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

|  |  |  |
| --- | --- | --- |
|  | **Item No** | **Recommendation** |
| **Title and abstract** | 1 | (*a*) Indicate the study’s design with a commonly used term in the title or the abstractPage 4 line 19 - 28 |
|  |  | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was foundPage 4 line 30 – page 5 line 7 |
|  **Introduction**  |  |  |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reportedPage 5 - 8 |
| Objectives | 3 | State specific objectives, including any prespecified hypothesesPage 8 line 34 – page 9 line 2 |
|  **Methods**  |
| Study design | 4 | Present key elements of study design early in the paperPage 9 line 17 - 26 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collectionPage 9 line 17 - 26 |
| 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 participantsPage 9 line 17 - 26 |
|  |  | (*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 casePage 9 line 17 - 26 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicablePage 10 line 8 - 19 |
| 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 groupPage 9 line 17 - 26 |
| Bias | 9 | Describe any efforts to address potential sources of biasPage 16 line 2 - 6 |
| Study size | 10 | Explain how the study size was arrived atPage 11 line 3 - 11 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and whyPage 10 line 8 - 19 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confoundingPage 10 line 8 - 19 |
|  |  | (*b*) Describe any methods used to examine subgroups and interactionsPage 10 line 8 - 19 |
|  |  | (*c*) Explain how missing data were addressedPage 10 line 14 - 34 |
|  |  | (*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 strategyPage 10 line 14 - 34 |
|  |  | (*e*) Describe any sensitivity analyses |

Continued on next page

|  |  |  |
| --- | --- | --- |
|  **Results**  |  | Page 13 line 30 - 31 |
| 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 analysedPage 11 line 3 - 11 |
|  |  | (b) Give reasons for non-participation at each stagePage 11 line 3 - 11 |
|  |  | (c) Consider use of a flow diagramNot applicable |
| Descriptive data | 14\* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confoundersPage 11 line 14 - 34 |
|  |  | (b) Indicate number of participants with missing data for each variable of interestPage 11 line 3 - 11 |
|  |  | (c) *Cohort study*—Summarise follow-up time (eg, average and total amount)Page 9 line 17 - 26 |
| Outcome data | 15\* | *Cohort study*—Report numbers of outcome events or summary measures over timePage 10 line 14 - 34 |
|  |  | *Case-control study—*Report numbers in each exposure category, or summary measures of exposureNot applicable |
|  |  | *Cross-sectional study—*Report numbers of outcome events or summary measuresNot applicable |
| 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 includedNot applicable |
|  |  | (*b*) Report category boundaries when continuous variables were categorizedNot applicable |
|  |  | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time periodNot applicable |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analysesPage 13 line 3 - 15 |
|  **Discussion**  |  |  |
| Key results | 18 | Summarise key results with reference to study objectivesPage 17 line 21 - 27 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential biasPage 16 line 2 - 6 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidencePage 15 line 19 - 35 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study resultsPage 15 line 19 - 35 |
|  **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 basedPage 2 line 30 – Page 3 line 1 |

\*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/,](http://www.plosmedicine.org/) Annals of Internal Medicine at [http://www.annals.org/,](http://www.annals.org/) and Epidemiology at [http://www.epidem.com/).](http://www.epidem.com/%29) Information on the STROBE Initiative is available at [www.strobe-statement.org.](http://www.strobe-statement.org/)