, S. bilirubin, and S. creatinine, have been included

in the tool to be assessed for all patients registered under the intervention based on discussions with physicians and pulmonologists. The existing values mentioned in the national guidelines were revised because, during the implementation of the guideline-based scoring, many values remained undetermined with the outcome.

- Various factors from the patient's side were assessed, such as stay, willingness, wage loss due to admission, etc., considering the patient's clinical condition and the successful program implementation. Patients were counseled by the health care provider or project staff for indoor admission if required.

  The following protocol is established to identify referral networks:

  - Mapping of secondary and tertiary care facilities for severe/emergency referrals made at the appropriate health facility (Community Health Centres, District Hospitals, Medical Colleges) based on the package of care that the patient's condition warrants. Assessment of facilities at various levels of the health system is indicated in Annexure 3.

  - Existing ambulance services were utilized for referral transportation to ensure no out-of-pocket expenditure to the patient. A similar approach was followed to carry out investigations under the Free Diagnostics Services Initiative by the State.

  - Referral health facilities will be oriented to the protocol prior to the start of implementation.

## C. FOLLOW-UP MECHANISM

- The confirmed TB patients underwent a follow-up examination for the parameters if the results revealed values outside the normal range. However, the final follow-up decision rested with the treating medical officer and not solely on the scoring parameters. The initial follow-up strategy depended on the patient's deteriorating conditions, concomitant illnesses, and pre-existing conditions. The frequency of the initial follow-up examination is detailed in Annexures 4, 5, and 6

- **History –** Monthly
  - Symptoms of TB.
  - Symptoms of any adverse action
  - Dose Consumption
  - Adherence Status

- **Clinical examination:**
  - Weight (in kg) and height (in centimeters) to ascertain nutritional status. Body Mass Index (BMI) was calculated and recorded monthly. If the patient could not stand, measure the mid-upper arm circumference (MUAC).
  - **Vitals** - Temperature, Pulse, Respiratory rate, and Blood Pressure were measured and recorded monthly.
  - **Oxygen Saturation**: Using a Pulse Oximeter, the SPO2 level was to be measured and recorded monthly.

- **Pedal Oedema**: Over feet/pretibial/hands/generalized to be observed and recorded monthly.
- **General condition** to be assessed monthly.
- **Investigations:**
  - **Haemoglobin levels**: If the baseline Hb was low, it was measured and recorded monthly in the intensive phase and further every month if it was found low until the treatment completion.
  - **Complete blood count (Total Count, Differential Count, Platelet Count):** If the baseline value of CBC was deranged, the measurement and recording was carried out monthly in the intensive phase and subsequently every month if found low until the treatment completion.
  - **Blood sugar:** If blood sugar was high, it was measured and recorded monthly in the intensive phase and every month if found high until the treatment completion.
  - *If indicated:*
  - **S. Creatinine:** If it was high at initial management, it was measured and recorded monthly in the intensive phase and subsequently every month if found high until the treatment completion.
  - **SGPT, Bilirubin:** If any of these were altered at initial management, they were measured and recorded monthly in the intensive phase and subsequently every month if found deranged until the treatment completion.
- **Imaging:**
  - **Chest X-ray:** End of 2 months of treatment if symptoms persist and as clinically indicated.

*Note: If a patient is diagnosed with Drug-Resistant Tuberculosis (DR-TB), the follow-up remains the same as per Programmatic Management of Drug-Resistant TB (PMDT) guidelines.*

## D.  STATUS OF INTERVENTION WITHIN THE PROJECT STATES

**Jharkhand State:**
- Following the directives of STO Jharkhand, the NTEP Staff (State and District Team) along with the WHP team in Jharkhand planned to implement and roll out the differentiated care intervention at PHI DTC under Sadar TU of Ranchi District starting from 2nd December 2021. An inaugural ceremony for launching the differentiated care intervention was scheduled at the state level in Jharkhand. On 15th December 2021, a letter from the Additional Chief Secretary, Dept of Health and Family Welfare, Jharkhand, was issued to implement the Differentiated Care intervention across the State.
- In February 2022, a meeting was convened with the WHO consultant, DTO, and DPC of the Ranchi district to identify a health facility at the state level for implementing the differentiated care intervention. A detailed discussion took place regarding the

parameters and selection criteria for the health facility, including considerations for human resources allocation and capacity building from the program's perspective.

- Bokaro and Dhanbad districts of Jharkhand were approached on the 20th and 25th of April 2022 to scale up the differentiated care intervention. Both districts were selected for the scale-up of the post-treatment follow-up intervention through the Ni-kshay Sampark team. DTOs of both districts were oriented towards the program process and its output indicators, and they agreed to initiate the intervention with the letter from the ACS (Additional Chief Secretary), Health and Family Welfare Department, Jharkhand (refer to Annexure 1).

- Four facilities were identified from each district for the scale-up of the differentiated care intervention during June 2022. Care Coordinators (CCs) maintained data for the indicators in an Excel sheet, while the hard copy was kept with the health facility staff for the further management of TB patients.

- **Gujarat State:**

  - In Gujarat, the differentiated TB care intervention was initiated at GMERS Medical College & Hospital Gandhinagar on 30th December 2021. Subsequently, efforts were made to initiate the intervention at SMIMER Hospital & Medical College, Surat. Various parameters were considered during the facility selection, including patient load, the feasibility of conducting tests for patients, availability of specialists/physicians, willingness to implement interventions, and suggestions from the State TB cell, among others.

  - Discussions were held with the Pulmonology Department, medical college hospitals, and District TB cells in Gandhinagar and Surat to establish an implementation framework and follow-up mechanism to ensure the continuum of care. The Gujarat State NTEP team was briefed with updates to provide necessary support in the implementation.

The next phase of implementing the differentiated care approach will involve a joint consultative approach with the health system to adopt a comprehensive care approach, expanding service areas, and the PHI network.

## E. UTILIZATION OF COMMCARE TOOL FOR DATA CAPTURING

Data were collected using a mobile phone-based Commcare application, and task lists were provided to project staff to ensure sequential follow-ups as outlined in the protocol.

**June-July 22:** Drawing from past learning experiences, the team developed the data entry section in the Commcare tool to digitize patient records for all 19 parameters and streamline the follow-up process for high-risk patients. Care Coordinators (CCs) were responsible for patient data entry in the Commcare tool.

**On 22nd August**, all Health System Coordinators (HSCs) and CCs received training on entering data into the Commcare application.

