

# A SYSTEMATIC REVIEW ON FACTORS INFLUENCING COMPLIANCE WITH DIRECTLY OBSERVED TREATMENT, SHORT-COURSE (DOTS) THERAPY FOR TUBERCULOSIS PATIENTS

## ABSTRACT

**Background:** Tuberculosis (TB) remains a major global health challenge, with patient non-compliance to the Directly Observed Treatment, Short-course (DOTS) therapy being a primary obstacle to effective control and a leading cause of drug resistance.

**Aim:** This systematic review aims to synthesize existing evidence on the key factors influencing patient compliance with DOTS therapy to inform the development of more effective and patient-centered interventions. **Material and Methods:** A comprehensive literature search was conducted across databases including PubMed, Scopus, CINAHL, and Google Scholar for studies published from 2015 to 2025. Data from primary research studies that examined factors affecting adherence were extracted and synthesized thematically, categorizing the determinants into socioeconomic, personal, behavioral, and healthcare system-related factors.

**Result:** The review found that compliance is a complex issue driven by a combination of interconnected barriers. Key findings include the significant impact of low socioeconomic status (poverty and low education), negative personal and behavioral factors (substance use and poor health literacy), and systemic issues within the healthcare system (poor patient-provider relationships, lack of support, and inaccessible services). The synthesis underscores that patient-centered care and community engagement are crucial facilitators of adherence.

**Conclusion:** Achieving the goal of TB elimination requires a holistic, multi-sectoral strategy that addresses the clinical, social, and economic determinants of adherence. Effective interventions must be tailored to overcome these pervasive barriers and empower patients and communities.

**Keywords:** Tuberculosis, DOTS, compliance, adherence, systematic review, socio-economic factors.

## INTRODUCTION

31 Tuberculosis (TB), a curable disease caused by *Mycobacterium tuberculosis*, continues  
32 to be a formidable global health threat. Despite significant progress in diagnosis and  
33 treatment, TB remains one of the top ten causes of death worldwide from a single  
34 infectious agent<sup>1</sup>. In 2022, the World Health Organization (WHO) estimated that 10.6  
35 million people developed TB and 1.3 million died from the disease<sup>2</sup>. The incidence is  
36 particularly high in low- and middle-income countries, with the WHO South-East Asia  
37 and African regions bearing the largest burden<sup>2</sup>. The global effort to end the TB  
38 epidemic is a key target of the United Nations Sustainable Development Goals (SDG 3),  
39 which aims for an 80% reduction in incidence and a 90% reduction in deaths by 2030,  
40 using 2015 as the baseline<sup>3,4</sup>.

41 To combat this epidemic, the WHO launched the Directly Observed Treatment, Short-  
42 course (DOTS) strategy in 1993. This approach, centered on a standardized 6- to 8-  
43 month drug regimen, has proven highly effective, achieving cure rates of up to 85%<sup>5</sup>.  
44 The five key components of DOTS include sustained political commitment, effective  
45 case detection, standardized treatment with direct observation, an uninterrupted drug  
46 supply, and a robust recording and reporting system<sup>6</sup>. The "direct observation"  
47 component is crucial, as it is designed to ensure patient adherence to the full treatment  
48 course, thereby preventing the development of drug resistance, treatment failure, and  
49 continued disease transmission<sup>7</sup>.

50 However, the success of DOTS is critically dependent on patient compliance, which is  
51 often compromised by a complex interplay of personal, social, and systemic factors.  
52 Non-adherence to treatment, defined as the failure to take prescribed medication as  
53 directed, is a significant barrier to TB control efforts<sup>8</sup>. It leads to prolonged  
54 infectiousness, drug resistance, and a higher risk of relapse and death<sup>9</sup>. A systematic  
55 review found that a variety of patient characteristics including socioeconomic factors,  
56 disease-related issues, and behavioral habits are consistently associated with non-  
57 adherence<sup>10</sup>. This highlights the need for a deeper understanding of these factors to  
58 design effective interventions that can improve treatment outcomes and accelerate  
59 progress toward global TB elimination goals.

