Systematic reviews and meta-analyses 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 systematic reviews and meta-analyses in *The Lancet*. Please provide a non-declamatory title, including the trial descriptor (eg, Efficacy and safety of influenza vaccines: a systematic review and meta-analysis). A structured summary should be included, of maximum length 250 words. The main text of the Article should be 3000 words; the reference limit is flexible, but should comprise only studies included in the Article plus up to 30 others. All systematic reviews and meta-analyses should include a table containing characteristics of studies and a study-selection flow chart (and usually a Forest plot of individual study estimates with an overall estimate for meta-analyses). 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), and your figures as editable files (eg, .eps, .pdf). Reports must conform to PRISMA 2009 guidelines.

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 be 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 250 words; no references)

Background

- State briefly the clinical problem, followed by a specific aim or hypothesis; do not include references here.

Methods

- State study design (ie, systematic review, meta-analysis, or systematic review and meta-analysis).
- Indicate the data sources assessed, including exact search date cutoffs.
- Indicate the criteria for study inclusion, including participant criteria (eg, those given influenza vaccine during 2000–15), eligible study type (eg, only randomised controlled trials), and study dates.
- State study exclusion criteria and reasons.
- Describe method of data appraisal and extraction (eg, were individual patient-level data requested from study authors or were data extracted from published reports).
- What was the main outcome assessed and what statistical method was used? We do not, as standard, include additional outcomes in the Summary.
- Provide the study's registration number (eg, with PROSPERO).

Findings

- State how many studies were identified by the search and how many studies and patients were eligible for analysis.
- For systematic reviews, present simple summary data for each intervention group (with numbers of patients/number of studies included) and effect estimates with 95% CI. Use SI units. For risk changes or effect sizes, give absolute values rather than relative changes. Report SDs for mean values and IQRs for medians, and give exact p values unless p<0·0001.
- For meta-analyses, also report the results of the overall effect estimate with 95% CI.
- Report results on the assessment of the risk of bias and variability between studies (eg, I^2).
- Findings 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. Mention any key limitations and strengths of the study. The interpretation should be justified by the results and should explain their importance or relevance to clinical practice.

Funding

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

For **appendix guidelines** see http://www.thelancet.com/lancet/information-for-authors/web-extra-guidelines

For **artwork guidelines** see http://www.thelancet.com/pb/assets/raw/Lancet/authors/artwork-guidelines.pdf

For the **PRISMA 2009 guidelines** see http://www.prisma-statement.org

For **author statement forms** see http://www.thelancet.com/pb/assets/raw/Lancet/authors/tl-author-signatures.pdf

For **conflicts of interest forms** see http://www.icmje.org/conflicts-of-interest

For **PROSPERO** see http://www.crd.york.ac.uk/prospero/

Department of XX, University of XX, City, State (for USA, Canada, and Australia), Country (X X Surname PhD); **Department of XX, XX Hospital, City, State, Country** (Prof X Surname MD); **and Company XX, City, State, Country** (X X Surname MSc)

Correspondence to:
Dr Firstname X Surname, Department of XX, University of XX, City, Postcode, Country
email@address.com

	Population	Study type	Dates	Participants vaccinated	Controls	Vaccine efficacy (95% CI)
Ahmed et al (2001)[1]	Healthy adults aged 16–24 years	Randomised, controlled trial	1990–92	674	341	75% (68–82)
Brice et al (2002)[2]	Children aged 8–16 years; adults aged 16–24 years	Randomised, controlled trial	1993–94	16 children; 112 adults	18 children; 129 adults	81% (76–87)
Cooper et al (2003)[3]	Healthy adults aged 16–24 years	Observational study	2000–01	120	126	50% (40–60)
Davies et al (2004)[4]	Healthy adults aged 16–24 years	Randomised, controlled trial	2000–01	119	109	65% (60–70)

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. Footnote symbols should be used in the order * † ‡ § ¶ || then ** etc.