**In Jharkhand**, a care coordinator assigned for differentiated TB care intervention at the facility screened DS-TB patients at the initial and follow-up visits of high-risk patients, while CCs in the field would screen patients at the end of IP and CP.

**In the State of Gujarat**, one designated CC was selected for DCM screening at the intervention facility (GMERS Medical College, Gandhinagar) and performed the screening of high-risk DS-TB patients at both the initial visit and during follow-up visits. At the end of IP and CP, patients were screened by CCs available in the field.



*Figure 1 Commcare tool screenshots*

## 6. UPDATE BASED ON INITIAL EXPERIENCE

- Since scoring various indicators was confusing and challenging for the field staff, the pattern to identify patient health conditions based on parameters was changed to "Normal" and "Deranged" vital parameters. Following these changes, the follow-up mechanism pattern was also modified from "Aug '2022".
- The patient was followed up based on deranged parameters and their general conditions. Deranged parameters were monitored in patients every 15 days until they returned to normal (refer to Annexure-3).
- Patients were further followed up at the end of the Intensive Phase (IP) for four parameters: respiratory rate, oxygen saturation, blood pressure, weight, and general condition. If a patient was found to be abnormal, they would be referred to the Peripheral Health Institute (PHI) for further investigations. All patients were followed up at the end of the Continuation Phase (CP) under the ETA–PR Intervention. The follow-up mechanism with the new approach has been established and will be implemented as outlined below:
- **Follow-up of High-Risk Patients (15 days post-initial assessment; done for patients with abnormal parameters only):**
  - High-risk patients are defined as those who fall outside the normal range of the listed clinical parameters (refer to Annexure 2). These high-risk patients will be followed up

15 days post the initial assessment via a call by project staff to assess if the patient has been admitted, the date of admission & discharge, and if any modifications are to be made to their treatment plan based on clinical parameters. The listing of parameters collected during the follow-up of high-risk patients is indicated in Annexure 3.

- It is observed that strict rules of escalation are applied so that all patients with a deviation in any single clinical parameter are followed up to evaluate complications. The retrospective analysis will identify the parameters deemed high-risk based on outcomes.

- **End of Intensive Phase (IP) Assessment (56 days post-treatment initiation; done for high-risk patients who received an initial assessment):**
  - End-of-IP assessments are conducted for high-risk patients who underwent the initial differentiated care assessment. This assessment is performed by project staff through home visits or at the facility if the patient can return to the same facility. A subset of clinical parameters will be assessed, including respiratory rate, oxygen saturation, weight, general condition, and an update of comorbidity information. Any hospital admission or change in clinical management during the IP phase will also be documented. A list of all parameters collected in the End of IP assessment is provided in Annexure 4.

- **End of Treatment Assessment (24-28 weeks post-treatment initiation; done for all patients who received an initial assessment):**

End-of-treatment assessments was conducted for all patients who received the initial differentiated care assessment, irrespective of normal or abnormal parameters. Project staff conducted a home visit for all patients between 24-28 weeks of treatment initiation. A list of parameters collected is provided in Table 4, including:

- Assessment of basic clinical parameters (temperature, SPO2, respiratory rate, pulse rate, blood pressure); weight; comorbidity details.
- Clinical evaluation by MO-PHI/ treating private doctor.
- Sample collection for sputum smear microscopy and liquid culture (outsourcing with private labs for MGIT).
- All culture-positive samples will be referred to IRL for further evaluation.
- Chest X-ray will be carried out either through PHI or engaged private CXR facilities under the project. Existing CXR reports will be considered if the report is 15 days before the end of treatment.
- Pulmonary rehabilitation assessment (verbal screening) to evaluate symptoms of lung impairment, including chronic cough, wheezing, breathlessness, chest tightness, and respiratory infections.

**Note:** For any patient requiring support (at any point in time) due to severe and life-threatening clinical deterioration or injury, emergency services will be called for the patient.

## 7. PRELIMINARY STATUS OF RESULT

**Jharkhand**

- As of July 31st, 2022, 232 DSTB patients were diagnosed at Sadar TU, (DCM intervention TU) Ranchi. Out of those, 184 (79%) patients were enrolled in Differentiated TB Care interventions. Among the screened patients, 46 (25%) reported deranged parameters. Of those, almost 45 (98%) were referred on an OPD basis, and one patient was referred for IPD care services. During the implementation period , no deaths were reported among patient enrolled under the intervention.

**Gujarat**

- Until July 31st, 2022, 497 DS-TB patients were diagnosed at GMERS Medical College and Hospital in Gandhinagar (DCM intervention TU). Out of this group, 175 patients underwent screening as part of the DCM intervention. Among the screened patients, 123 exhibited altered parameters. Unfortunately, there is no available information on indoor admissions and subsequent outcomes.