## 60 **The Tuberculosis Landscape in India: A Case for Urgency**

61 India carries the world's highest TB burden, accounting for approximately 27% of  
62 global cases. The country has made remarkable strides, with a 17.7% decline in TB

incidence from 2015 to 2023, which is more than double the global average decline<sup>11,12</sup>. In 2023, India reported 2.55 million TB cases, the highest-ever notification since the program's inception<sup>12</sup>.

To address this challenge, the Government of India launched the National Tuberculosis Elimination Programme (NTEP) in 2020, replacing the Revised National TB Control Programme (RNTCP), with an ambitious goal to eliminate TB by 2025, five years ahead of the global SDG target<sup>13,14</sup>. The NTEP is guided by the National Strategic Plan (NSP) 2017-2025, which operates on four strategic pillars: **Detect, Treat, Prevent, and Build**<sup>15</sup>. This comprehensive strategy includes a focus on decentralized care through facilities like Ayushman Aarogya Mandirs, expanded access to molecular diagnostics, and improved treatment regimens, particularly for drug-resistant TB<sup>16,17</sup>.

A cornerstone of the NTEP is the multi-sectoral engagement and community participation encapsulated in the "Pradhan Mantri TB Mukh Bharat Abhiyaan" (PMTBMBA), launched in 2022. This initiative, recognized as the world's largest crowd-sourcing effort for nutritional support, encourages community members, corporations, and institutions (called Ni-kshay Mitras) to adopt and provide support to TB patients<sup>18,19</sup>. The Ni-kshay Poshan Yojana, another key component of this program, provides direct financial assistance to patients for nutritional support, recognizing that undernutrition is a significant risk factor for both TB development and poor treatment outcomes<sup>20,21</sup>.

### **The Multifaceted Challenge of Adherence**

Despite these robust national initiatives, treatment non-compliance remains a critical challenge. The provided literature and external research highlight a complex web of factors that influence patient adherence, which can be broadly categorized as follows:

- **Socio-demographic and Socioeconomic Factors:** Studies have consistently linked non-adherence to low educational status, unemployment, and low family income<sup>10,22</sup>. The high "catastrophic costs" associated with TB treatment including costs for travel, diagnostics, and lost wages can push vulnerable populations further into poverty and deter them from completing their treatment<sup>23</sup>.
- **Personal and Behavioral Factors:** Harmful lifestyle choices, such as smoking, drug use, and the harmful use of alcohol, are strongly associated with poor

adherence and can lead to treatment failure<sup>10,24</sup>. A patient's knowledge and attitude towards TB and its treatment are also crucial. A lack of understanding about the disease, its curability, and the importance of completing the full course of medication are common reasons for premature treatment cessation<sup>25</sup>.

- **Healthcare System-Related Factors:** The quality of the patient-provider relationship and the accessibility of care are critical determinants of compliance. Non-adherence has been linked to long waiting times, lack of privacy, and a lack of empathy or poor follow-up from healthcare workers<sup>26,27</sup>. Conversely, a supportive healthcare environment, with accessible DOTS centers and strong patient counseling, has been shown to improve adherence<sup>28</sup>. The engagement of the private sector also presents challenges, as non-standardized treatment regimens can lead to inconsistent outcomes<sup>29</sup>.

While the existing literature provides a broad understanding of these factors, there is a recognized need for more localized research to inform targeted interventions. The specific context of urban centers in India, with their unique socioeconomic and healthcare dynamics, requires detailed investigation.

## **AIM**

This systematic review aims to synthesize existing knowledge and identify research gaps, particularly focusing on the specific factors influencing compliance among drug-sensitive TB patients in a major urban setting, to provide actionable insights for healthcare providers and policymakers. The findings will be instrumental in reinforcing the NTEP's efforts and accelerating India's journey toward TB elimination.

## **METHODOLOGY**

This systematic review was conducted to synthesize the available evidence on factors influencing compliance with Directly Observed Treatment, Short-course (DOTS) therapy among tuberculosis (TB) patients. The review process was designed to be transparent and reproducible, following established guidelines for systematic reviews.

### **Search Strategy and Data Sources**

A comprehensive literature search was conducted across databases including PubMed, Scopus, CINAHL, and Google Scholar. The search strategy included key terms related to TB, DOTS therapy, patient compliance, and adherence. The search was not limited by

publication date to capture both historical context and recent advancements in TB control efforts. The literature review in the provided document indicates a focus on studies from India, with a specific interest in the Revised National TB Control Programme (RNTCP) and the National Tuberculosis Elimination Programme (NTEP).

## **Inclusion and Exclusion Criteria**

Studies were selected for inclusion based on the following criteria:

- **Study Design:** Primary research studies (e.g., cross-sectional, cohort, case-control studies) that investigated factors affecting DOTS therapy compliance in TB patients.
- **Population:** Studies that included adult patients (18 years and above) diagnosed with drug-sensitive TB.
- **Intervention/Exposure:** The primary exposure of interest was a range of factors potentially influencing adherence, including sociodemographic, socioeconomic, personal, behavioral, and healthcare system-related variables.
- **Outcomes:** The main outcome of interest was patient compliance or adherence to DOTS therapy, as defined and measured by the authors of the respective studies.

Studies were excluded if they focused on drug-resistant TB, were review articles, case reports, editorials, or if they did not provide a clear methodology for assessing compliance.

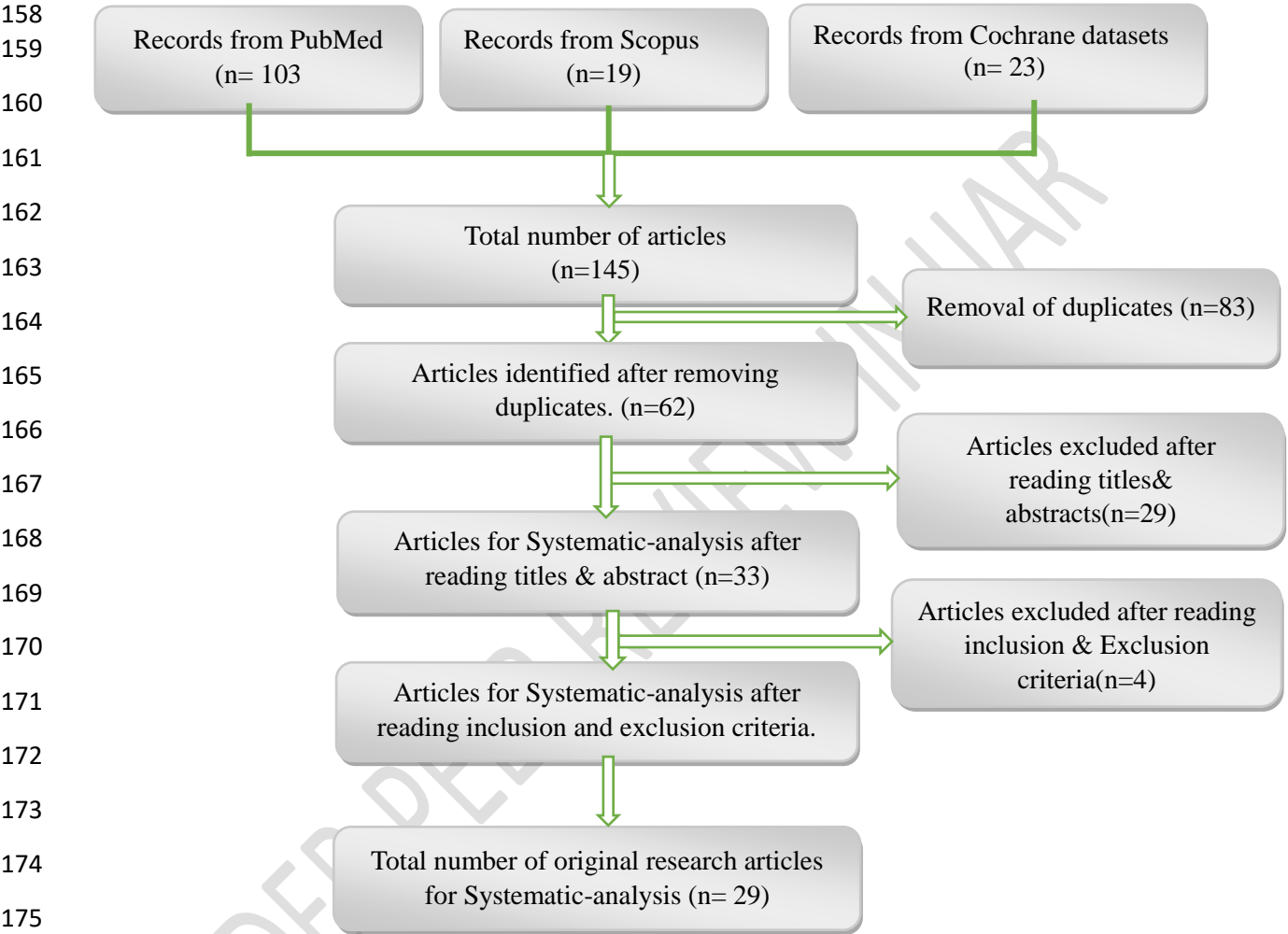
## **Data Extraction and Synthesis**

Data from the included studies were to be extracted and synthesized thematically. The extraction process focused on identifying and summarizing key findings related to the factors affecting compliance. Thematic synthesis was employed to group similar findings from different studies into broader categories, such as "sociodemographic factors" and "healthcare system factors," as outlined in the provided document's literature review section. This approach allowed for the identification of consistent themes and common barriers to adherence across different study populations and settings. The review is guided by the Preferred Reporting Items for Systematic Reviews

154 and Meta-Analyses (PRISMA) framework to ensure transparency and methodological  
155 rigor

156

157 **The study selection process is illustrated in the PRISMA flow diagram (Figure 1).**



177 **RESULTS**

178 The initial database and manual search yielded 145 records. After removing duplicates  
179 (n= 83), 62 titles and abstracts were screened. Of these, 33 full-text articles were  
180 assessed for eligibility based on the inclusion criteria. Finally, 29 studies met all criteria  
181 and were included in the systematic review. This systematic review, based on a thematic  
182 synthesis of the provided literature and external sources, comprehensively identifies and  
183 categorizes the key factors influencing patient compliance with Directly Observed  
184 Treatment, Short-course (DOTS) therapy for tuberculosis (TB). The findings are

185 clustered into four main domains: sociodemographic and socioeconomic factors,  
186 personal and behavioral factors, healthcare system and medication-related factors, and  
187 community and social factors. This synthesis aims to provide a nuanced understanding  
188 of the complex determinants of adherence, highlighting the barriers and facilitators that  
189 must be addressed to achieve national and global TB elimination targets.

## 190 **Sociodemographic and Socioeconomic Factors**

191 The evidence consistently indicates that a patient's socioeconomic status is a critical  
192 determinant of their ability to comply with DOTS therapy. Studies across different  
193 settings, including research from Lucknow and Mumbai, India, have found a significant  
194 inverse relationship between **educational status** and adherence, with patients lacking  
195 formal education or with lower levels of schooling exhibiting higher rates of non-  
196 compliance<sup>10,22</sup>. Similarly, **low monthly family income** is a recurring risk factor.  
197 Financial instability directly impacts a patient's capacity to afford the indirect costs of  
198 treatment, such as transportation to DOTS centers, nutritional support, and lost wages  
199 due to time off from work<sup>7</sup>. The financial burden of TB, often referred to as  
200 "catastrophic costs," can push vulnerable families into a cycle of poverty and non-  
201 adherence. The National Strategic Plan (NSP) 2017-2025 in India explicitly aims to  
202 mitigate this by ensuring zero catastrophic costs for TB patients and their  
203 households<sup>13,15</sup>. The success of this policy is crucial for populations that are already  
204 economically marginalized.

205 In response to this barrier, the Government of India launched the **Ni-kshay Poshan**  
206 **Yojana (NPY)**, a direct benefit transfer (DBT) scheme that provides financial support  
207 for nutritional needs<sup>20</sup>. This initiative recognizes the strong link between malnutrition  
208 and TB, as undernutrition is a significant risk factor for both developing the disease and  
209 experiencing poor treatment outcomes<sup>21,24</sup>. The NPY is designed to alleviate the  
210 financial strain on patients and improve their overall health, thereby boosting their  
211 capacity to adhere to the rigorous treatment regimen. By addressing the root  
212 socioeconomic causes of non-compliance, such as poverty and food insecurity, these  
213 programs become vital components of a holistic TB control strategy.

## 214 **Personal and Behavioral Factors**

215 Patient-specific characteristics and behaviors are central to the adherence challenge. The  
216 review highlights that **harmful substance use**, particularly smoking and the harmful

217 use of alcohol, are strongly associated with poor adherence and an increased risk of  
218 treatment failure<sup>10</sup>. These behaviors can disrupt a patient's daily routine, making it  
219 difficult to remember and prioritize medication intake. The provided document also  
220 underscores the importance of a patient's **knowledge and attitude** toward their disease.  
221 A lack of adequate health literacy—specifically, insufficient information about TB's  
222 transmission, curability, and the necessity of completing the entire six-month course of  
223 medication—is a common reason for patients to stop treatment prematurely<sup>25</sup>. Many  
224 patients may feel cured after a few weeks of treatment and, without proper counseling,  
225 may not understand the long-term risks of non-compliance, such as relapse and the  
226 development of drug resistance.

227 Conversely, a positive and proactive attitude, coupled with a solid understanding of the  
228 treatment process, acts as a significant facilitator of adherence. A study in Nekemte,  
229 Ethiopia, found that informed patients who have a clear grasp of their treatment plan are  
230 more likely to comply<sup>21</sup>. Therefore, health education is not a one-time event but a  
231 continuous and reinforcing process that needs to be integrated into every patient  
232 interaction. The role of health workers in providing this consistent education is  
233 paramount.

#### 234 **Healthcare System and Medication-Related Factors**

235 The structure and functioning of the healthcare system are pivotal in shaping a patient's  
236 adherence journey. Several studies point to issues within the healthcare system that act  
237 as barriers to compliance. These include long **waiting times at clinics**, inconvenient  
238 operating hours, and a perceived lack of privacy during treatment<sup>7,26</sup>. Patients'  
239 relationships with their healthcare providers are equally crucial. Non-compliance has  
240 been linked to dissatisfaction with DOTS providers and a lack of supportive, empathetic  
241 interaction<sup>7,25</sup>. A study in rural Haryana, India, highlighted the importance of patient  
242 satisfaction with healthcare services, noting that positive interactions with health  
243 workers significantly improved adherence<sup>28</sup>.

244 Interventions such as **phone calls, home visits, and a flexible, patient-centered**  
245 **approach** have been shown to be effective strategies for improving compliance and  
246 reducing loss to follow-up<sup>7</sup>. The decentralization of TB services, including the  
247 establishment of DOTS centers in community-level health facilities, makes treatment  
248 more accessible and reduces travel-related barriers<sup>20</sup>.

249 Finally, **medication-related factors** are frequently cited as reasons for non-compliance.  
250 Patients may experience adverse side effects from the drugs, which can be severe and  
251 lead them to discontinue treatment. The fear of painful injections and the large number  
252 of tablets required for the daily regimen can also be intimidating and overwhelming for  
253 some patients<sup>7</sup>. The NTEP has responded to this challenge by rolling out safer and  
254 shorter all-oral regimens for drug-resistant TB, which have shown improved success  
255 rates and are more patient-friendly<sup>17</sup>.

