

## Observational studies in *The Lancet*: formatting guidelines

To assist authors with submission and to streamline the peer review and editing process, we have compiled the following guidance for reporting of observational studies (cohort, cross-sectional, or case-control) in *The Lancet*. Please provide a non-declamatory title, including the study descriptor (eg, Performance of intensive care unit severity scoring systems across different ethnicities in England: a retrospective cohort study). A structured summary should be included, of maximum length 300 words. The main text of the Article should be 3500 words with up to 30 references. The report should include a table of participant baseline characteristics, and a panel that puts the results into context with previous work. Extra description or analyses can be included as an appendix. Please submit your text and tables in a Word document (removing Endnote or other referencing software), your figures as editable files (eg, .eps, .pdf), and the appendix as a .pdf with page numbers. Reports of observational studies must conform to STROBE guidelines and any other relevant EQUATOR guidelines (eg, STARD, TRIPOD) or extensions (eg, STREGA).

*Authorship line: please include first names and surnames for all authors. Affiliations and degrees should be supplied as shown in the margin; only one degree is listed per author, and indicate any full professors. For papers with more than 30 authors we suggest that a collaborative group authorship is considered, to be listed at the end of the paper or in an appendix, dependent on length. Collaborators listed in this way are recognised by PubMed. Author statement forms and International Committee of Medical Journal Editors conflicts of interest forms should be submitted and should match summary statements at the end of your paper. Please list one corresponding author and state their preferred title, postal address including zip code or postcode, and email address.*

### Summary (maximum length 300 words)

#### Background

- State briefly why the study was done, followed by a specific aim or hypothesis; do not include references in the Summary.

#### Methods

- State study design (eg, a retrospective/prospective cohort study; a cross-sectional study of nationally representative, individual-level data; or a matched case-control study).
- Indicate the setting (countries and sites).
- Participants: key inclusion and exclusion criteria
  - *Cohort and cross-sectional studies*: sources and methods of selection of participants
  - *Case-control studies*: case ascertainment and control selection. For matched case-control studies provide details of how matching was done and how many controls per case there were.
- Participant data: state how these data were retrieved and where from (eg, medical records). Provide details of survey data (if applicable), such as inclusion and exclusion criteria, and dates of survey permitted.
- Describe sources of other data used.
- What was the main outcome(s) of this report? How was the main outcome(s) assessed and in whom?

#### Findings

- Dates of participant recruitment, follow-up (for cohort studies), exposure, and data collection (no need to repeat dates already included in the Methods), where relevant.
- Numbers of participants at each stage of the study (ie, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study [including the total number of participants in each sex and/or gender category], completed follow-up, and analysed); no need to repeat numbers already included in the Methods.
- Outcome data:
  - *Cohort studies*: report numbers of outcome events (numbers of participants and percentages) or summary measures over time
  - *Cross-sectional studies*: report numbers of outcome events (numbers of participants and percentages) or summary measures.
  - *Case-control studies*: report numbers in each exposure category, or summary measures of exposure.
- Provide data for the main results (with adjustments for confounders if applicable) along with estimates of their precision (eg, 95% CI); unadjusted estimates should be provided if these are important to the interpretation of the study findings.
- General note: report SDs for mean values and IQRs for medians, and give p values to two significant figures (capped at four decimal places), or  $p < 0.0001$ . For risk changes or effect sizes, give absolute values rather than relative changes.

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- Results stated should agree with what is in the main paper, and all data here should also appear in the main paper.

**Interpretation**

- Provide a general interpretation of the results and their significance rather than reiterating them. The interpretation should be justified by the results and should explain their importance or relevance to clinical practice or policy, or future research.

**Funding**

- Source of funding (if none, say so).

**Copyright**

- See Copyright and reuse information in the Information for authors guidelines.

**Translated abstract**

- *The Lancet* journals encourage the submission of translated summaries in languages that are relevant to the country where the research was done. If you are interested in submitting a Summary translation, please let your handling Editor know.

**Introduction**

- Provide the scientific background and rationale for your study, providing references for data presented and studies mentioned.
- State the specific objectives, including any prespecified hypotheses.

