

# Impact and Cost-Effectiveness Evaluation of Nutritional Supplementation and Complementary Interventions for Tuberculosis Treatment Outcomes under Mukti Pay-for-Performance Model in Madhya Pradesh, India: A Study Protocol

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## Abstract

**Background:** A “pay-for-performance” (P4P) intervention model for improved tuberculosis (TB) outcomes, called “Mukti,” has been implemented in an underdeveloped tribal area of central India. The target of this project is to improve nutritional status, quality of life (QoL), and treatment outcomes of 1000 TB patients through four interventions: food baskets, personal counseling, peer-to-peer learning and facilitation for linkage to government schemes. The current study aims to assess the success of this model by evaluating its impact and cost-effectiveness using a quasi-experimental approach. **Methods:** Data for impact assessment have been collected from 1000 intervention and control patients. Study outcomes such as treatment completion, sputum negativity, weight gain, and health-related QoL will be compared between matched samples. Micro costing approach will be used for assessing the cost of routine TB services provision under the national program and the incremental cost of implementing our interventions. A decision and Markov hybrid model will estimate long-term costs and health outcomes associated with the use of study interventions. Measures of health outcomes will be mortality, morbidity, and disability. Cost-effectiveness will be assessed in terms of incremental cost per quality-adjusted life-years gained and cost per unit increase in patient weight in intervention versus control groups. **Results:** The evidence generated from the present study in terms of impact and cost-effectiveness estimates will thus help to identify not only the effectiveness of these interventions but also the optimal mode of financing such measures. Our estimates on scale-up costs for these interventions will also help the state and the national government to consider scale-up of such interventions in the entire state or country. **Discussion:** The study will generate important evidence on the impact of nutritional supplementation and other complementary interventions for TB treatment outcomes delivered through P4P financing models and on the cost of scaling up these to the state and national level in India.

**Keywords:** Cost-effectiveness, impact, India, nutritional interventions, pay-for-performance financing, tuberculosis

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## INTRODUCTION

India accounts for 27% of the global tuberculosis (TB) burden, with more than 35% of global TB deaths among HIV-Negative people.<sup>[1]</sup> The country recorded a total notification of 2.40 million TB cases in 2019, of which 78% were of pulmonary TB.<sup>[2]</sup> It is estimated that about 40% of the Indian population is infected with TB bacteria, the vast majority of whom have latent TB rather than TB disease.<sup>[3]</sup> The country also accounts for 16% of the estimated 480,000 new cases of multidrug-resistant TB detected globally.<sup>[4]</sup> Taking this into

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consideration, the Government of India rolled out a National Strategic Plan (NSP) for TB elimination in 2017 and set an ambitious target of TB elimination by 2025.<sup>[5]</sup> Several new initiatives have been proposed under this NSP, such as provision of digital X-ray enabled with computer-aided diagnosis and tele-radiology services across the health sector, universal drug susceptibility testing to at least rifampicin for all diagnosed TB patients, mandatory notification of new cases by private health providers to the government, active case finding in vulnerable and marginalized groups, drug resistance surveys, and linking eligible TB patients with social welfare schemes including nutritional support.<sup>[6,7]</sup>

India, as a country, also fares poorly in terms of nutritional status of the population. The Global Hunger Index placed it at 101 rank out of the total 117 countries in 2021.<sup>[8]</sup> While 53% of women aged 15–49 years were reported to be anemic, 34.7% and 17.3% of children under 5 years of age were stunted and wasted, respectively.<sup>[9]</sup> About 19.6% males and 22.4% females above 18 years of age were reported to be underweight for their age.<sup>[10]</sup> While both, the TB incidence and the outcomes of TB treatment, in terms of patients' recovery, disease recurrence, progression to drug-resistant form or mortality, are dependent upon a number of predisposing and concurrent factors, undernutrition has been known to play an inextricable role.<sup>[11–14]</sup> Around 55% of the annual incidence of TB (more than one million new cases) in India is considered attributable to undernutrition.<sup>[15]</sup> There is a high prevalence of moderate to severe undernutrition in both men and women with active TB across both rural and urban settings.<sup>[16]</sup> Poverty and food insecurity prevents weight gain in TB patients, which undermines the results of an effective TB treatment.<sup>[16,17]</sup> Undernutrition in patients with active TB may also be associated with a higher mortality, hence tackling under nutrition may significantly reduce TB treatment outcomes.<sup>[18–20]</sup>