### Status of TB patients under the DCM Intervention

| Category | Jharkhand | Gujarat |
|---|---|---|
| DSTB Patients Diagnosed | 232 | 497 |
| Screened under DCM | 182 | 175 |
| Deranged Parameters | 46 | 123 |
| OPD/IPD Referral | 46 | - |
| Death Reported | 0 | - |
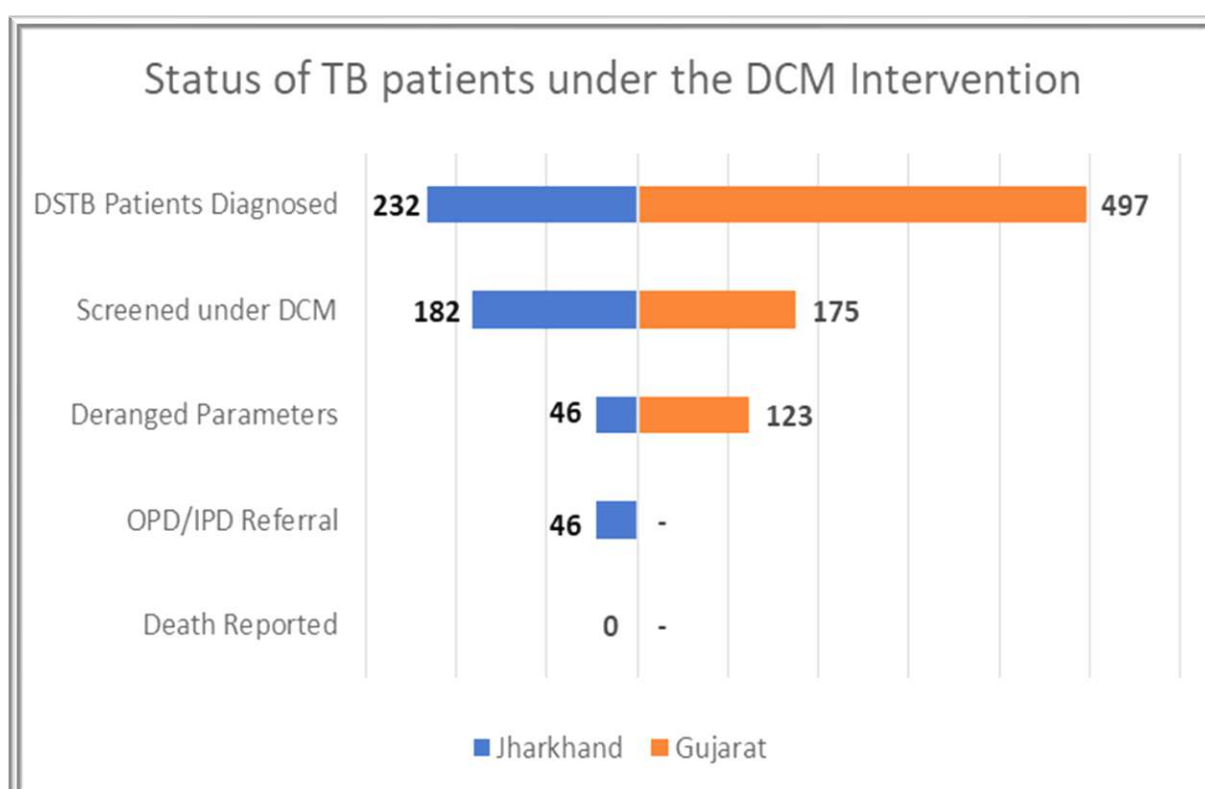
- **Status of the assessment criteria-based scoring for the screened TB patients (N =375) (Frequency of patients under each parameter (in %))**

| SN. | Parameters | 0 | 1 | 2 | 3 | Data not available |
|---|---|---|---|---|---|---|
| 1 | Chest X-ray | 64 (18%) | ■ | 245(69%) | ■ | 48(13%) |
| 2 | Pulse Rate | 234 (66%) | ■ | 118(33%) | ■ | 5(1%) |
| 3 | BMI | ■ | 239(67%) | 63(18%) | 32(9%) | 23(6%) |
| 4 | Blood Pressure | 182 (51%) | 118(33%) | 45(13%) | 1(0.1%) | 11(2.9%) |
| 5 | RBS | 229 (64%) | 45(13%) | 39(11%) | 10(3%) | 34(1%) |
| 6 | Haemoglobin | 223 (62%) | 74(21%) | 16(4%) | 4(1%) | 40(11%) |
| 7 | SGPT | 259 (72%) | ■ | 16(4%) | 1(0.1%) | 81(22.9%) |
| 8 | WBC | 231 (64%) | 41(11%) | 12(3%) | 28(8%) | 45(13%) |
| 9 | Respiratory Rate | 191 (53%) | 146(41%) | 9(3%) | 4(1%) | 7(2%) |
| 10 | HIV | 333 (93%) | 8(2%) | 8(2%) | ■ | 8(2%) |
| 11 | S. Creatinine | 270 (75%) | 2(1%) | 6(2%) | 2(1%) | 77(22%) |
| 12 | Oxygen Saturation | 332 (92%) | 13(4%) | 6(2%) | ■ | 6(2%) |
| 13 | S. Bilirubin | 253 (70%) | 16(4%) | 3(1%) | 1(0%) | 84(24%) |
| 14 | Temperature | ■ | 349(97.7%) | 2(1%) | ■ | 6(2%) |
| 15 | Pedal Oedema | 339 (94%) | 11(3%) | ■ | ■ | 7(%1.9) |
| 16 | Haemoptysis | 326 (91%) | 6(1.6%) | ■ | ■ | 25(7%) |
| 17 | Icterus | 346 (96%) | 1(0.1%) | ■ | ■ | 10(2.9%) |
| 18 | General Condition | 342 (96%) | 5(1%) | ■ | ■ | 10(3%) |
| 19 | MUAC | 95 (27%) | 13(4%) | ■ | ■ | 249(70%) |

* Note: The above table in row 0,1,2,3 value shows the score of risk severity (Annexure:6)

A total of 357 patients were screened from Jharkhand and Gujarat States under the DCM intervention, with 116 (32%) recording a deranged pulse rate, and 63 (18%) patients showing altered values in BMI. In Chest X-rays, 245 (69%) patients recorded consolidation (2 scores).

The intervention revealed that a total of 169 (47%) TB patients required additional consultation from medical officers or specialists.



Percentage of TB patients with altered Parameters (N=357) (Score 2 & 3)

Legend:
- Chest X-ray
- Pulse Rate
- BMI
- Blood Pressure
- RBS
- HEMOGLOBIN
- SGPT
- WBC
- Respiratory Rate
- HIV
- S. Creatinine

Chest X-ray, 69; Pulse Rate, 32; BMI, 27; RBS, 14; Blood Pressure, 13; WBC, 11; HEMOG... 6; SGPT, 5; Res... Rate, 4; HIV, 2; Ox...; S....; S....; Te....
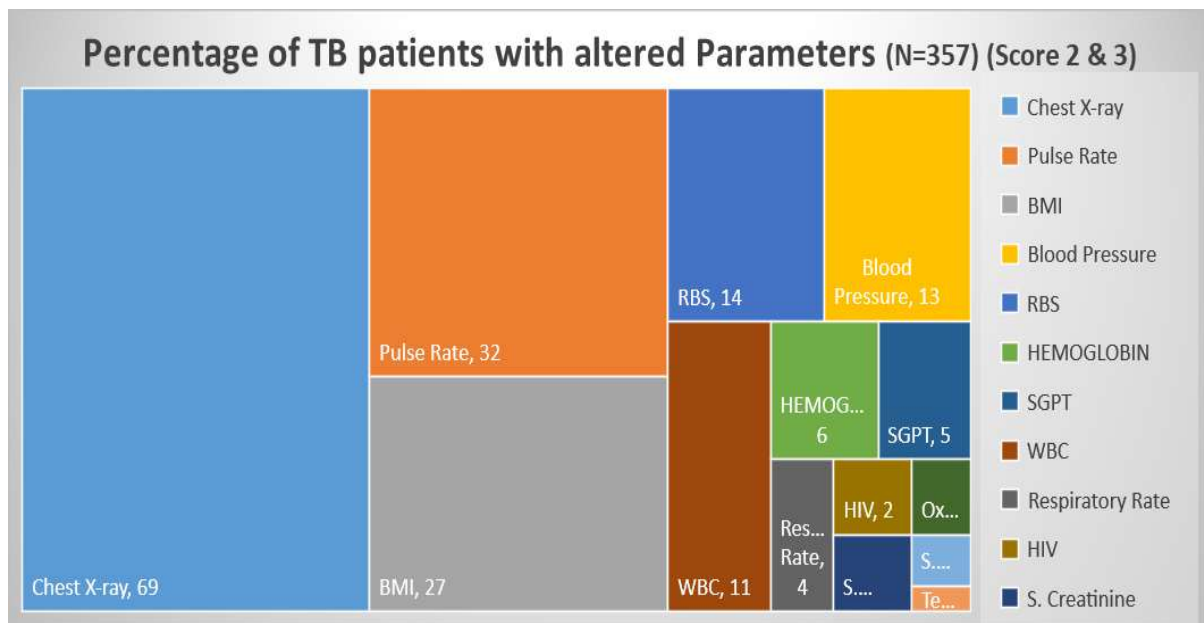
## 8. CHALLENGES AND LEARNINGS

