



Sep 22, 2022

## ADR Assessment of TB Patients IIPHG

Harsh Shah<sup>1</sup>, Sandul Yasobant<sup>1</sup>, Jay Patel<sup>1</sup>, Priya Bhavsar<sup>1</sup>,  
Deepak Saxena<sup>1</sup>, Somen Saha<sup>1</sup>,  
Anish Sinha [ Department of Public Health Science<sup>1</sup>

<sup>1</sup>Department of Public Health Science, Indian Institute of Public Health, Gandhinagar

[Other](#)[Share](#)

[dx.doi.org/10.17504/protocols.io.bp2l69n11lqe/v1](https://dx.doi.org/10.17504/protocols.io.bp2l69n11lqe/v1)



Harsh Shah

### DISCLAIMER

Data of this study is with the Indian Institute of Public Health Gandhinagar (IIPHG), Gujarat, India. Researchers who want to access to this confidential data are encouraged to approach Dr Harsh Shah, IIPHG. Email: [harsh.423@gmail.com](mailto:harsh.423@gmail.com) and [hdshah@iiphg.org](mailto:hdshah@iiphg.org).

## ABSTRACT

Tuberculosis (TB) is the second leading cause of death due to infectious diseases globally, and delay in TB care cascade is reported as one of the major challenges in achieving the goals of the TB control programs. The main aim of this study was to investigate the delay and responsible factors for the delay in the various phases of care cascade among TB patients in two Indian states, Jharkhand and Gujarat. This cross-sectional study was conducted among the 990 TB patients from the selected TUs of two states. This study adopted a mixed-method approach for the data collection. The study targeted a diverse profile of TB patients, such as drug-sensitive TB (DSTB), drug resistance TB (DRTB), pediatric TB, and extra-pulmonary TB. It included both public and private sector patients. The study's findings suggested that 172 (29%) patients experienced ADRs with at least one symptom. Out of those, 80% had mild symptoms, and 133 (77%) experienced them during the early (intensive) phase of the treatment initiation. The 18 (56%) drug-resistant TB patients on second-line ATTs reported ADR, 50% of whom reported moderate and severe ADRs. The association between ADR experience and drug susceptibility was significant (p value of 0.005; Chi-squared 12.193) and drug-resistant TB patients experience two times more ADRs than drug-sensitive TB patients (odds ratio 2.049, CI: 1.47–2.86). The TB patients had experienced gastric disturbances, skin-related symptoms, peripheral nervous system symptoms, arthralgia, ophthalmic discomfort, and psychological disorders during ATT. The regression model showed that the Nagelkerke R<sup>2</sup> value was 0.139 with a classification accuracy of 71%. The present study focused on adverse events pertaining to TB patients missed by the health system. The analysis delivered crucial conclusions that could direct policymakers to educate and train all healthcare professionals and high-risk patients on how to solicit and manage ADRs among patients receiving programmatic treatment effectively. It is crucial to strengthen the program by carefully examining treatment plans based on medical history, ensuring treatment compliance, managing adverse events aggressively and proactively, and establishing a training cascade for health care providers and treatment supporters.

## ATTACHMENTS

[ADR Questionnaire Tool.docx](#)

[ADR Questionnaire Tool - Gujarati.docx](#)

[Protocol Methodology for the study assessing the Adverse Drug Reactions among TB patients.docx](#)

[STROBE-checklist-ADR Article.docx](#)

[Gujarat Baseline Data for Online Publication.xlsx](#)

## DOI

[dx.doi.org/10.17504/protocols.io.bp2l69n11lqe/v1](https://dx.doi.org/10.17504/protocols.io.bp2l69n11lqe/v1)

## COLLECTION CITATION

Harsh Shah, Sandul Yasobant, Jay Patel, Priya Bhavsar, Deepak Saxena, Somen Saha, Anish Sinha [ Department of Public Health Science 2022. ADR Assessment of TB Patients IIPHG. **protocols.io** <https://protocols.io/view/adr-assessment-of-tb-patients-iiphg-cgyctxsw>

## FUNDERS ACKNOWLEDGEMENT



United States Agency for International Development (USAID)

Grant ID: 72038620CA00012

## KEYWORDS

Tuberculosis, TB care cascade, Adverse drug reaction, National TB elimination Program, India, Gujarat, IIPHG

## LICENSE

————— This is an open access collection distributed under the terms of the [Creative Commons Attribution License](https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited

## CREATED

Sep 22, 2022

## LAST MODIFIED

Sep 22, 2022

## COLLECTION INTEGER ID

70372

## DISCLAIMER:

Data of this study is with the Indian Institute of Public Health Gandhinagar (IIPHG), Gujarat, India. Researchers who want to access to this confidential data are encouraged to approach Dr Harsh Shah, IIPHG. Email: [harsh.423@gmail.com](mailto:harsh.423@gmail.com) and [hdshah@iiphg.org](mailto:hdshah@iiphg.org).

## ABSTRACT

Tuberculosis (TB) is the second leading cause of death due to infectious diseases globally, and delay in TB care cascade is reported as one of the major challenges in achieving the goals of the TB control programs. The main aim of this study was to investigate the delay and responsible factors for the delay in the various phases of care cascade among TB patients in two Indian states, Jharkhand and Gujarat. This cross-sectional study was conducted among the 990 TB patients from the selected TUs of two states. This study adopted a mixed-method approach for the data collection. The study targeted a diverse profile of TB patients, such as drug-sensitive TB (DSTB), drug resistance TB (DRTB), pediatric TB, and extra-pulmonary TB. It included both public and private sector patients. The study's findings suggested that 172 (29%) patients experienced ADRs with at least one symptom. Out of those, 80% had mild symptoms, and 133 (77%) experienced them during the

early (intensive) phase of the treatment initiation. The 18 (56%) drug-resistant TB patients on second-line ATTs reported ADR, 50% of whom reported moderate and severe ADRs. The association between ADR experience and drug susceptibility was significant (p value of 0.005; Chi-squared 12.193) and drug-resistant TB patients experience two times more ADRs than drug-sensitive TB patients (odds ratio 2.049, CI: 1.47–2.86). The TB patients had experienced gastric disturbances, skin-related symptoms, peripheral nervous system symptoms, arthralgia, ophthalmic discomfort, and psychological disorders during ATT. The regression model showed that the Nagelkerke R<sup>2</sup> value was 0.139 with a classification accuracy of 71%. The present study focused on adverse events pertaining to TB patients missed by the health system. The analysis delivered crucial conclusions that could direct policymakers to educate and train all healthcare professionals and high-risk patients on how to solicit and manage ADRs among patients receiving programmatic treatment effectively. It is crucial to strengthen the program by carefully examining treatment plans based on medical history, ensuring treatment compliance, managing adverse events aggressively and proactively, and establishing a training cascade for health care providers and treatment supporters.

#### ATTACHMENTS

[ADR Questionnaire Tool.docx](#)

[ADR Questionnaire Tool - Gujarati.docx](#)

[Protocol Methodology for the study assessing the Adverse Drug Reactions among TB patients.docx](#)

[STROBE-checklist-ADR Article.docx](#)

[Gujarat Baseline Data for Online Publication.xlsx](#)

#### FILES