



The Role of Treatment Supporters in Addressing Adverse Effects of Anti-Tuberculosis Treatment: Cross-Sectional Study in Timor-Leste

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Article Info

Article History:

Submitted November 2025

Accepted April 2026

Published April 2026

Keywords:

tuberculosis; adverse drug reactions; DOTS; treatment supporter; Timor Leste

DOI

<https://doi.org/10.15294/kemas.v21i4.38216>

Abstract

Tuberculosis (TB) remains a critical health challenge in Timor-Leste, as one of the 30 countries with the highest TB burden globally. The involvement of Treatment Supporters or Pengawas Minum Obat (PMO) has been widely implemented to address these challenges. Purpose: This study aims to examine the relationship between the presence of active PMO and the incidence of OAT adverse effects among TB patients in Timor-Leste. Methods: A descriptive-correlational study was conducted from July to November 2023. A total of 69 pulmonary TB patients who had completed the intensive treatment phase were selected through purposive sampling. Data were collected using a validated questionnaire; analysis was conducted using a chi-square test via SPSS version 26. Results: Among 69 respondents, 10 (14.5%) reported adverse effects, while 59 (85.5%) did not. The most common symptoms included reddish urine (97.1%), loss of appetite (91.3%), and joint pain (34.8%). A significant correlation was found between active PMO presence and absence of reported adverse effects ($p < 0.001$). Conclusion: The presence of active PMO significantly influences the perception and reporting of OAT adverse effects among TB patients. Strengthening the training and involvement of PMO in TB programs can enhance patient adherence and improve treatment outcomes.

Introduction

Tuberculosis (TB) remains a major communicable disease and a persistent global health challenge, particularly in developing countries, such as Timor-Leste. According to the World Health Organization's (WHO) Global Tuberculosis Report 2023, Timor-Leste is among the 30 countries with the highest TB burden globally, characterized by a high incidence rate and elevated mortality levels. The country's TB control strategies align with WHO recommendations, one of which includes the long-term administration of Anti-Tuberculosis Drugs (ATDs). Effective TB treatment requires strict patient adherence to ATD regimens,

typically ranging from 6 to 24 months. However, achieving successful treatment outcomes is often hindered by adverse drug reactions (ADRs). These adverse effects can vary in severity, from mild symptoms, such as nausea and loss of appetite, to more serious complications including hepatotoxicity and peripheral neuropathy. A study by Singla (2016), published in the Journal of Clinical and Diagnostic Research, identified ADRs as a major contributor to treatment non-adherence, which may ultimately lead to treatment failure and drug resistance.

To address these adherence challenges, the Directly Observed Treatment, Short-

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course (DOTS) strategy has been widely implemented. The core of this approach is the role of a Treatment Supporter — commonly referred to as a Directly Observed Therapy (DOT) observer or PMO (*Pengawas Minum Obat*) — who is responsible for ensuring that patients take their medications as prescribed. These individuals, often family members or community volunteers, play a crucial role in supporting patients throughout their treatment journey. Research by Diefenbacher (2018), published in *Public Health Action*, highlighted that trained PMOs not only improve treatment adherence, but also provide vital social and emotional support to patients.

Despite the recognized importance of PMOs, studies examining their role in managing and shaping patient perceptions of ATD adverse effects — especially in the Timor-Leste context — remain scarce. Given the country's high TB incidence and the potentially disruptive nature of ATD-related adverse effects, investigating the interaction between these effects and the role of PMOs is both timely and relevant. This study aims to explore in depth how active PMO involvement influences the reporting and management of ATD adverse effects among TB patients in Timor-Leste, and to identify the most commonly experienced ADRs. The findings are expected to offer valuable insights to the national TB program in Timor-Leste, helping strengthen PMO engagement and improve overall treatment success rates.