The intervention evolved during its demonstration at the PHIs, where challenges were addressed through field facilitation or consultation with health system staff. These challenges, learnings, or potential solutions may provide a broader perspective for the health system or program to scale up the differentiated care approach, benefiting not only TB patients but also beneficiaries of other national health programs. The list of challenges at each stage with assigned possible solutions is mentioned below:

| Challenges observed | Learnings / Possible Solutions |
|---|---|
| **Development of the assessment Criteria and Scoring** | |
| • The clinical parameters and scoring values provided in the National DCM operational guidelines need to be revisited, as some values showed limited categorization. This led to confusion during application in the field. | • The project team created a group of experts to identify specific parameters and deliberated on the categorization through consultations with clinical experts. The final tool was designed with categorization for each of the 19 parameters. |
| **Patient Assessment and Screening** | |
| • Patients residing in other TUs who have opted for consultation services in selected PHIs could not be recruited for the further stages. | • The enrolment criteria were established based on experience, where the initial assessment was made available to all TB patients who received care from selected PHIs. |
| • Tests such as certain pathological investigations and chest X-rays required at least 24-48 hours to provide reports. | • The linkage between laboratory and radiological facilities was established and facilitated by care coordinators deputed at PHI for the completion of assessments. |
| **Risk Stratification and Primary Data collection on 19 parameters** | |
| • Missing data in the physical tool, such as MUAC and BMI, resulted from a lack of equipment or incomplete assessment information prescribed or provided by health system staff due to a high workload or periodic non-availability of tests within selected PHIs at the time of patients' visits. This affected patients' risk scoring and resulted in issues at the stages of risk stratification. | • Field staff were assigned at selected PHIs to ensure the completion of primary information in physical tools, facilitate TB patients for diagnostic or CXR completion, and address gaps observed during the initial period of implementation through digital reporting in the Commcare application. |
| **Inpatient Care** | |
| • The infrastructure and availability of health staff for specialized care, such as nutrition support centres and advanced | • Resource mapping within PHIs and tertiary-level facilities was conducted before the initiation of the |

| | |
|---|---|
| radiological and laboratory tests, were lacking. There still exists a deficiency in proper infrastructure (both essential and desired) within health facilities as per the National DCM guidelines. | intervention. Based on that, prior intimation via project staff was undertaken when a patient was referred to ensure indoor admission. |
| • Few patients are unwilling to get admitted to government facilities with one or two deranged parameters due to previous experiences, inadequate attention given by the health staff, distance from home, and fear of out-of-pocket expenses (OOPE). | • The patients were counselled, and if found suitable for higher referral, they were followed up by the project team via calls to ensure hospital admission whenever required.<br>• Various factors such as patient wage compensation, feasibility, transportation, etc., play a significant role in the admission of patients to the facility. |
| **Referral for further clinical care** | |
| • Some patients' parameters, such as pulse rate, blood pressure, and body mass index, were altered based on the score; nevertheless, medical officials did not refer to those individuals.<br>• In the case of successful referral of such patients to a higher facility, further management was not clear to the treating physician at the referral health facility. | • The health staff of the concerned PHIs were consulted for the issues and resolved with the orientation of medical officers, but there is a need to develop clinical standards for TB patient management based on clinical scoring at higher centres like medical colleges or district hospitals. |
| **Follow-up stage** | |
| • Patients were unwilling to visit the PHI at the time of the follow-up within a particular time frame. Patients didn't respond during telephonic calls.<br>• Transferred in and out from other TUs.<br>• Availability of follow-up patients' data. | • The follow-up mechanism was modified, and efforts were made through telephonic calls to obtain the status of the health of TB patients. The lists of high-risk categorized patients were submitted to the respective DTCs for further support. |

## 9. CASE STUDIES DOCUMENTED DURING FIELD VISITS

**Case study of a beneficiary from Sadar TU, Ranchi, Jharkhand**

I had a cough for two weeks and was concerned that I might have tuberculosis because two family members had it. I went to my nearest healthcare provider (HCP), who prescribed lab tests and had my vitals and other measurements taken. During the measurement, I was informed that my vital parameters were deranged (BMI score of 2), Hb score of 1 (9.4 mg/dl), TC score of 3 (17,900 mm3), Chest X-ray score of 2 (consolidation), and needed further evaluation by a physician. I was then referred to a physician who informed me that admission was not required and that it could be managed with medicine. My investigations were completed on the same day, and I was started on treatment. I was urged to visit regularly because my therapy progress would be recorded. Since I was advised at every step of my treatment, I have completed my full treatment and feel considerably better. Regular follow-ups were also quite beneficial.



*Sonu Gari, 24-year-old*

**Case study of Medical Officer:**

I observed a patient, who is 35 years old and was diagnosed with DS-TB when he consulted me for a check-up. He did not appear in good health, so I called the TB-HV to screen for all DCM parameters. After the screening, we discovered his BMI was abnormal (score: 17), and his HB status was 9.2. Despite his young age, I initiated his medicine, explained the food plan to him, and recommended that he come for a routine follow-up every two weeks. After four follow-up visits, his BMI, HB, and general condition are okay. The project's follow-up system ensured the patient received a continuum of care. This intervention has allowed me to focus on high-risk patients. - Medical Officer NTEP, GMERS Gandhinagar.