The World Health Organization (WHO) guidelines on nutritional care and support for patients with TB express that an adequate diet with all essential macro and micronutrients is necessary for the recovery of patients with TB disease.<sup>[21]</sup> The Government of India guidelines state that patients with active TB require approximately 40 kcal/kg of ideal/desirable target body weight, hence a protein intake of 1.2–1.5 g/kg of ideal/desirable body weight per day is desired.<sup>[22]</sup> The guidelines recommend the state departments of health and family welfare to establish linkages with the department of food and civil supplies at all levels to provide supplement food basket for the duration of anti-TB treatment to all patients through the existing public distribution system. As an alternative, the delivery of the supplemental food basket may be entrusted to nongovernmental organizations (NGO) already working in this area.<sup>[22]</sup> Working on these lines, USAID-supported “Partnership for Affordable Healthcare Access and Longevity,” in collaboration with the MP state health leadership (National Health Mission and National TB Elimination Program (NTEP) and international NGO ChildFund, launched a “Mukti Impact Bond (Termed Mukti P4P hereafter)” a Pay-for-Performance (P4P) financing instrument for improved TB outcomes. The target of this

project, initially, is to employ P4P model of financing the results instead of traditional input-based financing to improve nutritional status and treatment outcomes of 1000 TB patients in Dhar district of MP, which can be scaled up later to the state/national level depending upon the success of the intervention.

There are numerous observational studies and randomized trials in published literature comparing the results of oral nutritional supplementation with a scenario of no nutritional intervention, placebo or dietary advice.<sup>[23–32]</sup> These studies tested the hypothesis that better nutrition improves TB treatment outcomes through restoration of cell-mediated immunity and promotes nutritional recovery, with improved weight gain, restoration of muscle strength, function, and quality of life (QoL). Some of these studies report a significant increase in body weight, higher sputum conversion rates, higher treatment completion rates and improvements in the QoL scores in the supplementation group.<sup>[24,26,27]</sup> As per two systematic reviews, however, while food or energy supplements may improve weight gain and Body mass index during recovery from TB, and shortens the time of sputum conversion, there is limited evidence for improvement in TB treatment outcomes as compared to the counterfactual.<sup>[33,34]</sup> Thus, the impact of Mukti intervention also needs to be measured in terms of both the health impact as well as its cost-effectiveness.

Since Mukti is being implemented in a P4P model, the effectiveness of this model of financing the results as against the traditional input-based financing approaches also needs to be established. Although literature cites significant improvements in TB cure rates and average length of treatment for cured cases after implementation of P4P programs, systematic reviews in healthcare did not find consistent positive associations of P4P programs with improved health outcomes.<sup>[35,36]</sup> Drawing general conclusions of the marginal effectiveness of P4Ps is difficult because P4P programs are complex interventions intertwined with other simultaneous technical and behavioral interventions, apart from being influenced by the program design, modalities of payments, amount of additional funding and the organizational context within which such programs are implemented.<sup>[37]</sup> Methodologically, it is difficult to disentangle the effects of financial incentives as a unique element in a P4P program, and it seems that to be effective, P4Ps need to be part of a comprehensive package of technical interventions and capacity building support within the interventions.<sup>[38]</sup> Given these methodological issues, this study focusses on assessing the treatment success rates and assess the incremental cost per quality adjusted life-year (QALY) gained due to Mukti intervention against a counterfactual scenario of routine NTEP services, with the understanding that the effect of P4P model will be embedded in the values of the effectiveness and impact measures.

## METHODS

### Study settings

The state of Madhya Pradesh, with 6% of population of the country, is the third largest contributor to the TB cases, with

7% of the total notifications (1960 cases/million population).<sup>[2]</sup> A total of 160,144 TB cases were notified in the state in 2019, however, only 145,756 (~91%) patients were initiated on TB treatment.<sup>[2]</sup> Among the notified patients, state reported a cure rate of 68% in the public sector, with a treatment success rate of 87% in public sector and 63% in private sector.<sup>[2]</sup> The state also fares poorly in terms of nutritional outcomes. About 54% of children in Madhya Pradesh in age group of 1–4 years are anemic, while 32% of adolescents (10–19 years) in the state are moderately or severely thin.<sup>[39]</sup> The state has one of the highest prevalence of multiple burden of malnutrition (under-five children who are stunted, wasted, and underweight); and was among the top five states in terms of stunting, under-weight, and wasting.<sup>[40]</sup> For providing interventions under the Mukti program, and their subsequent cost-effectiveness evaluation, Dhar district, a partially tribal, economically backward district of the state was selected. The district population is predominantly rural (81%) and indigenous communities classified as “scheduled tribes” comprise 56% of the population. The district has a district TB center and 13 subdistrict administrative units called TB Units (TU). These TUs administer 31 Designated Microscopy Centres (DMC).