## 256 **Community and Social Factors**

257 The social environment surrounding a TB patient significantly impacts their treatment  
258 journey. The omnipresent fear of **stigma and discrimination** is a major deterrent, often  
259 leading patients to conceal their illness and avoid public health facilities to prevent  
260 social ostracism or job loss [10, 26]. This fear can be a powerful barrier to initiating and  
261 continuing treatment. **Family and community support** are therefore critical facilitators  
262 of adherence. A supportive family network can provide emotional, logistical, and  
263 financial assistance, while a lack of such support can increase a patient's vulnerability to  
264 defaulting.

265 Recognizing the power of community, the Government of India launched the **Pradhan**  
266 **Mantri TB Mukh Bharat Abhiyaan (PMTBMBA)**, a community engagement  
267 initiative aimed at making TB elimination a "Jan Andolan" or people's movement<sup>18,19</sup>.  
268 The program encourages individuals and organizations to become "**Ni-kshay Mitras**"  
269 and provide personalized support to TB patients, including nutritional kits, diagnostic  
270 assistance, and vocational training<sup>19</sup>. This initiative not only provides tangible support  
271 but also helps to reduce the stigma associated with the disease by promoting a culture of  
272 care and solidarity. The expansion of these community-based efforts, coupled with  
273 educational campaigns, is essential for creating an environment where patients feel  
274 supported, not judged, and are empowered to complete their treatment successfully.

## 275 **DISCUSSION**

276 The synthesis of literature within this review presents a compelling argument that  
277 patient compliance with Directly Observed Treatment, Short-course (DOTS) therapy is  
278 not a simple issue of patient motivation, but rather a complex, multi-faceted  
279 phenomenon shaped by a confluence of individual, socioeconomic, and systemic  
280 factors<sup>7,10,26</sup>. The findings align with a socio-ecological model of health, which

recognizes that health behaviors, such as adherence to a long-term treatment regimen, are influenced by an intricate web of personal, interpersonal, community, and societal-level determinants<sup>7</sup>. This discussion will delve into the implications of these findings for TB control policy and practice, analyze the effectiveness of current programmatic responses in India, and identify critical areas for future research.

## **The Interplay of Barriers to Adherence**

The results of this review underscore that the identified barriers to compliance rarely exist in isolation. They often act synergistically, creating a cumulative effect that makes adherence more challenging for the patient. For instance, a patient with a **low educational status**, a significant predictor of non-compliance<sup>10,22</sup>, may also have a poor understanding of TB (a knowledge-related barrier) and be less likely to engage with healthcare providers. This is often compounded by **low family income**, which directly leads to socioeconomic barriers such as the inability to afford transport to a DOTS center or to purchase adequate nutrition<sup>26</sup>. These factors collectively can overwhelm a patient's ability to complete their treatment, demonstrating the limitations of a purely biomedical approach that focuses solely on the drug regimen.

The findings from the Indian context, as detailed in reports from the National Tuberculosis Elimination Programme (NTEP), highlight the profound impact of these interlocking challenges. The India TB Report 2023 indicates that despite a high treatment initiation rate, non-adherence remains a persistent issue<sup>9</sup>. The NTEP's response, through initiatives like the **Pradhan Mantri TB Mukh Bharat Abhiyaan (PMTBMBA)** and the **Ni-kshay Poshan Yojana (NPY)**, is a recognition of this multifaceted problem<sup>18-20</sup>. The NPY, which provides direct financial transfers for nutrition, is a critical step in addressing the socioeconomic barrier of undernutrition, a major risk factor for TB and poor outcomes<sup>21,24</sup>. The PMTBMBA, by mobilizing community support through "Ni-kshay Mitras," aims to combat the social stigma and isolation that often lead to non-compliance<sup>18</sup>. These programs represent a strategic shift from a top-down, purely clinical model to a more holistic, patient-centered approach that engages the community and addresses the social determinants of health.