## 10. POSITIVE ENABLERS

- **Expenditure:** With the intervention in place, a noticeable reduction in patients' out-of-pocket expenses (OOPE) was observed as their laboratory and radiographic examinations were conducted free of charge, thanks to the DTC stamp register on their TB case documents in Jharkhand. In Gujarat, the district NTEP staff guided and assisted patients throughout the procedure, and the WHP team's support facilitated the investigations.

- **Private Sector Involvement**: Patients from the private sector are referred to government PHIs for comprehensive diagnosis and prompt treatment initiation, especially when they cannot afford TB treatment and diagnostics.

- **Results from Laboratory:** Initially, the medical officer had to wait 48 hours for laboratory results. However, after the intervention, basic laboratory investigation results were made available within 24 hours, thanks to improved lab coordination.

- **Data:** To assess and track all 19 characteristics of each TB patient, the team established a mechanism to record and preserve data in an Excel sheet. Missing data was captured with the support of NTEP staff or CCs available in the field.

- **Revised Scoring:** The scoring of certain normal measures, initially set at one, was later adjusted based on new scoring criteria for parameters such as pulse rate, temperature, and BMI.

- **Mortality:** No deaths have been reported among TB patients screened as part of the differentiated care intervention in selected PHIs since its initiation in Jharkhand.

- **Scale-up:** State officials in Jharkhand plan to expand the activity throughout the Ranchi district, collaborating with other PHIs, considering the success of the intervention. Similarly, in Gujarat, the State TB Comorbidity Committee discussed tailored expansion of differentiated TB care interventions.

- **Ni-kshay:** The development of the screening tool for the Ni-kshay beta version was facilitated by the team's sharing of initial learning findings with CTD officials.

## 11. STRENGTH AND LIMITATION OF THE INTERVENTIONS

- This study utilized the largest cohort from a National TB program, providing data on key and cutting-edge clinical parameters of TB patients. Moreover, the intervention introduced risk stratification indicators both at the beginning of therapy and during follow-up, making it unique among interventions of its kind nationwide.

- However, the structure for the intervention's implementation had some shortcomings. Patients with severe clinical conditions admitted to hospitals (government or private) were missed during the initial assessment. Additionally, the missed-out patients who only attended intervention sites for investigations and transferred out to other TUs, districts, and states were not included and followed up.

- The availability of specialized centres for TB patients' malnutrition support (such as CMTC/NRC) and advanced radiological and laboratory tests, along with the absence of a protocol on escalation matrix for referral and follow-up mechanisms, was not covered in the national guidelines, and states had limited infrastructure.

## 12. RECOMMENDATIONS

- **Burden of High-risk TB patient Pool:**

- The recent COVID-19 pandemic and increased burden of NCDs may result in more high-risk TB patients, necessitating a clinical definition of high risk beyond a programmatic definition. The burden of high-risk TB patients was limited to the definition of the key population, relying on clinical, laboratory, or radiological parameters other than sputum microscopy grade and drug susceptibility. There is no structured mechanism defined in the national guidelines to undertake DCM at the PHI or TUs level. Ni-kshay should establish a data recording system that enables PHIs to comprehensively register basic initial assessment details.

- A total of 169 (47%) TB patients required further consultation from medical officers or specialists. These patients were only from the selected sites of project districts. More numbers in the private sector (formal or informal) will also require additional assessment. So, the actual burden of the high-risk TB patient pool will be higher in the population.

- **Assessment Criteria and Feasibility of Indicators:**

  - Feasibility indicators in favor of screening included the short time interval for screening, the collection of all indicators in most patients, and acceptable data quality for a program setting. However, the national guidelines suggested 16 parameters with undefined ranges and actions. This requires wider and more specific operational research to establish clinical standards for initial screening and specialized IPD admission assessment.

  - The intervention was in limited geography with project staff but scaling it up in a three-tier health system requires additional research and deliberation on developing a standard operating procedure for differentiated TB care. Several studies suggested creating a wide window for screening that allows the maximum number of patients for the second-level assessment by the medical officer PHI. Still, having a consensus on parameters needs efforts to revise or develop a national guideline.

- **Health System Strengthening and Capacity Building:**

  - There is a need to expand the availability of recommended diagnostic and treatment services across the country and create mechanisms for all healthcare providers, including private sector doctors, to link their patients to these services without any obstacles.

  - Advocacy at the highest levels is required to ensure the availability and convenient linkage of comorbidity-related services at all TB care facilities for all TB patients. Essential diagnostic packages can be created for presumptive patients under a differential care model (as part of Janani Shishu Suraksha Karyakram and under the Free Diagnostic Scheme of NHM) to ensure pre-treatment evaluation for all, reducing out-of-pocket expenditure. It is critical to ensure that all patients can access affordable essential diagnostic test packages in government health facilities. The program can leverage the free diagnostic scheme from the National Health Mission.

- Substantial investment is also needed in training providers on clinical TB guidelines in both the public and private sectors to triage patients and refer them for advanced clinical care if required. There is a need to improve an alternative intervention model through Community Health Officers (CHOs) and Auxiliary Nurse Midwives (ANMs) to enhance coverage.

- **Integration with National Health Programs:**
  - Bi/multidirectional referrals from health programs like maternal & child health programs, Rashtriya Bal Swasthya Karyakram (RBSK), National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke (NPCDCS), National Mental Health Program (NMHP), National AIDS Control Program (NACP), National Tobacco Control Program (NTCP) will provide a "window of opportunity" for screening of presumptive cases.
  - PMJAY impaneled hospitals, railway hospitals, ESIS hospitals, trust hospitals, and medical colleges should be aware of TB notification, and regular meetings can be planned locally. Developing platforms/mechanisms to interlink information management systems across different programs, including strengthening recording and reporting activities through data reconciliation at all levels.
  - To increase screening coverage at the time of diagnosis, expand the availability of free diagnostic tests at all TB diagnostic centres through the National Health Programme.