### Program interventions

Four interventions were delivered as part of the Mukti program to TB patients by cluster coordinators of ChildFund India. These included counseling support through home visits, provision of locally procured protein-rich food baskets to patients, group-based community sessions (positive deviance [PD] sessions) for enabling peer-to-peer learning, and facilitation of linkages to nutrition support schemes provided by the government, including the direct benefit transfer scheme. Cluster Coordinators made an average of 7 home visits per patient and counseled patients on the importance of treatment compliance and nutrition intake. Food baskets were distributed to patients either during home visits or PD sessions. These contained wheat flour, groundnuts, yellow split pigeon peas lentils and a flour made from a mixture of roasted and ground pulses and cereals such as barley and gram [Table 1]. PD sessions were conducted at a central place in clusters of 3–4 villages or 8–10 patients, where successful practices of positive deviants identified and adapted as local solutions. The final intervention included providing necessary support to the patients to open bank accounts and assisting Government to register TB patients on the *Nikshay* portal. This is in compliance with the *Nikshay Poshan Yojana*, a financial incentive of INR 500/month to each notified TB patient for their treatment duration initiated by the Ministry of Health and Family Welfare, Government of India in April 2018.

### Study framework

There are three components of the study: data collection related to the measurement of costs, the impact of the intervention, and finally, the cost-effectiveness of the intervention [Figure 1]. While the measurement of costs was a cross-sectional facility-based exercise, impact evaluation was conducted using two approaches: a retrospective design

and a quasi-experimental prospective cohort study design. The retrospective arm involved data collection from patients who had been provided interventions at two previous time-frames (in the years 2019 and 2020) and have already completed their treatment. These data will help to understand the sustained effects of the nutritional interventions after a period of time. The prospective data were collected from a cohort of TB patients who registered for treatment in the district between July and September 2021.

### Impact assessment

#### Sample size

Results of an earlier study reported an 8% improvement in treatment success rate among TB patients receiving oral nutritional supplementation as compared to patients only on anti-tuberculous treatment regimen. Assuming an improvement of 5% in our study, with 95% confidence interval, 80% power and equal number of subjects in intervention and control groups, a sample size of 754 participants for each group was estimated. Assuming a nonresponse rate of 10% and 1.2% design effect, a sample size of 995 participants in each arm of the study was considered appropriate.

#### Sampling approach

We included all 282 and 237 patients studied in the intervention and control arms, respectively under a pilot conducted in the Dhar district between October 2018 and May 2019 (Pilot phase). Another 1000 patients were provided the intervention in Dhar district between March and September 2020 and hence recruited in our study (Phase 1). Patients in the district who registered for treatment at DMCs between October 2020 and March 2021 were recruited under the study as control patients against Phase I intervention patients. Finally, 300 more patients were recruited for each of the intervention and control groups for the prospective cohort study. These patients were selected through consecutive sampling from new TB treatment registrations at DMCs in Dhar district from July to September 2021 (Phase 2) [Table 2].

#### Sampling criteria

New microbiologically confirmed or clinically diagnosed TB patients ( $\geq 18$  years of age) receiving treatment at the DMCs were considered eligible for inclusion in the study. Patients with multi-drug resistance or extra-pulmonary TB, requiring treatment for more than 8 months' duration, though receiving the benefits of the intervention, were excluded from the study.

#### Randomization

The DMCs in the district were cluster randomized into intervention and control arms for the phase 2 of the study. The participants and field staff were not blinded after the assignment. All 31 DMCs from the selected districts were line-listed (Supplementary Material 1) and randomized equally to both the arms by computer-generated random numbers.

#### Data collection

##### Quantitative data

All quantitative data were collected by trained data collectors through face-to-face interviews with patients at their homes

using structured questionnaires. Separate tools were drafted for the pilot phase, phase 1 and phase two patients. Data on socio-demographic characteristics, including gender, caste, religion, education, occupation, marital status, and socioeconomic assessment with household consumption expenditure were collected. While data on treatment success (sputum negativity and weight gain) and client satisfaction with program intervention were collected from all intervention patients, the administration of other sections was subjective to patient category. Pilot phase patients were also administered questions related to TB relapse and transmission to other family members, and long-term retention of knowledge gained earlier due to the intervention [Table 3]. Data on treatment outcomes will be collected from NTEP *Nikshay* records. The phase 2 participants were followed up at a monthly frequency for their entire treatment duration. They were administered additional sections on treatment adherence, health-care

seeking behavior, and out-of-pocket expenditure (OOPE) on treatment. Data on both direct medical and nonmedical OOPE incurred were collected, along with coping mechanisms for OOPE. In addition, the patients and their caregivers were interviewed for days away from work due to treatment to ascertain the indirect costs in terms of productivity losses. Data on health-related QoL were collected once from phase one patient and three times from phase two patients using the using Euro-QoL five dimensions' questionnaire Eq5D5 L tool. The QoL score will be estimated using the tariff value set from India for EQ5D5 L.

### Anthropometric evaluation

Weight and height of the phase two patients were measured at a monthly frequency by the data collectors [Table 3]. Digital weighing scales with error margin <100 g and portable stadiometers with error margins of <1 mm were used for these purposes. Both measurements were taken three times and their

**Table 1: Composition of food baskets distributed as part of intervention**

Item	Quantity per basket (kg)	Approximate quantity per day (g)	Energy requirement fulfillment per day (calories)	Protein requirement fulfillment per day
Wheat flour	4	133	465	11
Groundnuts	2	65	360	16
Yellow split pigeon peas lentils	1	35	122	7
Roasted, ground barley-gram flour	1	35	142	7
Total	8	268	1089	41

**Table 2: Patient sampling for impact evaluation**

Study design	Study arm			
	Intervention		Control	
	Sample size	Treatment registration period	Sample size	Treatment registration period
Retrospective: Pilot phase	282	October 2018-May 2019	237	October 2018-May 2019
Retrospective: Phase 1	1000	March 2020-September 2020	1000	October 2020-Mar 2021
Prospective: Phase 2	300	July 2021-September 2021	300	July 2021-September 2021

**Table 3: Tool sections and their data collection frequencies for different categories of patients**

Section	Pilot phase	Phase 1	Phase 2
Treatment outcome (sputum negativity)	Once, at treatment completion	Once, at treatment completion	Once, at treatment completion
Anthropometric measurements	Monthly <sup>@</sup>	Twice, at initiation and completion of treatment <sup>@</sup>	Monthly
Socioeconomic determinants	Once, at treatment completion	Once, at treatment completion	Once, at treatment initiation
Client satisfaction*	Once, at treatment completion	Once, at treatment completion	Once, at treatment completion
TB relapse, transmission to family members	Once, at treatment completion	-	-
Treatment adherence	-	-	Monthly
QOL measurement	-	Once, at treatment completion	Three times: At treatment initiation, postintensive phase, posttreatment completion
Health-care seeking behavior and out of pocket expenditure <sup>#</sup>	-	Once, at treatment completion	Monthly

\*Administered only to intervention patients, <sup>@</sup>Obtained from secondary data. <sup>#</sup>Administered only for hospitalizations due to TB. TB: Tuberculosis, QOL: Quality of life



mean was considered as the final value. Weight and height measurements of pilot-phase patients were being obtained from ChildFund records. A weight measurement of Phase 1 patients was collected from *Nikshay* records. We are using standard definitions provided by WHO for the classification of under nutrition.

**Qualitative data collection**

Three focused group discussions were conducted in each of the intervention and control district to collect qualitative information on the perceived benefits of the counseling and PD sessions, food baskets, and utilization of cash received under the government scheme. Data collection was done using both Pen-and-Paper Personal Interview approach as well as audio recording of the interviews. The audio records were used to supplement interviewer notes wherever necessary. Both data collection and entry tools were pretested before actual data collection.

**Data quality**

Data quality was monitored consistently during the survey to ensure adherence to the sampling plan, correctness, completeness, and accuracy. Data collectors were supervised by a team of supervisors, who also recollected about 10% of the data for cross-verification. Missing data at the end, if any, will be imputed with the standard regression imputation technique.

