Section: Community Medicine

Original Research Article

# OPERATIONAL FEASIBILITY OF IMPLEMENTING NUTRITIONAL SUPPLEMENTATION AMONG PULMONARY TUBERCULOSIS PATIENTS UNDER NTEP IN KALABURAGI DISTRICT, KARNATAKA

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ABSTRACT

**Background:** Nutritional support is increasingly recognized as essential to tuberculosis (TB) care, but its large-scale feasibility under India's National Tuberculosis Elimination Programme (NTEP) remains uncertain. The objective is to evaluate the operational feasibility, adherence, and acceptability of nutritional supplementation for pulmonary TB patients in Kalaburagi district.

**Materials and Methods:** A cohort of 800 smear-positive pulmonary TB patients was followed across seven tuberculosis units (TUs). Four TUs provided adjunct micronutrient supplementation in addition to routine care. Feasibility was assessed through patient adherence, acceptability surveys, side-effect reporting, TU staff workload, and supply chain monitoring.

**Results:** Supplement adherence was high (87.5%), with minimal reported side effects (<5%). Patient acceptability was positive, with 72% perceiving supplements as beneficial. TU staff reported manageable additional workload, with 84% stating distribution was feasible within routine DOTS visits. Stock-outs occurred in 6% of months, resolved through district-level redistribution. Supplemented patients demonstrated faster smear conversion (81.2% vs. 72.5%) and higher treatment completion (92.3% vs. 86.1%).

**Conclusion:** Nutritional supplementation is feasible and acceptable within NTEP, with minimal disruption to TU operations. Integration alongside financial transfers could strengthen patient outcomes and equity.

**Keywords:** Tuberculosis, Nutritional supplementation, NTEP, Operational feasibility, India, Program implementation.

## INTRODUCTION

Tuberculosis (TB) remains a leading cause of morbidity and mortality globally, with India accounting for nearly a quarter of the world's cases and deaths.[1] Despite the availability of effective chemotherapy, treatment outcomes are strongly influenced by undernutrition, which impairs immunity and delays bacteriological response.[2,3] Malnutrition is both a risk factor for TB disease and a consequence of chronic infection, creating a vicious cycle that worsens patient prognosis.[4]

Recognizing this, the World Health Organization (WHO) recommends nutritional assessment and counseling as integral to TB care.[5] In India, the Government introduced the Nikshay Poshan Yojana, a direct benefit transfer scheme to provide financial assistance for nutrition support.[6] However, cash-based transfers may not fully translate into improved dietary intake, especially in vulnerable households where funds may be diverted to non-food needs.[7]

Micronutrient supplementation has therefore been proposed as a practical adjunct to standard therapy, but its operational feasibility within routine NTEP settings has not been systematically evaluated.[8]

Feasibility extends beyond clinical outcomes—it encompasses adherence, patient acceptability, side effects, supply chain management, and staff workload. Successful integration requires that supplementation be acceptable to patients, logistically sustainable for tuberculosis units (TUs), and minimally disruptive to existing workflows.[9] Previous pilot studies in India and other high-burden countries have shown promising results but highlighted challenges such as procurement bottlenecks, stock-outs, and staff training gaps.[10,11] Given the paucity of evidence from programmatic settings, this study aimed to assess the operational feasibility of implementing nutritional supplementation for pulmonary TB patients under NTEP in Kalaburagi district, Karnataka. Specifically, we evaluated patient adherence, acceptability, tolerability, and TU-level operational challenges, while also documenting supplementary effects on smear conversion and treatment completion.

## MATERIALS AND METHODS

**Study design and setting:** This was a programmatic cohort study conducted between October 2019 and August 2020 in Kalaburagi district, Karnataka, a high-burden district under India's National Tuberculosis Elimination Programme (NTEP). The district is divided into seven Tuberculosis Units (TUs), each covering approximately 500,000 population. Four TUs were selected by the district health authority to pilot nutritional supplementation alongside routine TB services, while the remaining three served as comparison sites.

**Study population:** The study included newly diagnosed, smear-positive pulmonary tuberculosis (PTB) patients registered under NTEP in the participating TUs during the study period. Patients were eligible if they were ≥18 years, had initiated treatment under DOTS, and provided informed consent. Patients with drug-resistant TB, extra-pulmonary TB, pregnancy/lactation, serious co-morbidities, or those unwilling to participate were excluded.

**Nutritional supplementation intervention:** Patients in the four intervention TUs received a micronutrient-rich nutritional supplement formulated according to Indian Council of Medical Research (ICMR) guidelines. Supplements were dispensed monthly at TU/DOTS visits by trained staff. The formulation contained:

- Protein (soy-based),
- Iron, folic acid, vitamin B-complex, vitamin C, zinc, and other trace elements.

Distribution was linked to monthly drug refills to maximize feasibility and adherence. Patients in the three non-intervention TUs received only routine care and financial assistance under Nikshay Poshan Yojana.

**Feasibility indicators**

**Feasibility was assessed using multiple domains:**

1. Adherence to supplementation – defined as proportion of patients reporting ≥80% consumption of monthly dispensed supplements, measured through pill counts, self-report, and DOT provider feedback.
2. Patient acceptability – assessed using a structured questionnaire after 2 months, covering perceived benefits, ease of use, taste, and willingness to continue.
3. Tolerability and safety – side effects (e.g., gastrointestinal upset, nausea, allergic reactions) were recorded during follow-ups.
4. Operational feasibility at TU level – measured through staff workload logs, time-motion observations during distribution, and interviews with TU staff regarding integration with existing workflows.
5. Supply chain performance – monitored through TU-level records of stock availability, frequency and duration of stock-outs, and remedial actions taken (redistribution, procurement).
6. Clinical outcomes (context only) – although not the primary focus, two-month sputum conversion rates and treatment completion were recorded to contextualize operational findings.

**Data collection:** Data were collected by a trained team of medical social workers and community health officers using semi-structured questionnaires and TU record reviews. Patient-level data included socio-demographic information, adherence monitoring, and acceptability responses. Staff-level data were collected through key informant interviews. Monthly supervision visits ensured data completeness and accuracy.

**Sample size:** A total of 800 patients were included (400 in supplemented TUs and 400 in non-supplemented TUs). This sample was predetermined by program implementation scope rather than formal sample size calculation, but provided adequate power (>80%) to detect moderate differences in adherence and acceptability outcomes between groups.

**Statistical analysis:** Data were analyzed using SPSS version 25. Descriptive statistics summarized feasibility indicators. Adherence rates were expressed as proportions with 95% confidence intervals (CI). Acceptability was reported as frequencies of positive/negative responses. Logistic regression was performed to identify predictors of high adherence (≥80%) adjusting for age, gender, residence, and employment. TU-level operational issues (stock-outs, workload) were summarized qualitatively and quantitatively.

**Ethical considerations:** The study protocol was approved by the Institutional Ethics Committee of Mahadevappa Rampure Medical College, Kalaburagi. Written informed consent was obtained from all patients. Program staff interviews were conducted after verbal informed consent.

## RESULTS

**Study participants:** A total of 800 newly diagnosed pulmonary TB patients were included: 400 in supplemented TUs and 400 in non-supplemented TUs. The mean age was 41.6 years (SD ± 13.2), and 78.9% were male. Baseline socio-demographic distributions were similar across the two groups, indicating comparability.

**Adherence to supplementation:** Adherence among supplemented patients was high, with 87.5% (350/400) consuming ≥80% of their dispensed supplements. Adherence was slightly higher among urban residents (90.2%) compared to rural (84.1%). Younger patients (<35 years) demonstrated the highest adherence (91.4%). Logistic regression showed that employment status and urban residence were significant predictors of high adherence ($p<0.05$).

Non-adherence (12.5%) was primarily due to taste aversion (41%), forgetfulness (27%), or gastrointestinal upset (22%).

**Table 1: Adherence and Acceptability among Supplemented Patients**

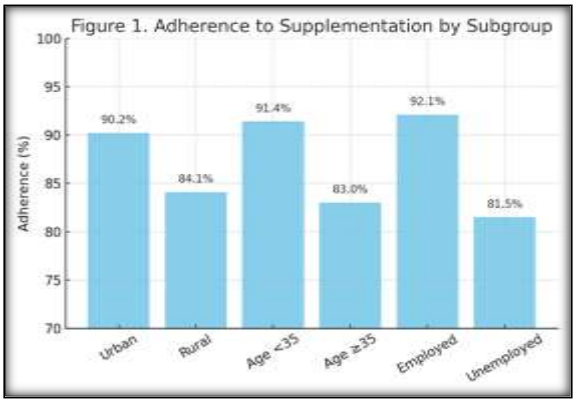
| Indicator | N (%) |
|---|---|
| Adherence ≥80% | 350 (87.5%) |
| Adherence <80% | 50 (12.5%) |
| Reported health benefits | 288 (72.0%) |
| Easy to consume | 324 (81.0%) |
| Willing to continue | 268 (67.0%) |
| Any side effects | 21 (5.2%) |

Footnote: Adherence defined as ≥80% consumption of supplements dispensed. Percentages are based on 400 supplemented patients.

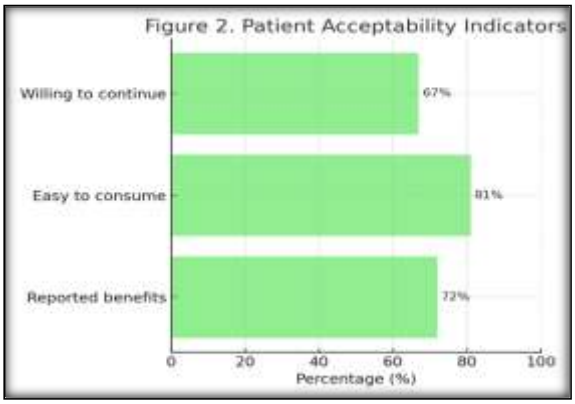
**Table 2: TU-level Operational Feasibility Indicators**

| Operational Indicator | Findings |
|---|---|
| Additional staff time per patient per month | 6–8 minutes |
| Months with stock-outs | 6% |
| Average stock-out duration | 7–10 days |
| Redistribution events | 4 events |
| Staff reporting feasibility of integration | 84% |

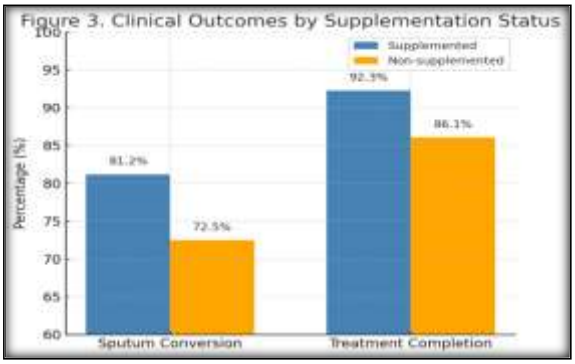
Footnote: Indicators derived from TU staff workload logs, stock records, and staff interviews.




Footnote: Data represent percentage of patients with ≥80% adherence.




Footnote: Percentages represent positive responses among 400 supplemented patients.




Footnote: Clinical outcomes shown for context only; study not powered for efficacy comparison

**Patient acceptability:** Patient perceptions were favourable 72% reported perceivable health benefits (increased strength, appetite improvement, reduction in fatigue), 81% rated the supplement as "easy to consume", 67% expressed willingness to continue supplementation beyond the study period, 5.2% reported minor side effects, mostly gastrointestinal disturbances, which did not require discontinuation.

Qualitative feedback highlighted acceptability when supplements were provided alongside DOTS drugs, reducing additional visits. Staff workload assessment revealed that supplementation distribution added an average of 6–8 minutes per patient per month, primarily during refill visits. TU staff (n=28 interviewed) reported that this was manageable

within routine DOTS activities, though initial orientation was necessary.

**Supply chain performance was satisfactory overall:** Stock-outs occurred in 6% of distribution months, mostly due to delayed procurement, average stock-out duration was 7–10 days, mitigated through redistribution between Tus, no TU reported long-term unavailability, supervisory staff noted the need for buffer stocks and streamlined procurement to prevent delays.