Table: **Trials of vaccine efficacy meeting inclusion criteria**

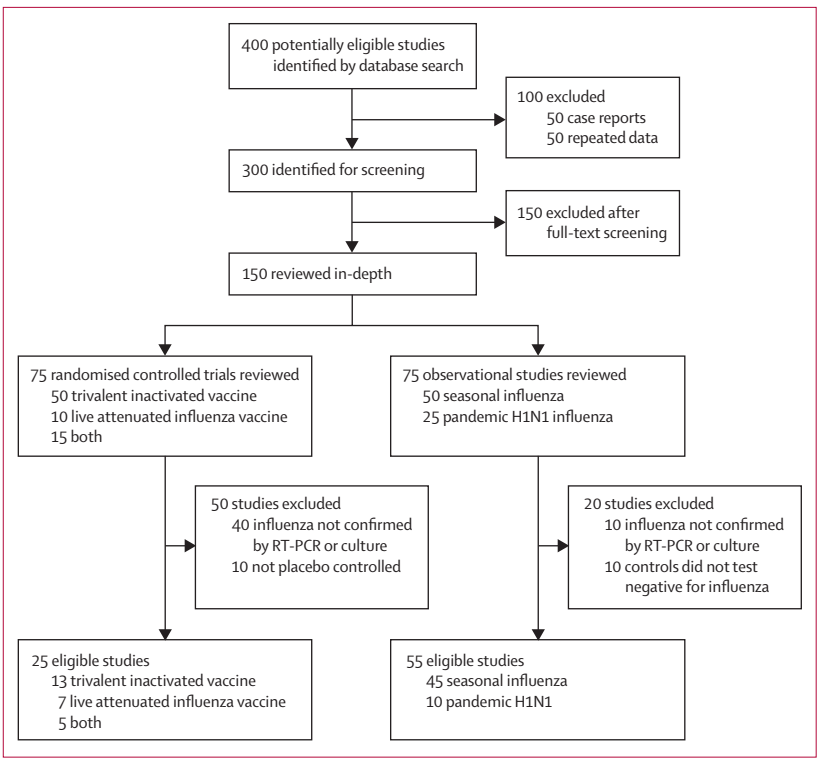

Figure 1: **Study selection**

Please account for all dropouts and supply in an editable format such as Word or Powerpoint. See http://www.thelancet.com/pb/assets/raw/Lancet/authors/trial-profile-template.pptx for a template. Keep figure legends to a minimum length; do not repeat methods of analysis or interpretation of findings from the main text.

Introduction

- Give the background to your study, providing references for data presented and all previous studies mentioned.
- State why now is an appropriate time to do a systematic review/meta-analysis?
- End with the aim of your study.

For more on the **rationale behind including trial registries** see http://www.bmj.com/content/356/bmj.j448

For more about **supplying editable files** see http://www.thelancet.com/pb/assets/raw/Lancet/authors/artwork-guidelines.pdf

Methods

Search strategy and selection criteria

- Start with a study descriptor. Is this a systematic review only (ie, an assessment of heterogenous trials with no summary estimate) or does it also include a meta-analysis (with an overall summary estimate from available data)?
- What were the criteria for study inclusion? List study dates, language requirements, populations assessed, and study design (eg, only randomised controlled trials or only observational studies).
- State any study exclusion criteria and reasons.
- Describe the data sources assessed. List databases searched and exact date cutoffs. Provide search terms used for at least one database such that the search could be repeated.
- How thorough was the search (eg, study authors contacted, grey literature sources assessed, and articles translated)?
- Did you search trial registries and seek data from any unpublished studies identified?
- What level of data was sought (individual patient-level data *vs* summary estimates)?
- Who did the searches and data extraction, and how were conflicts over inclusion resolved? Describe criteria for inclusion in the systematic review and also for inclusion in the meta-analysis (if different).
- Provide a link to the study protocol if available online.

Data analysis

- Describe the method of data extraction and method for dealing with duplicate data.
- Give details of main summary measures (eg, risk ratio [95% CI]) and list all preplanned secondary outcome measures.
- Describe how you assessed quality (bias) of the studies.
- What methods did you use to account for bias between studies?
- Define all variables for which data were extracted (eg, number of patients, age, sex, vaccination status, vaccine efficacy) and any summary measures used (eg, amalgamation of age groups).
- Describe methods used to assess variability within studies (sampling error), between studies (eg, I^2 estimate of heterogeneity), and how studies were combined. Was a fixed-effects or a random-effects model used?

- State statistics package and version number used for analyses.
- List study registration number and name of registry, if available.

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. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication."
- If the study had no funder, state: "There was no funding source for this study". Information about access to data and responsibility for submission are still required.

Results

- Describe your study findings, without subheadings, in the following order: a description of number of studies screened and included in analysis (with a study selection figure); study characteristics (with a summary table showing the main characteristics for which data were extracted; table); findings for the primary assessment, secondary findings, details on heterogeneity and bias, and finally any post-hoc or sensitivity analyses.
- The first paragraph should include a citation to the study selection figure (see figure 1 for an example), including the number of studies assessed for eligibility, the number ineligible, the number included in the systematic review and the number included in the meta-analysis (if different), and the number of exclusions or dropouts at each stage; list reasons for exclusion.
- Provide simple summary data for each study and effect estimates with 95% CI (eg, in a Forest plot).
- The main outcome measures must include a point estimate (eg, risk ratio) plus a measure of precision (95% CI) of the difference between groups.
- Use SI units. State absolute numbers of studies, participants, or events alongside percentages. Mean values should be accompanied by SDs or 95% CI, and medians by IQRs. Supply exact p values unless p<0·0001.
- Forest plots should contain numbers of events/numbers of patients, split by intervention group and study, if available (see figure 2).

Discussion

- The Discussion section, without subheadings, should provide readers with a balanced description of the implications of your findings, explain the strengths and weaknesses of your research, and contextualise the study in terms of policy and practice. You should also provide a panel putting your research into context (see panel for details).
- Start by summarising your main findings and move on to relate your results to your hypothesis and data previously published.
- Discuss limitations and strengths of your study, noting sources of bias or imprecision.
- 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.

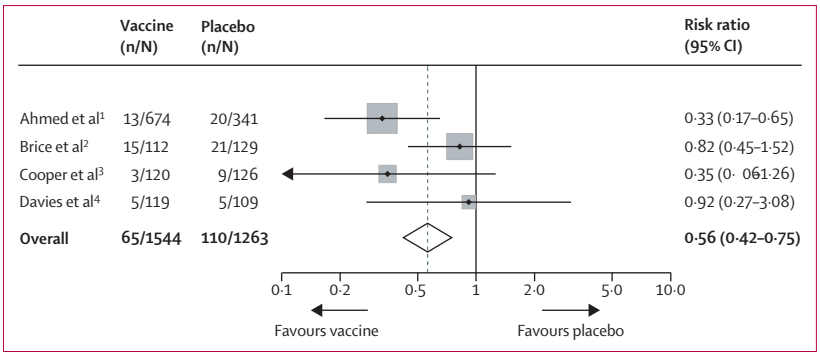

Figure 2: **Forest plot**
Please supply in an editable format, with absolute numbers of patients (n/N) for treatment and control groups. Please do not convert the x-axis to a log scale if the effect estimate is not calculated that way (ie, error bars should typically be even lengths around the point estimate). n=cases of influenza. N=group size.

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. Authors should briefly 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
Authors should describe here how their findings add value to the existing evidence.

Implications of all the available evidence
Authors 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.

For the **trial profile template** see http://www.thelancet.com/pb/assets/raw/Lancet/authors/trial-profile-template.pptx

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.

Declaration of interests

Declare any competing interest for all authors, if none then add "I/We declare no competing interests." Ensure this statement matches what is reported on the ICMJE forms.

Acknowledgments

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

References (reference limit is flexible, but should comprise only studies included in the systematic review or meta-analysis plus up to 30 others)

- 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.[15] 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

For **journal name abbreviations** see http://www.ncbi.nlm.nih.gov/nlmcatalog/journals

- 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).
- Unpublished material is cited in the text as unpublished if it is the author's own observation, or as a personal communication from a named individual (with their institution stated) if it is by someone else. Written permission is needed to cite personal communications.
- References that have been submitted to a journal but not accepted for publication should be cited as unpublished data in the text and not included in the reference list. References that have been accepted by a journal and are in press can be included in the list; please supply a copy of the letter of acceptance.