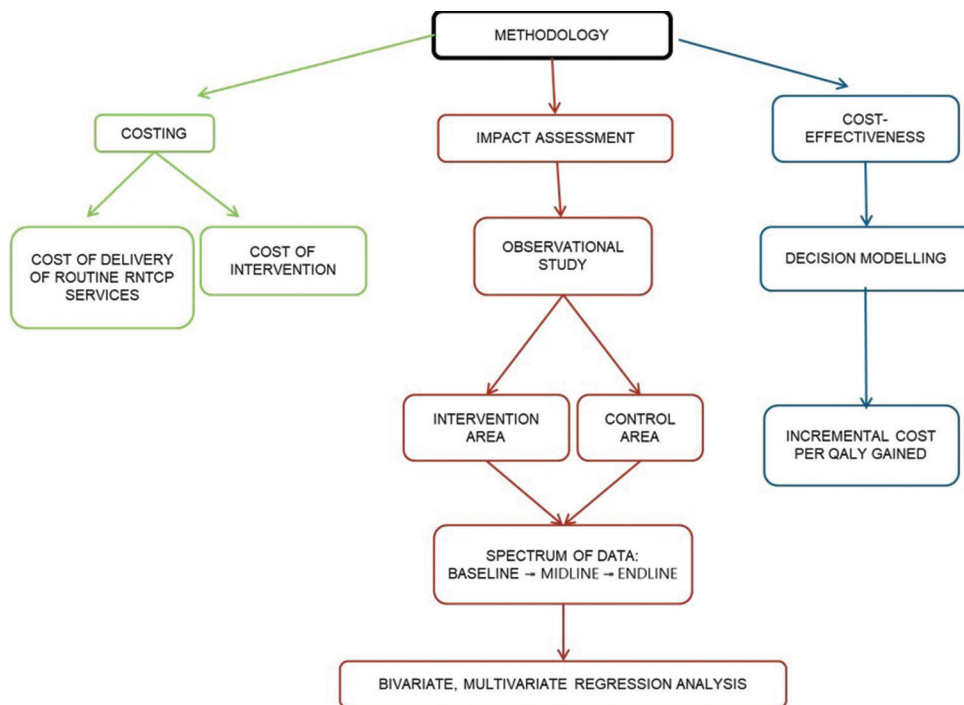
**Data analysis**

The data will be cleaned and analyzed using Microsoft Excel (Microsoft Corporation, 2016, Washington, US) and IBM SPSS ver. 21 software (IBM Corp., 2012. Armonk, NY, US). A descriptive analysis of the primary study outcomes will

be followed by a comparative evaluation of results in the intervention and control groups. We plan to use a Difference in difference analysis to evaluate the impact of the interventions from the data obtained through a quasi-experimental design (with controls recruited in the second phase from the intervention district). Rates of completion of treatment and clinical outcomes will be analyzed with logistic regression with adjustment for confounding factors. We also plan to conduct Kaplan–Meier survival estimates to examine the relationship between the intervention and the weight gain. Since monthly weight data is expected to be balanced short panel, fixed effects least-squares dummy variable model (FEM) or random effects model (REM) will be used to analyze this data, depending upon the correlation between predictors and error term.<sup>[41]</sup> Hausman test will be employed to assess the statistical significance of the correlation between predictor variables and error term. If a correlation is established, FEM will be preferable over REM.<sup>[41]</sup>

**Costing of the routine services and program interventions**

The cost assessment for the TB services under Mukti P4P model will be undertaken both from an economic and financial perspective. The cost estimates from an economic perspective will be used for undertaking the cost-effectiveness of Mukti P4P program, while the same from financial perspective will be used to inform the budget decisions pertaining to scale-up of the program.<sup>[42]</sup> Under the economic perspective, following the principles of opportunity cost, all resources being utilized to deliver the services under the Mukti P4P program will be cost irrespective of who pays for these resources (or may be voluntary services in some cases).<sup>[43]</sup> In contrast, only the additional cost that the health system is liable to pay for implementing Mukti TB interventions will be considered under



**Figure 1:** Proposed methodology

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financial costing. The cost estimates generated from the latter approach will be more appropriate to project the budgetary requirements for the scale of the program.

### Program costs

The cost of delivering TB services will be estimated under both Mukti P4P model as well routine services. The cost associated with the interventions delivered under Mukti: counselling sessions, provision of food baskets, PD sessions, and linking patients to various government schemes, will be obtained from the financial records of program to be received from the implementing agency. As this is a P4P model, the normative provider payment rates per person covered under Mukti program will be appropriate to reflect the program costs. A similar approach will be used to assess the costs associated with the TB service package as routine care.<sup>[5]</sup>

### Treatment costs

We presume a standard treatment protocol for TB patients under both the arms and therefore, similar stage-specific treatment costs for TB patients. The only expected difference between the intervention and control arm is a higher treatment success rate in the intervention group.