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## 15. ANNEXURES

<p align="center"><span style="color:red">**Annexure-1**</span></p>

ACS (Additional Chief Secretary letter) Health, Jharkhand letter.
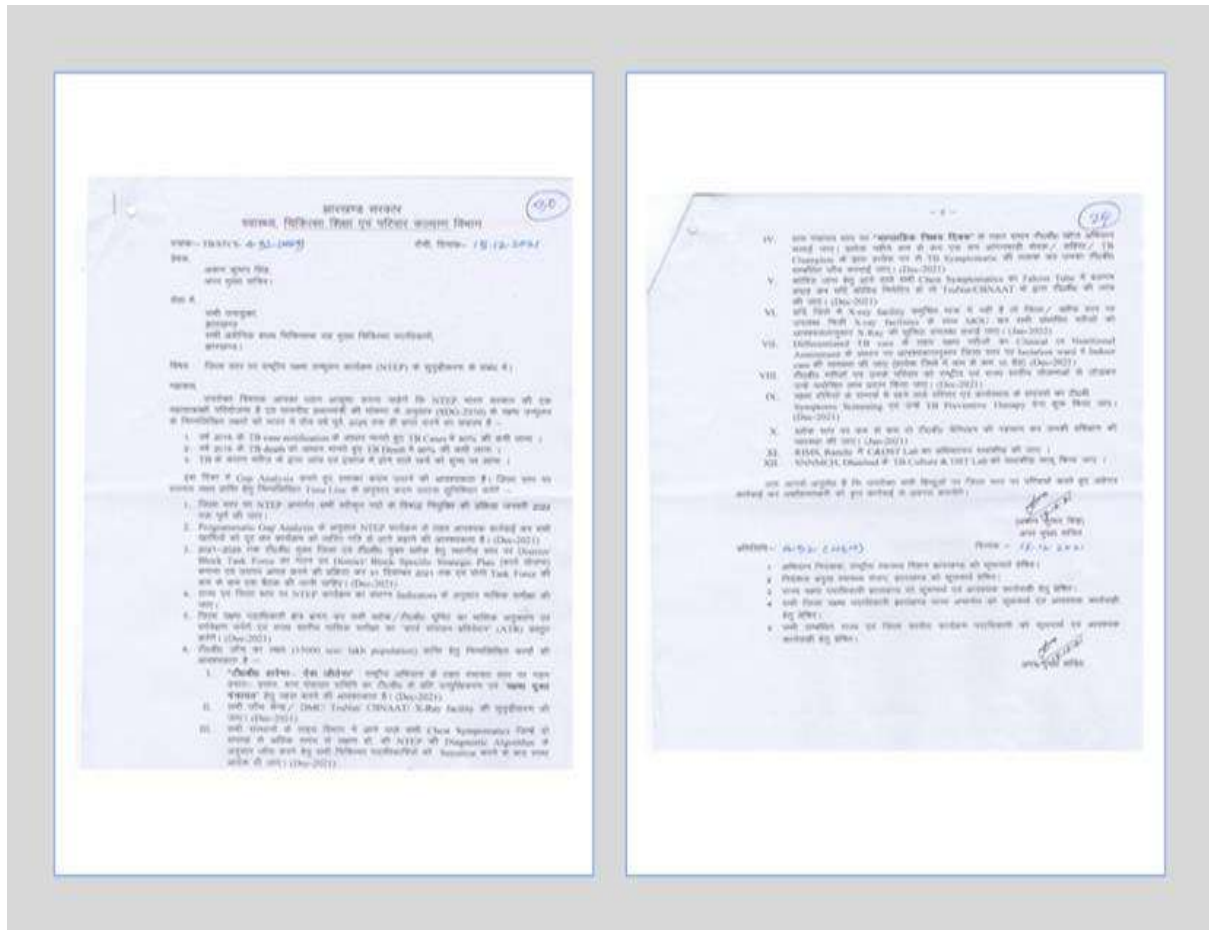
**Initial protocol applied for assessment**

**Basic Clinical and Laboratory Investigations, Normal Range, and Criteria for Referral of TB Patients for in-patient Care.**

| SN. | Clinical/ Lab test | Range | Score | Test Result | Score |
|-----|--------------------|-------|-------|-------------|-------|
| 1 | Pulse Rate | X < 60 OR X > 100<br>60 to 100 | 2<br>0 | | |
| 2 | Temperature | X < 35 OR X > 41<br>35 to 41 | 2<br>1 | | |
| 3 | Blood Pressure | Normal (120/80mmHg)<br>Higher Normal (< 140/90mmHg)<br>Hypertension (> 140/90 mmHg)<br>Hypotension (Diastolic < 60 mmHg)<br>Hypertension (>200/100 mm Hg) | 0<br>1<br>2<br>3<br>3 | | |
| 4 | Respiratory Rate | X < 8<br>X < 12<br>X >= 12 to X<= 18<br>X > 18 to X<= 24<br>X > 24 to X< 30<br>X>= 30 | 3<br>2<br>0<br>1<br>2<br>3 | | |
| 5 | Oxygen Saturation | X >= 94 to X<= 100<br>X < 94 to X>= 90<br>X < 90 to X>= 85<br>X < 85 | 0<br>1<br>2<br>3 | | |
| 6 | BMI | X < 14<br>X >= 14 to X < 16<br>X >= 16 to X < 30<br>X >= 30 to X < 33<br>X >= 33 | 3<br>2<br>1<br>2<br>3 | | |
| 7 | MUAC | X >= 19<br>X < 19 | 0<br>1 | | |
| 8 | Pedal Oedema | Yes<br>No | 1<br>0 | | |
| 9 | General Condition | Conscious and normal<br>Inability to walk but conscious and oriented<br>Conscious and not oriented<br>Drowsy/Unconscious/Comatose | 0<br>1<br>2<br>3 | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10 | Icterus | Yes<br>No | 1<br>0 | | | |
| 11 | HEMOGLOBIN | X < 4<br>X >= 4 to X < 7<br>X >= 7 to X < 10<br>X >= 10 to X <= 18<br>X > 18 | 3<br>2<br>1<br>0<br>2 | | | |
| 12 | WBC | X <= 2000<br>X > 2000 to X < 3000<br>X >= 3000 to X < 4000<br>X >= 4000 to X < 11000<br>X >= 11000 to X < 14000<br>X >= 14000 to X < 16000<br>X >= 16000 | 3<br>2<br>1<br>0<br>1<br>2<br>3 | | | |
| 13 | RBS | X < 50<br>X > =50 to X < 70<br>X >= 70 to X < 80<br>X >= 80 to X <= 128<br>X > 128 to X < =140<br>X > 140 to X < 250<br>X >= 250 | 3<br>2<br>1<br>0<br>1<br>2<br>3 | | | |
| 14 | HIV | -Ve<br>+Ve and on ART<br>+Ve and not on ART | 0<br>1<br>2 | | | |
| 15 | Chest X-ray | No abnormality<br>Consolidation<br>Hydro Pneumothorax | 0<br>2<br>3 | | | |
| 16 | Haemoptysis | Yes<br>No | 1<br>0 | | | |
| 17 | S. Creatinine | X = 0.6 to 1.2 mg/dl<br>X =1.3 to 3 mg/dl<br>X more than 3 mg/dl | 0<br>2<br>3 | | | |
| 18 | S. Bilirubin | X = 0.3 to 1.2 md / dl (Direct < 0.3 mg/dl, Indirect < 0.9 mg dl)<br>X = 1.3 to 2 mg / dl<br>X = 2.1 to 3 mg/dl<br>X > 5 mg/dl | 0<br><br>1<br>2<br>3 | | | |
| 19 | SGPT | 7 to 60 units per litre (U/L) = 0<br>61 - 180 units per litre (U/L) = 2<br>More than 180 units per litre = 3 | 0<br>2<br>3 | | | |