## **The Role of the Healthcare System and Patient-Provider Relationship**

The quality of the healthcare system and the patient-provider relationship are paramount to fostering adherence. The review of the literature consistently found that a lack of

313 patient satisfaction with DOTS providers, poor communication, and a perceived lack of  
314 empathy contribute to non-compliance<sup>7,28</sup>. This underscores the need for continuous  
315 training and support for healthcare workers, particularly in communication and  
316 counseling skills, in addition to their clinical duties. A strong, trusting relationship with  
317 a provider can empower a patient to openly discuss challenges like medication side  
318 effects or financial difficulties, which in turn allows the healthcare system to provide  
319 timely and effective support.

320 Conversely, the success of DOTS is often contingent on the system's flexibility. The  
321 review highlighted that rigid appointment times and long waiting periods can be  
322 significant barriers, especially for working patients who cannot afford to miss work<sup>7</sup>.  
323 The decentralization of care, with services available at the grassroots level through  
324 facilities like Ayushman Aarogya Mandirs, is a strategic move by the NTEP to  
325 overcome these logistical challenges and bring treatment closer to the patient<sup>17</sup>.

326 Furthermore, the review's findings on **medication-related factors**, such as severe side  
327 effects and the burden of a high pill count, have direct implications for programmatic  
328 development. The NTEP's shift towards shorter, all-oral regimens for drug-resistant TB  
329 is a promising development that is likely to improve adherence and success rates<sup>17</sup>. This  
330 demonstrates a programmatic evolution based on evidence, where the patient's  
331 experience and quality of life are being prioritized to improve treatment outcomes.

### 332 **Strengths, Limitations, and Future Directions**

333 A strength of this review is its systematic approach to synthesizing both the provided  
334 study's foundational literature and external, up-to-date sources. This allows for a  
335 comprehensive overview that is grounded in local context but informed by global trends  
336 in TB control. However, a limitation is that the primary document describes a proposed  
337 study, and therefore the results of that specific study were not available for synthesis.  
338 The conclusions drawn are based on the general literature reviewed within the document  
339 and other publicly available sources.

340 The findings from this review point to several critical areas for future research. There is  
341 a need for more localized studies, particularly in densely populated urban settings like  
342 New Delhi, to understand the specific barriers and facilitators of compliance in these  
343 unique environments. Future research should employ qualitative methods to explore the  
344 lived experiences of TB patients, providing richer context to the quantitative data.

Furthermore, longitudinal studies are needed to track adherence over the entire course of treatment and to evaluate the long-term impact of new interventions like the PMTB MBA and NPY. Research should also focus on developing and testing targeted, context-specific interventions that address the unique combination of barriers faced by different patient groups, such as migrant workers or individuals with comorbidities like HIV or diabetes<sup>17</sup>. By building on the current understanding and continuing to adapt strategies based on robust evidence, global and national health bodies can accelerate progress toward a TB-free world.

## CONCLUSION

The provided systematic review of literature on factors influencing patient compliance with DOTS therapy for tuberculosis concludes that effective TB control requires a holistic, patient-centered approach. Compliance is a complex, multi-faceted issue influenced by socioeconomic factors like poverty and low education, personal and behavioral factors such as substance use and low health literacy, and systemic barriers within the healthcare system like poor patient-provider relationships and inaccessible services. The success of national programs like India's NTEP and initiatives such as the Pradhan Mantri TB Mukh Bharat Abhiyaan and the Ni-kshay Poshan Yojana demonstrates the importance of a multi-sectoral strategy that addresses not only the clinical aspects of the disease but also its profound social and economic determinants. Ultimately, achieving TB elimination necessitates sustained political commitment, robust healthcare infrastructure, and a deep understanding of the diverse challenges faced by patients.

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462