In order to assess the cost of treatment of TB patients, a bottom-up micro-costing approach will be followed.<sup>[44,45]</sup> All cost centers pivotal to service delivery will be identified and resource utilization will be measured in the reference period. The costs will be segregated broadly based on nature of the resource: capital or recurrent. Data collection process for different resources will include a review of financial and stock records, physical observation of building space used and interviews of personnel

involved in service delivery. Capital resources/costs will be annualized to estimate correct value of resource utilized in the reference period. The total cost of the recurrent resources (drugs and consumables) will be estimated by multiplying the unit price with the quantity of respective resource consumed. Health system cost per outpatient visit and in-patient admission will be estimated. A discount rate of 3% will be used wherever applicable.

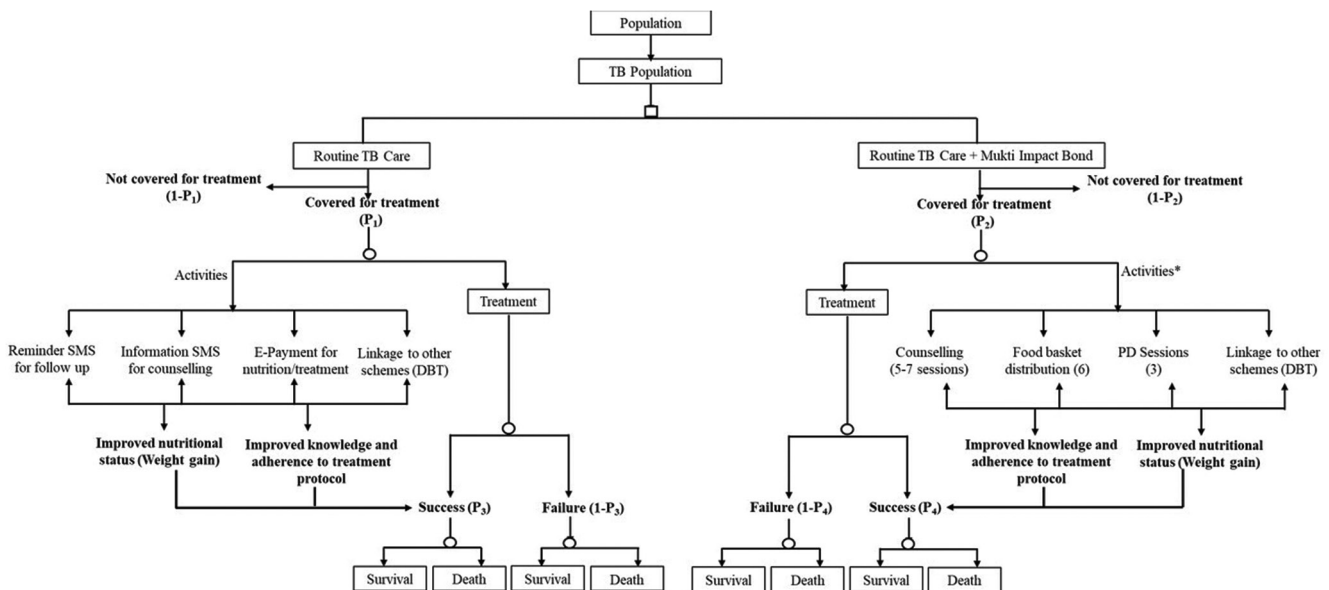
### Cost-effectiveness analysis

#### Model overview

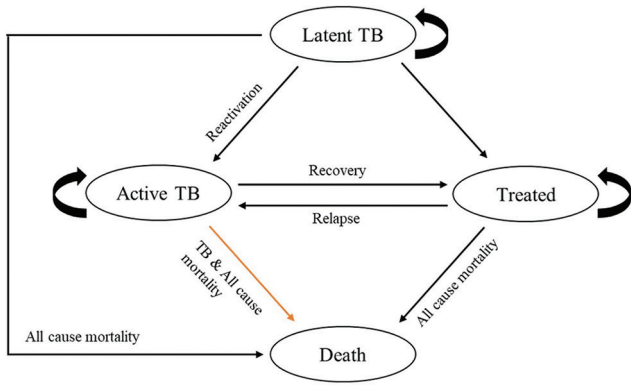
We propose to use a two-part hybrid model in this evaluation. A decision tree [Figure 2] will be prepared in MS Excel to demonstrate the modalities under two arms followed by the development of a Markov model [Figure 3] to simulate the progression of TB. A lifetime horizon and societal perspective will be considered for cost-effectiveness analysis (CEA). We will model the lifetime costs and effects of delivering TB services through Mukti P4P model in comparison to routine service delivery in the state of Madhya Pradesh. Both the costs and outcomes will be discounted at a rate of 3% for future years. This choice of discounting rate is based on standard international guidelines along with being consistent with other Indian economic evaluations.<sup>[46-48]</sup>

#### Valuation of outcomes

The impact of the Mukti interventions will be assessed in terms of treatment success rates (treatment completion) and change in the weight of the patients. The improved cure rate will further enhance the longevity and QoL among TB population. The endpoints for effectiveness will be incremental life years (LY) gained and QALYs gained among the TB patients in the two arms.