Methods

This research employed a descriptive-correlational design using a cross-sectional approach. This methodology was selected to describe the frequency and characteristics of ATD adverse effects experienced by TB patients and to analyze the correlation between the role of PMOs and the occurrence of these adverse effects at a specific point in time. The cross-sectional design enables simultaneous data collection from respondents without intervention, thereby facilitating efficient identification of associations among variables. The study was conducted from July to November 2023 at several healthcare facilities in Timor-Leste, including the Hospital Nacional Guido Valadares (HNGV) in Dili, Klipur Domin

Tibar in Liquiça, and the Sentru Saúde Bairro Pite in Dili. The target population comprised all pulmonary TB patients who had completed the intensive phase of treatment and were enrolled in the DOTS program at the selected facilities. Inclusion criteria were: (1) having undergone ATD therapy for at least four weeks since initiation, (2) being at least 17 years of age, and (3) the ability to understand verbal and written instructions.

A purposive sampling technique was employed to ensure that selected participants met the inclusion criteria, thereby enhancing the relevance and quality of the collected data. Participants were recruited through direct contact at the participating health facilities. A total of 69 eligible respondents were successfully recruited, with the sample size justified by the availability of qualified individuals during the study period.

Data were collected using a structured questionnaire developed by the research team. The questionnaire assessed two primary variables: adverse effects of ATDs and the role of the PMO. To measure ATD adverse effects, the questionnaire included a list of common symptoms drawn from the WHO (2020) literature, with respondents asked to indicate whether they had experienced each symptom (yes/no format). The PMO's role was assessed through items identifying whether the respondent had an active PMO who regularly supervised their medication intake. The questionnaire was translated and culturally adapted to ensure clarity and comprehensibility for all respondents. A back-translation method was employed to maintain the instrument's validity and reliability. Data collection was carried out by the principal investigator with the assistance of trained research assistants. The process began after obtaining informed consent from each participant. Respondents were provided with the questionnaire and received assistance where needed to ensure accurate and complete responses.

The collected data were analyzed using both descriptive and inferential statistical methods. Descriptive analysis was employed to outline the characteristics of the respondents and to summarize the frequency of reported adverse effects associated with anti-tuberculosis

drugs (ATDs). Inferential analysis utilized the Chi-square test to examine the association between the role of treatment supporters (PMOs) and the incidence of ATD-related adverse effects. This test was deemed appropriate as both variables were categorical in nature. All statistical analyses were performed using IBM SPSS Statistics version 26. This study adhered to established ethical standards and received approval from the Health Research Ethics Committee of Timor-Leste. Ethical clearance was granted under reference number: 43/INSP-TL/UEPD/X/23. Before data collection, the researchers provided a detailed explanation to prospective participants regarding the study's objectives, procedures, potential benefits, and associated risks. All participants were asked to sign an informed consent form. Participation in the study was entirely voluntary, and respondents retained the right to decline or withdraw at any time without any negative consequences. The confidentiality of participant identities and the data provided was strictly maintained throughout the research process.

Results and Discussion

The findings of this study offer insight into the frequency of ATD-related adverse effects among TB patients and highlight the role of PMOs within the DOTS (Directly Observed Treatment, Short-course) program. Data were

obtained from 69 respondents, all of whom were TB patients receiving care in Timor-Leste. A key finding was the significant correlation between active involvement of PMOs and a reduced frequency of reported ATD adverse effects.

Most patients in this study did not report experiencing significant adverse effects. Of the 69 respondents, only 10 individuals (14.5%) reported experiencing adverse effects, while the remaining 59 (85.5%) did not report any. The most commonly reported adverse effect was reddish discoloration of urine, experienced by nearly all of those who reported adverse effects, followed by loss of appetite and joint pain.

The results showed that most patients had active PMOs. Of the 69 respondents, 59 (85.5%) had PMOs that routinely monitored their medication consumption, while 10 (14.5%) had inactive PMOs. This article explores the correlation between adverse effects of anti-tuberculosis drugs and the role of treatment supporters (PMOs) among TB patients in Timor-Leste, based on findings from a sample of 69 respondents. The discussion analyzes the study's results in relation to existing theories and previous research, while also highlighting the implications of PMO involvement in mitigating treatment-related adverse effects. Among the 69 respondents, 10 individuals (14.5%) reported experiencing ATD-related adverse effects, while

Table 1. Frequency of Reported Adverse Effects Associated with Anti-Tuberculosis Medicines (OAT)

Adverse Effect of OAT	Frequency (n)	Percentage (%)
Loss of Appetite	63	91.3
Nausea	11	15.9
Stomach Pain	9	13.0
Reddish Urine	67	97.1
Joint Pain	24	34.8
Chills	11	15.9
Tingling	14	20.3
Skin Redness	12	17.4
Burning Legs	15	21.7
Vision Impairment	1	1.4
Difficulty Distinguishing between Red and Green	1	1.4

Source: (Primary data, 2024)

the remaining 59 (85.5%) did not. These data suggest that the majority of TB patients in the sample did not experience significant adverse effects. However, the presence of adverse effects in a subset of patients remains a critical concern, as such effects can negatively impact treatment adherence and overall therapeutic outcomes. Regarding the role of PMOs, 59 patients (85.5%) reported having an active treatment supporter, while 10 patients (14.5%) did not. Interestingly, the number of patients with active PMOs was identical to the number of patients who did not experience any adverse effects, and likewise, all patients who reported adverse effects were among those without active PMOs. This pattern indicates a strong correlation between active PMO involvement and a reduced incidence — or at least reduced perception — of adverse drug reactions. The study identified 11 distinct types of adverse effects experienced by patients.

One of the most frequently reported adverse effects was loss of appetite (anorexia), experienced by nearly all of the respondents who reported any adverse effects. This suggests that appetite loss is a particularly prevalent and impactful issue among TB patients. The high number of respondents reporting anorexia underscores the need for targeted nutritional support during treatment. Anorexia is among the most commonly documented gastrointestinal adverse effects in TB therapy. Koirala (2014), in the *Journal of Clinical and Diagnostic Research*, also identified anorexia as a frequently occurring adverse reaction, often attributed to medications such as Isoniazid (INH) and Pyrazinamide (PZA). Anorexia can lead to weight loss and may compromise immune function, necessitating appropriate dietary interventions. Similarly, Al-Khaduri (2017), in the *Sultan Qaboos University Medical Journal*, reported that gastrointestinal complaints—including anorexia—were among the most prevalent adverse effects observed in TB patients. Their study emphasized that the combination of INH, Rifampicin (RIF), and PZA frequently results in gastrointestinal irritation, which contributes to decreased appetite. Koirala (2014) further reinforced that anorexia is one of the most commonly reported adverse effects among TB patients, with Pyrazinamide being a significant contributing

agent.

Nausea is a common gastrointestinal adverse effect associated with tuberculosis medications. In this study, 11 respondents reported experiencing nausea, which is typically correlated to the use of Isoniazid and Rifampicin. Awofisayo (2018), in the *International Journal of Mycobacteriology*, identified nausea as one of the leading causes of treatment discontinuation among TB patients, highlighting the importance of appropriate management. Similarly, Nandiswar (2020), in the *Journal of Family Medicine and Primary Care*, observed that nausea and vomiting are frequent adverse events, particularly within the first month of therapy. They recommended that anti-TB drugs be taken with or after meals to minimize gastric irritation. Lee (2019), writing in the *International Journal of Tuberculosis and Lung Disease*, emphasized that nausea is a major contributor to non-adherence and must be proactively addressed by healthcare providers. Stomach pain was reported by nine respondents and frequently overlapped with symptoms, such as nausea and loss of appetite. This symptom, often referred to as epigastric pain, is commonly associated with gastrointestinal irritation caused by drugs, including Isoniazid and Pyrazinamide. Clinical guidelines published in several sources, such as the *American Journal of Respiratory and Critical Care Medicine* (2021), include recommendations for managing these adverse effects, including the use of gastroprotective agents. According to the WHO's *Consolidated Guidelines on Tuberculosis* (2020), epigastric discomfort is a recognized adverse effect of anti-TB therapy, particularly Pyrazinamide, which is known to affect both hepatic and gastrointestinal function. Sohn *et al.* (2018), in *Clinical Infectious Diseases*, noted that Pyrazinamide carries a higher risk of hepatotoxicity and gastrointestinal distress compared to other first-line anti-TB drugs, often presenting as stomach pain.