**Methods**

**Study design**

- Start with the study descriptor (eg, In this [retrospective/prospective] cohort study; [repeated/national/multicentre] cross-sectional study; time-series analysis; [matched/nationwide/epidemiological/population-based] case-control study).
- Indicate where the study was done, in which countries, and in how many centres or hospitals, if applicable.
- Provide relevant dates (periods of recruitment, exposure, follow-up, and data collection).
- State the centre where ethics approval was obtained.
- Provide a link to the study protocol if available online (if relevant).

**Participants (or patients)**

- Inclusion and exclusion criteria.

- *Cohort studies*: where individuals were recruited from, how they were selected, how they were followed up. For matched cohorts provide the matching criteria and the number of exposed and unexposed individuals.
- *Cross-sectional studies*: where individuals were recruited from and how they were selected.
- *Case-control studies*: Sources and methods of case ascertainment and control selection. Provide rationale for the choice of cases and controls. For matched studies, provide matching criteria and the number of controls per case.
- State whether participants gave written or oral informed consent (if required). Note that consent is not usually required in observational studies using secondary data, but if the study was exempt from requiring consent, state which body deemed the study exempt.

**Procedures**

- State what data were collected, by whom, and when.
- State the method used to collect sex/gender data (eg, self-report, genetic testing). If self-reported by study participants, indicate what options were provided.

**Panel: Research in context**

**Evidence before this study**

This section should include a description of all the evidence that the authors considered before undertaking this study. You should state: the sources (databases, journal or book reference lists, etc) searched; the criteria used to include or exclude studies (including the exact start and end dates of the search), which should not be limited to English language publications; the search terms used; the quality (risk of bias) of that evidence; and the pooled estimate derived from meta-analysis of the evidence, if appropriate.

**Added value of this study**

You should describe here how your findings add value to the existing evidence (including an updated meta-analysis, if appropriate); avoid simply summarising the findings here.

**Implications of all the available evidence**

You should state the implications for practice or policy and future research of their study combined with existing evidence.

Research in context panels should not have references; anything mentioned that needs referencing should appear in the main text.

- Define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria (if applicable).
- For each variable of interest, give sources of data and details of methods of assessment (measurement); give information for cases and controls in case-control studies, and if applicable, for exposed and unexposed groups in cohort and cross-sectional studies. Describe comparability of assessment methods if there is more than one group.
- Describe any efforts to address potential sources of bias.

#### Outcomes (can be integrated into Procedures or Statistical analysis sections)

- State the primary/main outcome(s) of the study, and in whom this was assessed.
- State other outcomes and who they were assessed in.

#### Statistical analysis

- Explain how the study size was arrived at.
- Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why.
- Describe all statistical methods used in the following order: (1) primary or main outcome (and population definition); (2) other outcomes (and populations involved); and (3) sensitivity and post-hoc analyses.
- Provide the methods used to control for confounding, and any methods use to examine subgroups and interactions.
- Explain the methods for handling missing data.
- *Cohort studies*: explain how loss to follow-up was addressed (if applicable).
- *Case-control studies*: explain how matching of cases and controls was addressed (if applicable)
- *Cross-sectional studies*: describe analytical methods taking account of sampling strategy (if applicable).
- Describe any sensitivity or post-hoc analyses (if applicable).
- State statistics program and version number used for analyses.

#### Role of the funding source

- Include standard statement (if funder had no role in study) or amend as necessary: “The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.”
- If the study had no funder, state: “There was no funding source for this study”.

#### Results

In the following section, where \* is indicated, 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.

- Paragraphs in this section should follow this order:

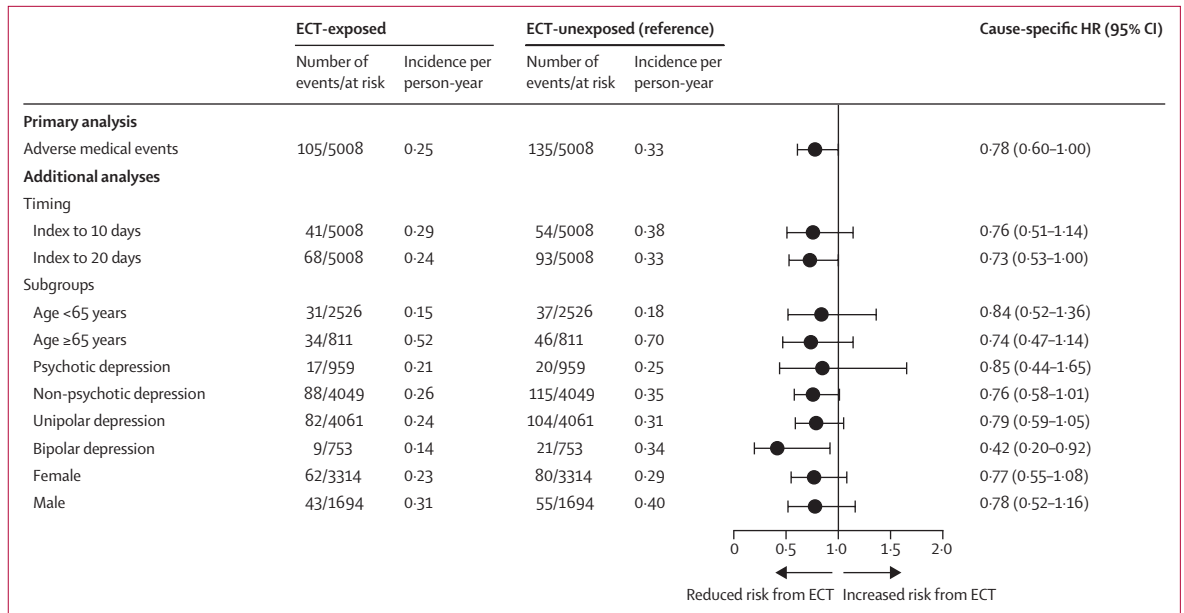
	Group with exposure or disease (n=500)	Group without exposure or disease (n=481)
Gender		
Male	447 (89%)	411 (85%)
Female	53 (11%)	70 (15%)
Age (years)	53.2 (48.3–59.6)	52.5 (48.4–58.7)
Ethnic origin		
White	445 (89%)	454 (94%)
Black	46 (9%)	18 (4%)
Asian	9 (2%)	98 (20%)
Smoking status		
Never	159 (34%)	183 (39%)
Former	151 (32%)	111 (24%)
BMI (kg/m <sup>2</sup> )	31.1 (4.5)	30.5 (5.3)
Mutation status*		
Wild-type EGFR	37/298 (12%)	32/296 (11%)
Unknown	261/298 (88%)	264/296 (89%)

Data are n (%), median (IQR), mean (SD), or n/N (%). BMI=body-mass index.  
\*Data not available for all patients. Supply tables in Word, rather than Excel or pdf.  
Use the % symbol alongside any percentage data. Keep legends to a minimum length; do not repeat details of analysis from Methods.

**Table 1: Baseline characteristics**

a description of the number of participants recruited and included in analysis; baseline characteristics; findings for the primary/main outcome, secondary outcomes, and finally any post-hoc or sensitivity analyses. The order of results should also match the order in which the analyses are presented in the Methods. No subheadings should be used in the Results or the Discussion sections.

- \*Participants: report numbers of individuals at each stage of the study (eg, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up [if applicable], and analysed). Consider the use of a flow diagram and whether it is appropriate to report the characteristics of those not deemed eligible or who declined, for comparison with those who were included.
- \*Descriptive data: details of participants' baseline characteristics should be provided (table), with a statistical test for differences between groups (if applicable), and information on exposures and potential confounders. Indicate the number of participants with missing data for each variable of interest.
  - *Cohort studies*: summarise the follow-up time (eg, average and total amount).
- \*Main results or outcome data: give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% CIs). Make clear which confounders were adjusted for and why they were included. Report category boundaries when continuous variables were categorised. If relevant,



**Figure: Forest plot (note: not all observational studies include a forest plot)**  
 Please supply in an editable format, with absolute numbers of patients (n/N) for treatment and control groups. Please do not convert the x-axis to a log scale if the effect estimate is not calculated that way (ie, error bars should typically be even lengths around the point estimate). ECT=electroconvulsive therapy. HR=hazard ratio.

consider translating estimates of relative risk into absolute risk for a meaningful time period

- *Cohort studies*: report numbers of outcome events or summary measures over time.
- *Case-control studies*: report numbers in each exposure category, or summary measures of exposure.
- *Cross-sectional studies*: report numbers of outcome events or summary measures.
- Other analyses: report other analyses done (eg, analyses of subgroups and interactions, and any sensitivity analyses)
- Additional notes:
  - State absolute numbers of participants or events alongside percentages. Mean values should be accompanied by SDs or 95% CIs, and medians by IQRs. Supply p values to two significant figures (capped at four decimal places), or  $p < 0.0001$ .
  - Estimates of survival (either median or at a specific timepoint) should be accompanied by 95% CI.
  - Forest plots should contain numbers of events/numbers of patients (cases and controls), split by intervention group and study, if available (see figure).

**Discussion**

- The Discussion section should contain a full description and discussion of the context.
- Start with a sentence summarising your main findings, with reference to your study objectives, and move on to relate your results to your hypothesis and data previously published. Discuss your research in the

context of existing evidence, highlighting areas of agreement, contradiction, and novel findings in the present study.

- Consider possible underlying mechanisms for your findings and how the findings could be implemented (eg, into the clinical workflow).
- Discuss limitations and strengths of your study, including how missing data affected the results (if applicable), noting sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias, the potential consequences of the bias, and how such biases could be mitigated.
- Discuss any controversies raised by this study.
- Suggest future research directions.
- State general interpretation of data in light of all evidence available, noting the clinical significance and effects on patient care and policy, expanding on the summary provided in your Research in context panel.

**Contributors**

Provide a statement outlining what every author named at the start of the Article contributed to the study—eg, AB did the statistical analysis. BCD wrote the first draft of the report with input from EF. Please confirm here that all authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. At least two authors must have accessed and verified the data, identified in this section by their initials.

**Declaration of interests**

Declare any competing interest for all authors, if none then add “I/We declare no competing interests.” This statement must match what is reported on the signed International Committee of Medical Journal Editors (ICMJE) disclosure of interest forms submitted for all authors.

**Data sharing**

All submitted research Articles must contain a data sharing statement, which must include: whether data collected for the study, including

individual participant data and a data dictionary defining each field in the set, will be made available to others (“undecided” is not an acceptable answer); what data will be made available (deidentified participant data, participant data with identifiers, data dictionary, or other specified data set); whether additional, related documents will be available (eg, study protocol, statistical analysis plan, informed consent form); when these data will be available (beginning and end date, or “with publication”, as applicable); where the data will be made available (including complete URLs or email addresses if relevant); by what access criteria data will be shared (including with whom, for what types of analyses, by what mechanism—eg, with or without investigator support, after approval of a proposal, with a signed data access agreement, or any additional restrictions). If relevant, software code should be shared too.

#### Acknowledgments

State the funding source for your work, including grant numbers here if applicable. If you wish to thank or acknowledge any individuals, please provide signed statements from them agreeing to be cited in your Article.

#### References (maximum of 30 for primary research articles)

- Cite references in the text sequentially in the Vancouver numbering style, as a superscripted number after any punctuation mark—eg, as reported by Saito and colleagues.<sup>15</sup> Two references are cited separated by a comma, with no space. Three or more consecutive references are given as a range. References in tables, figures, and panels should be in numerical order according to where the item is cited in the text. Do not include references in the Summary. See below for formatting examples of different reference types.

#### Journal references

- In print—eg, Author A, Author B. Title. *Journal* Year; **volume number**: page range linked by en rule.
- Published online before print—eg, Author A, Author B. Title. *Journal* Year; published online month day. DOI:xxx.xxx.xxx.

- Journal names are abbreviated in their standard form as in *Index Medicus*.
- If there are six authors or fewer, list all six (in the format: Smith R, Jones EH, Brown D, Green A); if there are seven or more give the first three, followed by et al.
- If the reference is to an abstract, we note that after the page range—eg, *BMJ* 1998; 255 (suppl 1): 25–26 (abstr).

#### Book or published report references

- For references to a whole book or report, list the authors or editors and the publisher, the city of publication, and year of publication—eg, Editor A, Editor B, eds. Title of book. City of publication: Publisher, Year of publication.
- For a chapter or section of a book or report, also give the authors and title of the section, and the page numbers—eg, Author A, Author B. Title of chapter. In: Editor A, Editor B, eds. Title of book. City of publication: Publisher, Year of publication: page range of chapter.

#### Other

- For online material, please cite the authors of the page, the title, and the date created, along with the URL and the date you accessed the website—eg, Author A, Author B (if available). Title of document. Date (if available). URL (accessed month day, year).
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