**Figure 2:** Decision model for cost-effectiveness analysis of mukti pay-for-performance program. TB: Tuberculosis, PD: Positive deviance, DBT: Direct benefit transfer, P1: Proportion of people covered for treatment under intervention arm, P2: Proportion of people covered for treatment under control arm, P3: Treatment success rate under intervention, P4: Treatment success rate under control. Activities\*: The activities under the intervention arm, i.e. Mukti impact bond, are in addition to those mentioned in the counterfactual arm, i.e. Routine TB care



**Figure 3:** Markov model

**Costs**

The total cost in each scenario will be calculated from a societal perspective including both health system costs as well OOPe. Under the health system costs, the cost of routine care services will act as baseline considering all the patients will utilize the routine care in both the intervention and control arm. In the intervention arm, total health system costs will be constituted by routine care costs and cost of services under Mukti P4P. Thus, lifetime costs for both intervention and comparator will be modeled.

**Cost-effectiveness**

The endpoint for the CEA will be Incremental Cost Effectiveness Ratio. The following formula will be used for this computation:

$$ICER = \frac{(C_2 - C_1)}{(E_2 - E_1)} \tag{1}$$

In (1), the numerator implies the incremental costs while the denominator implies the incremental effects. Here C2 and C1 are the costs of intervention and comparator respectively, while E2 and E1 are effects of intervention and comparator respectively, which are measured in terms of LYs/QALY lived by the population in the respective scenarios. A threshold willingness-to-pay equivalent to one-time per capita gross domestic product of India will be considered to assess the cost-effectiveness of Mukti P4P program.

**Sensitivity analysis**

In order to measure the extent of uncertainty present in the analysis and its impact on decision-making, both univariate and probabilistic sensitivity analysis will be conducted. Results from uncertainty analysis will be presented as a cost-effectiveness plane as well as a cost-effectiveness acceptability curve.

**Overall study outcomes**

The primary outcome from our study will be the difference in the treatment success rates among the intervention and control group patients [Table 4]. Other outcomes of interest include the changes in weight and QoL among patients as a results

of the intervention. Outcomes important from the program perspective will be the unit cost of service delivery under NTEP, incremental cost of service delivery for the Mukti interventions, incremental cost-effectiveness ratio for delivery of Mukti interventions, and the cost of scaling up the Mukti model to the state and national level. A detailed list of tentative study indicators have been appended as Supplementary Material 2.

**Study timeline**

The study was initiated in August 2020. Data collection from pilot and phase one patients was started in July 2021 after study tools finalization, necessary approvals, and training of data collectors. Data collection from phase two patients was initiated in October 2021. The costing data collection, data analysis for impact evaluation, and CEA is expected to be completed by the end of August 2023.

**Ethics approval and consent to participate**

Ethics clearance for the study has been obtained from the lead author’s institute. All patients enrolled in the study are being provided a detailed “Participant Information Sheet” in the local language and a written informed consent is obtained before data collection. Final datasets will be stored and analyzed without personal identifiers to maintain patient privacy and confidentiality.

**DISCUSSION**

Nutritional interventions have been well-documented to improve body weight and treatment adherence in TB patients, but there is limited evidence for higher treatment success rates. The present study is being undertaken to assess the impact and cost-effectiveness of Mukti P4P program, which provided interventions such as counseling sessions and peer-to-peer learning in addition to the food baskets for the TB patients in Dhar district of Madhya Pradesh. To the best of our knowledge, there is no cost-effectiveness evaluation for a such basket of interventions reported from India. Thus, this study holds immense significance to provide evidence from an economic standpoint on whether such interventions are successful, cost-effective and should be scaled up. Further importance of this study lies in the fact that the results would generate a validation for P4P financing mechanism for delivering interventions. This will enable attract additional funding resources and allow combination of the most cost-effective interventions under current government programs for scale. Since MP is a state with one of the highest burden of the disease in the country, the impact of the intervention, if successful, becomes all the more important and meaningful.