This is one of the most frequently reported adverse effects, noted by 67 out of 69 respondents, indicating its near-universal occurrence. Reddish or orange discoloration of urine is a well-documented and benign effect of Rifampicin. Both the WHO (2020) and

CDC (2022) affirm that Rifampicin can cause red-orange pigmentation in urine, sweat, tears, and saliva. Patients must be informed of this effect in advance, as unawareness may lead to anxiety or non-adherence. Mak (2015), in *The Lancet Respiratory Medicine*, stressed the importance of patient education regarding this phenomenon. Without adequate information, patients may misconstrue the discoloration as a sign of serious illness, potentially leading to treatment interruption. Joint pain, or arthralgia, was reported by 24 respondents as one of the more common adverse effects observed. This condition is frequently associated with Pyrazinamide, which can elevate serum uric acid levels and trigger gout-like symptoms. This mechanism is widely supported in clinical literature, including the CDC's TB treatment guidelines (2022). Joint pain management may involve analgesics or dose adjustments under physician supervision. Singla (2016), in the *Journal of Clinical and Diagnostic Research*, confirmed that joint pain—particularly in smaller joints—is one of the most common adverse effects correlated to Pyrazinamide. Maseko *et al.* (2019), in *PLOS ONE*, also reported joint pain as a significant adverse effect, often requiring medical intervention.

Chills and fever were reported by 11 respondents and may signal an allergic reaction or a flu-like syndrome. Though less common, such symptoms can indicate hypersensitivity to TB medications. They are also characteristic of Rifampicin-induced flu-like syndrome, particularly in patients on intermittent dosing schedules. Al-Khaduri. (2017), in the *Sultan Qaboos University Medical Journal*, noted the flu-like syndrome frequently occurs following intermittent Rifampicin administration. Diel (2017), in the *European Respiratory Journal*, described this syndrome as including fever, chills, and myalgia—often linked to Rifampicin use. Furthermore, Sohn *et al.* (2018) identified fever as a potential manifestation of hypersensitivity reactions to anti-TB drugs, which may necessitate drug discontinuation and further evaluation. A total of 14 respondents reported experiencing tingling sensations, consistent with peripheral neuropathy—a serious adverse effect commonly associated with Isoniazid. This condition arises due to Isoniazid's interference

with Vitamin B6 (pyridoxine) metabolism. The WHO (2020) recommends routine Vitamin B6 supplementation for all patients receiving Isoniazid to prevent neuropathy. The number of cases reported in this study indicates the need for strengthened nutritional evaluation and intervention. Schall *et al.* (2018), in the *Journal of the American Medical Association*, explained that Isoniazid impairs pyridoxine metabolism, leading to deficiency and subsequent neuropathy. Both the American Thoracic Society (2017) and WHO (2020) endorse routine pyridoxine supplementation to mitigate this risk.

Skin redness or rash was reported by 12 respondents and may reflect allergic reactions to anti-TB medications. These reactions range from mild rashes to severe manifestations such as Stevens-Johnson Syndrome (SJS). Mak (2015), in *The Lancet Respiratory Medicine*, emphasized the need for close monitoring of skin rashes, as they may indicate the necessity to revise the treatment regimen. Chen (2021), in *Allergy and Asthma Proceedings*, investigated cutaneous hypersensitivity reactions induced by anti-TB drugs. They stressed the importance of differentiating between mild rashes, which can be managed with antihistamines, and severe reactions such as SJS (Stevens-Johnson Syndrome), which require immediate drug discontinuation. This symptom, reported by 15 respondents, is a highly specific and classical manifestation of peripheral neuropathy. It is strongly associated with neuropathy induced by Isoniazid. The “burning sensation” is widely recognized in neurology literature as a hallmark symptom of peripheral nerve damage. Studies conducted by Singla (2016) and Schall *et al.* (2018) on Isoniazid-induced neuropathy explicitly identify this symptom as characteristic. This condition results from peripheral nerve damage, commonly triggered by vitamin B6 deficiency secondary to Isoniazid administration.