**As per treating doctor's opinion if the patient to be referred for IPD – Yes/ No**

**If Yes, Reason for referral:**

_____
_____

**Referred to Facility: -**                                    **Referred by: -**

| Total Score | Category | Action |
|---|---|---|
| Score between 0 or 1 | Low risk | Providing intermediate care and observing for symptoms subside |
| Score of 2or 3 | Moderate risk | Referring to a facility with the availability of an MBBS doctor or facility indicated in the referral column. |
| Score above 3 | High risk | Referring to DH/SDH or nearest secondary or tertiary care facility with availability of intensive care |

**Baseline assessment for facilities available at the various levels of the health system**

| SN. | Facility Name & Type: | Available (Yes/ No) Name: _____ _____ (SC/ HWC/ PHC/ UPHC/ CHC/ UCHC/ SDH/ DH/MC) | If outsourced |
|---|---|---|---|
| **District:** | | **Taluka:** | |
| 1 | **Diagnostics** | | |
| I | Chest radiography | | |
| Ii | Pulse oximetry | | |
| Iii | Complete blood count | | |
| Iv | HIV testing and Blood sugar | | |
| V | Renal function tests | | |
| Vi | Liver function tests | | |
| Vii | Blood grouping | | |
| Viii | Weighing machine | | |
| Ix | Stadiometer/staturemeter | | |
| X | CBNAAT | | |
| Xi | TruNAAT | | |
| 2 | **Drugs** | | |
| I | Weight-based anti-tuberculosis drugs$ | | |
| ii | Multivitamins | | |
| iii | Thiamine 100 mg daily | | |
| iv | Syp. Potklor 15 ml | | |
| v | Inj. Magnesium sulphate 50% 2 ml IM. | | |

| | | | |
|---|---|---|---|
| vi | Albendazole 400 mg single dose | | |
| vii | Iron and folic acid | | |
| viii | Ceftriaxone | | |
| ix | Gentamicin | | |
| x | Piperacillin-Tazobactam | | |
| xi | Hydrocortisone | | |
| xii | Dopamine | | |
| xiii | Phenylephrine | | |
| **3** | **Therapeutics** | | |
| i | Oxygen | | |
| ii | Broad spectrum antibiotics, including intravenous drugs | | |
| iii | Non-invasive ventilation for co-existing acute type 1 respiratory failure, COPD exacerbations | | |
| iv | Hydrocortisone, vasopressor drugs | | |
| v | Multivitamins and iron supplements | | |
| vi | Surgical expertise: Chest tube insertion for pneumothorax and empyema | | |
| vii | Blood transfusion facility | | |
| viii | Oral potassium, ORS including rehydration solution for malnutrition, enteral feeding with F- 75 and F-100 formula feeds ( can be made with milk or milk powder, sugar, vegetable oil) | | |
| ix | Facilities for invasive ventilation | | |
| x | laparotomy | | |
| xi | ventriculo- peritoneal shunt | | |
| xii | spinal decompression | | |
| xiii | decortication surgery | | |
| xiv | Bronchial artery embolism for control of massive hemoptysis | | |

| 4 | Human Resource | | |
|------|---------------------------------------------|--|--|
| i | Community Health officer | | |
| ii | STS* | | |
| iii | TBHV* | | |
| iv | Medical Officer | | |
| v | Medical Officer (AYUSH) | | |
| vi | Lab. Technician | | |
| vii | Pharmacist | | |
| viii | Multi-Purpose Health Supervisor (MPHS) | | |
| ix | Female Health Supervisor (FHS) | | |
| x | Specialist Doctor | | |
| | MD (Internal Medicine) | | |
| | MS (Surgery) | | |
| | MD/ DNB (Anesthesia) | | |
| xi | Radiographer | | |
| **\* STS, TBHV may be linked with PHI i.e. MC/ SDH/CHC/PHC/UPHC** | | | |

**Follow-up form for high-risk patient -via phone call**

1. Is the patient admitted?
2. Date of admission
3. Date of discharge
4. Was there any modification by a doctor to manage clinical parameters?

**Annexure-5 Follow up mechanism after initial risk stratification**

**End of IP, Assessment form**

1. Respiratory rate (breaths per minute) Normal: 12-24
2. Oxygen Saturation - Normal: 94-100
3. Weight (kilograms (kg)
4. General Condition
   - Conscious and normal
   - Inability to walk or stand on own (but conscious and oriented)
   - Conscious and not oriented
   - Drowsy/Unconscious/Comatose
5. HIV
   - Negative
   - Positive and on ART
   - Positive and not on ART
6. Diabetes
   - Negative
   - Positive and on treatment
   - Positive and not on treatment
7. Other Comorbidity
   - Arthritis
   - COVID-19
   - Cancer
   - Heart Disease
   - Mental Health Issue
   - Orthopaedic
   - Others
8. Was the patient admitted for abnormal clinical parameters? required
9. Date of admission
10. Name of Facility
11. Date of discharge
12. Was there any modification by a doctor to manage clinical parameters?

**Follow-up mechanism after risk stratification**

**Near End of CP (DSTB – PTB)**

A home visit was conducted by project staff for all patients between 24-28 weeks of treatment initiation. A list of parameters is mentioned below.