There is a common debate about the period between implementation of the interventions and initiation of their evaluation. This period is considered necessary, especially in other public health interventions, for the interventions to demonstrate a measurable impact. Since the interventions in our case were complementary to the TB treatment that the patients were receiving and enhanced the probability of

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**Table 4: Primary study outcomes**

Measurement	Study outcome
Sputum test	Proportion of patients testing sputum negative on treatment completion
Weight	Mean change in weight among intervention and control patients Mean change in BMI among intervention and control patients Comparison of rate of change in BMI in the two groups
QOL	Mean change in QOL among intervention and control patients Comparison of rate of change in QOL in the two groups Mean change in QALYs among intervention and control patients
Out-of-pocket expenditure	Comparison of out-of-pocket expenditure incurred by patients in the two groups
Treatment adherence	Comparison of treatment adherence rates and completion rates in the two groups
TB service utilization at public health facilities	Unit cost of service delivery under NTEP
Costs of resources used at facilities for service delivery	
Quanta and cost of resources utilization for Mukti P4P interventions	Unit cost of delivering Mukti program interventions; Incremental cost of delivering Mukti program interventions Incremental cost-effectiveness ratio for delivering Mukti interventions additional to routine TB services
TB patient load and existing resources involved in TB service delivery at state and national level*	Cost of scaling-up the Mukti interventions to state and national level

\*Obtained from secondary data sources. BMI: Body mass index, P4P: Pay-for-performance, QALYs: Quality adjusted life years, TB: Tuberculosis, NTEP: National TB Elimination Program, QOL: Quality of life

achieving outcomes, it makes it imperative to measure their impact concurrently. Still, we included two cohorts of TB patients who had already completed their interventions to identify long-term impact of study interventions.

The government of India through its *Pradhan Mantri TB Mukh Bharat Abhiyaan* has invited expression of interest from corporate and nonprofit societies to register as *Ni-kshay Mitra* and augment community involvement in meeting India's commitment to end TB by 2025.<sup>[49]</sup> These organizations will be involved in providing additional support to all the on-treatment TB patients, including nutritional and vocational support, as well as additional investigations for diagnosed patients. Previous studies from other countries have provided mixed evidence toward success of P4P funding mechanisms.<sup>[35,36,38]</sup>

## CONCLUSIONS

The evidence generated from the present study in terms of impact and cost-effectiveness estimates will thus help to identify not only the effectiveness of these interventions but also the optimal mode of financing such measures. Our estimates on scale-up costs for these interventions will also help the state and the national government to consider scale-up of such interventions in the entire state or country. However, since different areas in India have significant heterogeneity in terms of new TB notification rates as well as availability, utilization, and quality of health-care resources and services, the results of our study will need to be adapted/customized carefully, keeping these contextual factors in consideration.

## Limitations of study

There are certain limitations of this study. While all 31 DMCs in the district were cluster randomized into intervention and control arms for the phase 2 of the study, the phase 1

intervention was rolled out in all DMC areas simultaneously. This forced us to select the control patients against phase 1 intervention patients from a different period. This can limit the causal attribution if inherent differences in the two time periods influence the outcome. However, we will try to limit this bias by matching patients in the two groups of phase 1 according to their demographic and socioeconomic characteristics.

Second, the interventions involved the interaction of cluster coordinators with patients at facilities and patients' homes and delivery of food baskets and counseling. Given the nature of these interventions, it was not possible to blind the participants. Also since specific questions pertaining to the use of intervention were included in the structured questionnaire on delivery of intervention, the field staff who collected data on outcomes also cannot be blinded to the intervention.

Third, we aim to assess improvement in outcomes such as treatment success rates and gain in weight and QoL as a result of the four study interventions. However, these are not the primary objectives of the project, which is to assess the efficacy of a result-based financing approach (P4P model) over the conventional financing model to achieve the desirable health outcomes in the patients. Since financing is only a part of the whole dynamic, which includes technical and behavioral components of the interventions, it is methodologically not possible to identify the effects of the financing approach as a unique element and hence we believe that the impact of financing approach will be embedded in the values of the effectiveness and impact measures.

There are also some limitations in the way QALYs are defined. These types of study interventions have many other nonhealth benefits such as higher productivity and improved workplace performance. However, it is outside the scope of this study to



capture such benefits. We will try to capture the uncertainty in the cost and CEA using sensitivity analysis.

### Ethical statement

The study was approved by the Institute Ethics Committee of Post Graduate Institute of Medical Education and Research, Chandigarh, India (Approval No. IEC-09/2020-1768 dated 23 October, 2020).

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### Conflicts of interest

There are no conflicts of interest.

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