Only one respondent reported visual impairment. This adverse effect is clinically significant although the frequency is low. Visual disturbances are a well-established adverse effect of Ethambutol (EMB). Chan (2017), writing in the *Journal of Neuro-Ophthalmology*, provided a comprehensive review of Ethambutol-

induced optic neuritis, highlighting the need for visual screening—specifically, assessments of visual acuity and color vision—before and throughout treatment. The World Health Organization (WHO, 2023) likewise strongly recommends routine monitoring for visual symptoms in patients on Ethambutol, and immediate discontinuation if such symptoms occur. This adverse effect, reported by a single respondent, is a hallmark of optic neuritis caused by Ethambutol. Ethambutol-induced optic neuropathy—specifically retrobulbar neuritis—can impair both visual acuity and red-green color discrimination. Despite its rare occurrence in this study, it becomes a serious adverse event with the potential for permanent damage. Guidelines from the International Union Against Tuberculosis and Lung Disease (IUATLD, 2018) emphasize the importance of pre-treatment and ongoing vision screening. Chan (2017) further noted that difficulty distinguishing red from green is often one of the earliest clinical signs of optic neuritis, frequently preceding reductions in visual acuity, and thus serves as a critical early warning for discontinuation of the drug. This is corroborated by evidence showing that increased health cadre involvement and patient knowledge significantly improve treatment adherence among pulmonary TB patients (Wijaya, 2013). Such findings support the idea that education and social support—elements central to effective PMOs—are critical in overcoming barriers such as concerns about adverse effects.

Further analysis indicated a significant correlation between the role of PMOs and patient experience of OAT adverse effects. This finding is particularly important as it suggests that patients with active PMO tend not to report adverse effects, or consider them to be a problem. Study findings reveal a strong correlation between active PMO involvement

and lower reported incidence of OAT-related adverse effects. All 59 patients who did not report any adverse effects had an active PMO, while all ten patients who reported adverse effects lacked active PMO support. The role of a PMO extends beyond merely ensuring medication adherence. Active PMOs are instrumental in several areas that directly affect patients' experiences with adverse drug reactions (ADRs), including: Patient Education and Preparedness; Active PMOs serve as the first line of education, providing patients with accurate information on expected treatment effects. For instance, trained PMOs can inform patients that reddish discoloration of urine—caused by Rifampicin—is harmless. Role of family/PMO support in TB treatment adherence and patient supervision (Ratnasari, NY, Nurtanti, S, 2018). Diefenbacher (2018), writing in *Public Health Action*, confirmed that trained PMOs can effectively communicate common adverse effects. Without such guidance, patients might misinterpret normal changes as alarming, potentially leading to treatment discontinuation. This may explain why none of the 59 patients with active PMOs reported reddish urine as a concerning adverse effect—it was already anticipated and understood.

Statistical analysis using the Chi-square test revealed a statistically significant correlation between the two variables ($p < 0.05$), leading to the rejection of the null hypothesis (H_0). There was a highly significant correlation between the active involvement of treatment supporters (PMOs) and the occurrence of adverse effects related to anti-tuberculosis drugs (ATDs). Notably, none of the patients with active PMOs reported any adverse effects, whereas all patients who did report adverse effects did not have an active PMO. PMOs serve as the eyes and ears of healthcare teams in the community, monitoring patients daily and identifying early signs of

Table 2. The Role of Treatment Supporters (PMOs)

Role of PMOs	Frequency (n)	Percentage (%)
Active PMOs	59	85.5
Inactive PMOs	10	14.5
Total	69	100.0

Source: (Primary data, 2024)