1. Smear Result
2. Culture Result
3. Chest X-ray Interpretation
4. Weight (kilograms (kg)
5. Temperature(°C)
6. Oxygen Saturation - SPO2 levels
7. Pulse Rate (bpm)
8. Respiratory rate (breaths per minute)
9. Blood Pressure (mm Hg) (mm/Hg) Systolic
10. Blood Pressure (mm Hg) (mm/Hg) Diastolic
11. General Condition
    - Conscious and normal
    - Inability to walk or stand on own (but conscious and oriented)
    - Conscious and not oriented
    - Drowsy/Unconscious/Comatose
12. HIV
    - Negative
    - Positive and on ART
    - Positive and not on ART
13. Diabetes
    - Negative
    - Positive and on treatment
    - Positive and not on treatment
14. Other Comorbidity
    - Arthritis
    - COVID-19
    - Cancer
    - Heart Disease
    - Mental Health Issue
    - Orthopaedic
    - Others
15. Was the patient admitted for abnormal clinical parameters?
16. Date of admission
17. Date of discharge

18. Was there any modification by a doctor to manage clinical parameters?

19.  Do you have a chronic cough?

20.     Do you experience a wheezing sound while breathing?

21.     Do you feel any chest tightness?

22.     Do you use an inhaler for respiratory issues?

23.     Do you ever feel any breathlessness, if so, when? (Assess patient with MMRC scale)
- Grade 0 – I only get breathless with strenuous exercise
- Grade 1 – I get short of breath when hurrying or walking up a slight hill
- Grade 2 – I walk slower than people of the same age because of breathlessness, or I have to stop to breathe when walking at my own pace on the level
- Grade 3 – I stop for a breath after walking about 100 m or after a few minutes on level ground
- Grade 4 – I am too breathless to leave the house or when dressing

24.  Do you experience frequent respiratory infections?

25.  Adherence: How many days were missed overall throughout your treatment?

**Reporting format of basic clinical and laboratory investigations of TB patients and referral criteria**

District:                    TU:                              Facility Name:

Date: -                                                          Ni-kshay ID/ Episode ID: -

| SN. | Clinical/ Lab test | Normal value | Range | Score | Test Result | Score |
|---|---|---|---|---|---|---|
| 1 | Pulse Rate | 60 - 100/min | X < 60 OR X > 100<br>60 to 100 | 2<br>0 | | |
| 2 | Temperature | 36 - 38 C | X < 35 OR X > 41<br>35 to 41 | 2<br>1 | | |
| 3 | Blood Pressure | Systolic – 80 to 140 Diastolic – 60- 100 | Normal (120/80mmHg)<br>Higher Normal (< 140/90mmHg)<br>Hypertension (> 140/90 mmHg)<br>Hypotension (Diastolic < 60 mmHg)<br>Hypertension (>200/100 mm Hg) | 0<br>1<br>2<br>3<br>3 | | |
| 4 | Respiratory Rate | 12 – 14/min | X < 8<br>8 < X < 12<br>X >= 12 to X<= 18<br>X > 18 to X<= 24<br>X > 24 to X< 30<br>X>= 30 | 3<br>2<br>0<br>1<br>2<br>3 | | |
| 5 | Oxygen Saturation | 94 - 100% | X >= 94 to X<= 100<br>X < 94 to X>= 90<br>X < 90 to X>= 85<br>X < 85 | 0<br>1<br>2<br>3 | | |
| 6 | BMI | 18.5 – 24.9 | X < 14<br>X >= 14 to X < 16<br>X >= 16 to X < 30<br>X >= 30 to X < 33<br>X >= 33 | 3<br>2<br>1<br>2<br>3 | | |
| 7 | MUAC | = >19 cm | X >= 19<br>X < 19 | 0<br>1 | | |
| 8 | Pedal Oedema | No | Yes/ No | 1<br>0 | | |
| 9 | General Condition | Conscious & well oriented | Conscious and normal<br>Inability to walk but conscious and oriented<br>Conscious and not oriented<br>Drowsy/Unconscious/Comatose | 0<br>1<br>2<br>3 | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10 | Icterus | No | Yes/ No | 1<br>0 | | |
| 11 | HEMOGLOBIN | Male / Female – 10 to 18 g/dl | X < 4<br>X >= 4 to X < 7<br>X >= 7 to X < 10<br>X >= 10 to X <= 18<br>X > 18 | 3<br>2<br>1<br>0<br>2 | | |
| 12 | WBC | 3000 - 14000 | X <= 2000<br>X > 2000 to X <  3000<br>X >= 3000 to X < 4000<br>X >= 4000 to X < 11000<br>X >= 11000 to X < 14000<br>X >= 14000  to X < 16000<br>X >= 16000 | 3<br>2<br>1<br>0<br>1<br>2<br>3 | | |
| 13 | RBS | 79 – 140 mg/dl | X < 50<br>X > =50 to X <  70<br>X >= 70 to X < 80<br>X >= 80 to X <= 128<br>X > 128 to X < =140<br>X > 140  to X < 250<br>X >= 250 | 3<br>2<br>1<br>0<br>1<br>2<br>3 | | |
| 14 | HIV | Negative | -Ve<br>+Ve and on ART<br>+Ve and not on ART | 0<br>1<br>2 | | |
| 15 | Chest X-ray | No abnormality | No abnormality<br>Consolidation<br>Hydro Pneumothorax | 0<br>2<br>3 | | |
| 16 | Haemoptysis | No | Yes/ No | 1<br>0 | | |
| 17 | S. Creatinine | 0.6 – 1.2 mg/dl | X = 0.6 to 1.2 mg/dl<br>X =1.3 to 3 mg/dl<br>X more than 3 mg/dl | 0-<br>1<br>2<br>3 | | |
| 18 | S. Bilirubin | < 1.2 mg/dl | X = 0.3 to 1.2 mg / dl<br>X = 1.3 to 2 mg / dl<br>X = 2.1 to 3 mg/dl<br>X > 5 mg/dl | 0<br><br>1<br>2<br>3 | | |
| 19 | SGPT | < 60 U/L | 7 to 60 units per liter (U/L) = 0<br>61 - 180 units per liter (U/L) = 2<br>More than 180  units per litre  = 3 | 0<br>2<br>3 | | |

**Treating doctor's opinion, if the patient to be referred for IPD – Yes/ No**

**If Yes, Reason for referral:**

_____
_____
____

**Referred to Facility: -**                              **Referred by: -**

| Total Score | Criterion | Immediate Action |
|---|---|---|
| Score 0 or 1 | Low risk | Providing intermediate care and observing for symptoms to subside |
| Score of 2 or 3 | Moderate risk | Referring to PHC or any facility with availability of MBBS doctor or facility indicated in referral column. |
| Score above 3 | High risk | Referring to DH/SDH or nearest secondary or tertiary care facility with availability of intensive care |

**IEC material**: