STROBE Statement—checklist of items that should be included in reports of observational studies

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|  | Item No. | Recommendation | Page  No. | Relevant text from manuscript |
| **Title and abstract** | 1 | (*a*) Indicate the study’s design with a commonly used term in the title or the abstract | 1 | Characteristics and contributing factors of adverse drug reactions: an analytical study of patients with tuberculosis receiving treatment under the National TB Program of India |
| (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 1 | abstract |
| Introduction | | | |  |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 1-2 | Introduction |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 2 | Rationale |
| Methods | | | |  |
| Study design | 4 | Present key elements of study design early in the paper |  |  |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 2 | Study Design and Settings |
| Participants | 6 | (*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up  *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls  *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants | 3-4 | Study Population and Sampling Method |
| (*b*)*Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed  *Case-control study*—For matched studies, give matching criteria and the number of controls per case | - | Not Applicable |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 4 | Data Variables and Data Collection |
| Data sources/ measurement | 8\* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | *4* | *Data Variables and Data Collection* |
| Bias | 9 | Describe any efforts to address potential sources of bias | 3,9 | Study Population and Sampling Method and Discussion |
| Study size | 10 | Explain how the study size was arrived at | 3 | Study Population and Sampling Method |

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| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 4-5 | Data Analysis |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 5 | Data Analysis |
| (*b*) Describe any methods used to examine subgroups and interactions | 4,5 | Data Analysis |
| (*c*) Explain how missing data were addressed | 4 | Data Analysis |
| (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed  *Case-control study*—If applicable, explain how matching of cases and controls was addressed  *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy | 3 | Study Population and Sampling Method |
| (*e*) Describe any sensitivity analyses | - | Not applicable |
| Results | | | | |
| Participants | 13\* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 5 | Demographic and Clinical Profile of Study Participants |
| (b) Give reasons for non-participation at each stage | 6 | Adverse Drug Reactions among the Study Participants |
| (c) Consider use of a flow diagram | - | Not applicable. |
| Descriptive data | 14\* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 5 | Demographic and Clinical Profile of Study Participants |
| (b) Indicate number of participants with missing data for each variable of interest | 5 | Result (No missing data was recorded) |
| (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | - | Not applicable. |
| Outcome data | 15\* | *Cohort study*—Report numbers of outcome events or summary measures over time |  | Not applicable. |
| *Case-control study—*Report numbers in each exposure category, or summary measures of exposure |  | Not applicable. |
| *Cross-sectional study—*Report numbers of outcome events or summary measures | *6* | Adverse Drug Reactions among the Study Participants |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 6 | Logistic Regression on Predictive Independent Variables |
| (*b*) Report category boundaries when continuous variables were categorized | 6,7,8 | Demographic, clinical and ADR profile of the patient and Logistic Regression on Predictive Independent Variables |
| (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | - | Not applicable. |

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| Other analyses | 17 | Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses | 6,7,8- | Demographic, clinical and ADR profile of the patient and Logistic Regression on Predictive |
| Discussion | | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 7 | Discussion |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 8 | Limitations |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 8 | Conclusion |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 8 | Discussion and Limitations |
| Other information | |  | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 6 | Grant Information |

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.