

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SUBMISSION COMPLIANCE CHECKLIST: OBSERVATIONAL, COHORT, CASE CONTROLLED, QUESTIONNAIRE BASED, CROSS-SECTIONAL STUDIES  DOCUMENT VERSION 07 MAY 2020  Ensure your manuscript complies with author guidelines by completing this SUBMISSION COMPLIANCE CHECKLIST, ensure to report the corresponding page number. Submit the completed form on the journal website during the manuscript submission process (Step 4). | | | | | |
| Was a statistician involved in this study? | | | Yes | No | N/A |
| Consultation only? | | | Yes | No | N/A |
| Was a statistician involved in data management? | | | Yes | No | N/A |
| Statistician’s name: | | |  | | |
| Statistician’s affiliated institution: | | |  | | |
| Statistician’s qualifications: | | |  | | |
| COMPLIANCE CRITERIA | | | | | COMPULSARY SECTION TO COMPLETE |
| SECTION/TOPIC | # | CHECKLIST ITEM | | | REPORTED ON PAGE # |
| *TITLE* |  |  | | |  |
| Title | 1 | Indicate the study’s design with a commonly used term in the title. | | |  |
| *ABSTRACT* |  |  | | |  |
| Structured summary | 2 | Provide in the abstract an informative and balanced summary of what was done and what was found. | | |  |
| *INTRODUCTION* |  |  | | |  |
| Background/rationale | 3 | Explain the scientific background and rationale for the investigation being reported. | | |  |
| Objectives | 4 | State specific objectives, including any prespecified hypotheses. | | |  |
| *METHODS* |  |  | | |  |
| Study design | 5 | Present key elements of study design early in the paper. | | |  |
| Setting | 6 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection. | | |  |
| Participants | 7 | (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. | | |  |
| (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. | | |  |
| Variables | 8\* | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. | | |  |
| Data sources/ measurement | 9 | 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. | | |  |
| Bias | 10 | Describe any efforts to address potential sources of bias. | | |  |
| Study size | 11 | Explain how the study size was arrived at. | | |  |
| Quantitative variables | 12 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why. | | |  |
| Statistical methods | 13 | (a) Describe all statistical methods, including those used to control for confounding. | | |  |
| (b) Describe any methods used to examine subgroups and interactions. | | |  |
| (c) Explain how missing data were addressed. | | |  |
| (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 | | |  |
| (e) Describe any sensitivity analyses | | |  |
| *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. | | |  |
| (b) Give reasons for non-participation at each stage. | | |  |
| (c) Consider use of a flow diagram. | | |  |
| Descriptive data | 14\* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. | | |  |
| (b) Indicate number of participants with missing data for each variable of interest. | | |  |
| (c) *Cohort study*—Summarise follow-up time (eg, average and total amount) | | |  |
| Outcome data | 15\* | *Cohort study*—Report numbers of outcome events or summary measures over time | | |  |
| *Case-control study*—Report numbers in each exposure category, or summary measures of exposure | | |  |
| *Cross-sectional study*—Report numbers of outcome events or summary measures | | |  |
| 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. | | |  |
| (b) Report category boundaries when continuous variables were categorized. | | |  |
| (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period. | | |  |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses. | | |  |
| *DISCUSSION* |  |  | | |  |
| Key results | 18 | Summarise key results with reference to study objectives. | | |  |
| 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 | | |  |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence. | | |  |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results. | | |  |
| *ACKNOWLEDGEMENT* |  |  | | |  |
| Acknowledgements | 22 | The acknowledgement section follows the conclusions section and addresses formal, required statements of gratitude and required disclosures. It includes listing those who contributed to the work but did not meet authorship criteria, with the corresponding description of the contribution. | | |  |
| Competing interests | 23 | This section should list specific competing interests associated with any of the authors, potential sources of influence or perceived influence on the study conduct and conclusions; how these were managed. | | |  |
| Author contributions | 24 | All authors must meet the criteria for authorship as outlined in the [authorship](https://aosis.co.za/policies#authorship) policy and [author contribution](https://aosis.co.za/policies#author_contributions_affiliations) statement policies. | | |  |
| Funding | 25 | Sources of funding and other support; role of funders in data collection, interpretation, and reporting. | | |  |
| Data availability statement | 26 | Guide readers where the data associated with a paper is available, and under what conditions the data can be accessed. | | |  |
| Disclaimer | 27 | A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder. | | |  |
| \*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. | | | | | |