Although clinical outcomes were not the primary focus, supplemented patients showed favourable trends: Two-month sputum conversion rate: 81.2% in supplemented vs 72.5% in non-supplemented, Treatment completion rate: 92.3% in supplemented vs 86.1% in non-supplemented. These findings suggest that supplementation may contribute to improved treatment adherence and faster recovery, although causality cannot be fully established in this design.

## DISCUSSION

This programmatic evaluation in Kalaburagi district demonstrates that nutritional supplementation for pulmonary TB patients is operationally feasible, acceptable, and well-integrated into NTEP workflows. Supplement adherence was high (87.5%), most patients perceived benefits, and staff reported that distribution could be managed alongside DOTS with only modest additional workload. Although clinical outcomes were secondary, supplemented patients showed higher sputum conversion and treatment completion, supporting evidence that nutrition improves recovery trajectories.

**Adherence and acceptability:** Our adherence rate (>85%) compares favorably with other supplementation studies in resource-limited settings. Paton et al. in Singapore documented 84% adherence in newly diagnosed TB patients receiving high-energy supplementation.[12] In India, Bhargava et al. reported that sustained nutritional support reduced catastrophic costs and improved adherence to therapy.[13] Patient-reported benefits in our cohort (strength, appetite improvement, reduced fatigue) reflect similar findings from studies in sub-Saharan Africa where supplementation was associated with improved functional status.[14] Importantly, side effects were rare and mild, underscoring tolerability.

**Operational feasibility:** Operationally, supplementation distribution added only 6–8 minutes per patient per month—a manageable burden given DOTS structure. This aligns with experiences in Malawi and Tanzania, where integration of nutritional support into HIV/TB services was achieved without significant strain on staff time.[15,16] Stock-outs were limited (6% of months), shorter in duration, and mitigated through redistribution, showing that local supply chain resilience is achievable with modest adjustments. TU staff emphasized the importance of buffer stocks and streamlined procurement, echoing WHO recommendations for sustainable nutritional care in TB programs.[17]

**Clinical outcomes (contextual):** Although clinical outcomes were not the primary focus, the observed improvement in sputum conversion and completion rates among supplemented patients is encouraging. Previous randomized trials in Asia and Africa found that protein-energy supplementation accelerated weight gain and modestly improved bacteriological conversion.[18,19] A systematic review by Grobler et al. confirmed that while evidence remains mixed, nutritional interventions likely enhance adherence and may shorten infectious periods.[20] Our findings contribute real-world programmatic evidence to this debate, suggesting benefits extend beyond laboratory settings.

**Programmatic implications**

**The findings highlight three key lessons for policy and practice:**

1. **Feasibility and integration:** Nutritional supplementation can be delivered effectively through existing NTEP infrastructure with minimal disruption.
2. **Patient-centered care:** High acceptability suggests that patients value supplements and perceive tangible benefits, which may enhance trust in public health services.
3. **Equity-sensitive intervention:** Vulnerable subgroups (rural, unemployed, older patients) showed relatively lower adherence and worse outcomes, suggesting the need for targeted counseling and support to maximize equity impact.

**Strengths and limitations:** Strengths of this study include the large cohort, programmatic setting, and evaluation of both patient-level and system-level feasibility indicators. Limitations include the non-random allocation of supplementation (TU-level rather than patient-level), reliance on self-reported adherence alongside pill counts, and focus on early outcomes rather than long-term nutritional or immunological changes. Nevertheless, the consistency of findings across indicators strengthens confidence in the conclusion that supplementation is feasible and beneficial within routine TB care.

**Implications for scale-up:** Integrating supplementation with India's existing Nikshay Poshan Yojana offers a practical pathway to strengthen patient support. While cash transfers address household-level food insecurity, direct provision of micronutrient supplements ensures biological needs are met. Scaling such interventions will require strengthening procurement systems, training staff, and embedding monitoring tools within Nikshay, but the operational evidence from Kalaburagi suggests this is achievable.

## CONCLUSION

Nutritional supplementation is feasible and acceptable within NTEP, with minimal disruption to TU operations. Integration alongside financial transfers could strengthen patient outcomes and equity.

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