Table 3. Correlation of Adverse Effect of OAT and the Role of PMOs

Adverse Effect of OAT	Active PMO	Inactive PMO	Total
Experience Adverse Effect	0	10	10
No Adverse Effect	59	0	59
Total	59	10	69

Source: (Primary data, 2024)

Chi-Square Value (χ^2): 69.000; p-value: 9.85×10^{-17} ($p < 0.05$)

adverse effects, such as nausea, joint pain, or tingling. Through early detection, PMOs can report symptoms promptly, enabling timely medical intervention. Early diagnosis would strongly affect the success of the treatment program of the TB patients (Ratnasari *et al.*, 2019). Lee (2019), in the International Journal of Tuberculosis and Lung Disease, emphasized the PMO's role as a critical liaison between patients and health services. This facilitates rapid treatment adjustments, such as dose modifications or the introduction of supportive therapies (e.g., vitamin B6 supplements to prevent neuropathy), potentially preventing complications. Patients with active PMOs received such timely interventions, reducing the severity of adverse effects and negating the need to report them as major issues. Tuberculosis control problems are associated with a low level of mindfulness and knowledge of TB, substantially because of a low position of the community's high position of TB stigma (Ratnasari, Handayani, 2023).

Even mild adverse effects, such as appetite loss, can demotivate patients from completing prolonged treatment. PMOs offer moral support, reinforce the importance of treatment adherence, and encourage. Research by Nandiswar (2020) in the Journal of Family Medicine and Primary Care found that social support from PMOs significantly enhances patient compliance. By helping patients manage the emotional stress and anxiety associated with adverse effects, PMOs may prevent premature treatment dropout. This finding is particularly important to consider, as 97% of respondents were reported to have a moderate level of adherence to tuberculosis treatment (Ratnasari, 2024).

In summary, effective PMOs not only supervise drug intake, but also act as vital communicators, educators, and support

systems. Diefenbacher (2018) outlined several key roles of PMOs, including: 1) Initial Patient Education, educating patients about potential adverse effects (e.g., reddish urine) to prevent unnecessary concern; 2) Monitoring Adherence and Symptoms, conducting regular check-ins to detect and report adverse effects early; 3) Providing Emotional Support, helping patients cope with discomfort and maintain motivation; and 4) Serving as a Health System Liaison, facilitating prompt medical attention, including dosage adjustments or supportive therapy, such as vitamin B6 supplementation. In contrast, ten patients without active PMOs likely lacked adequate information and support. As a result, when they experienced adverse effects, they may have perceived them as serious or unfamiliar, leading to higher reporting rates. Conversely, the 59 patients with active PMOs may have been well-informed, better prepared, and emotionally supported, leading to fewer or no adverse effects being reported. This finding is supported by evidence from Purwanto *et al.* (2021), which reports that social support and adequate health knowledge are significantly associated with better tuberculosis treatment adherence. Patients who receive consistent supervision and encouragement from family members or community supporters demonstrate higher motivation to complete long-term therapy, even when experiencing treatment-related discomfort.

Conclusion

The findings of this study demonstrate a statistically significant correlation between the presence of an active Treatment Supervisor (PMO) and a reduced incidence of reported adverse effects related to anti-tuberculosis drugs (OAT) among TB patients in Timor-Leste. Patients who were overseen by active PMOs were notably less likely to experience

or report treatment-related side effects. These results underscore the critical contribution of PMOs in ensuring patient adherence, providing health education, and offering psychosocial support during the course of TB therapy. To enhance treatment outcomes, strengthening PMO capacity through comprehensive training programs and fostering collaboration with healthcare professionals should be considered a key component of national TB control efforts. The authors extend their gratitude to all study participants and healthcare personnel at Hospital Nacional Guido Valadares, Klibur Domin Tibar, and Sentru Saúde Bairro Pite in Timor-Leste for their cooperation and support during data collection. Special thanks are also extended to the Ethics Committee of the Timor-Leste Ministry of Health for approving the study. This research was fully self-funded by the authors without external financial support.

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