STROBE Explanation

Limitations (19)

- The identification and discussion of the limitations of a study are an *essential part* of scientific reporting
  - to identify the *sources of bias and confounding*
  - to discuss the *relative importance* of different biases, including the likely *direction and magnitude* of any potential bias
  - to discuss any *imprecision* of the results (eg. sample size and measurement bias)

Vandenbroucke JP, et al. PLoS Med 4(10): e297.

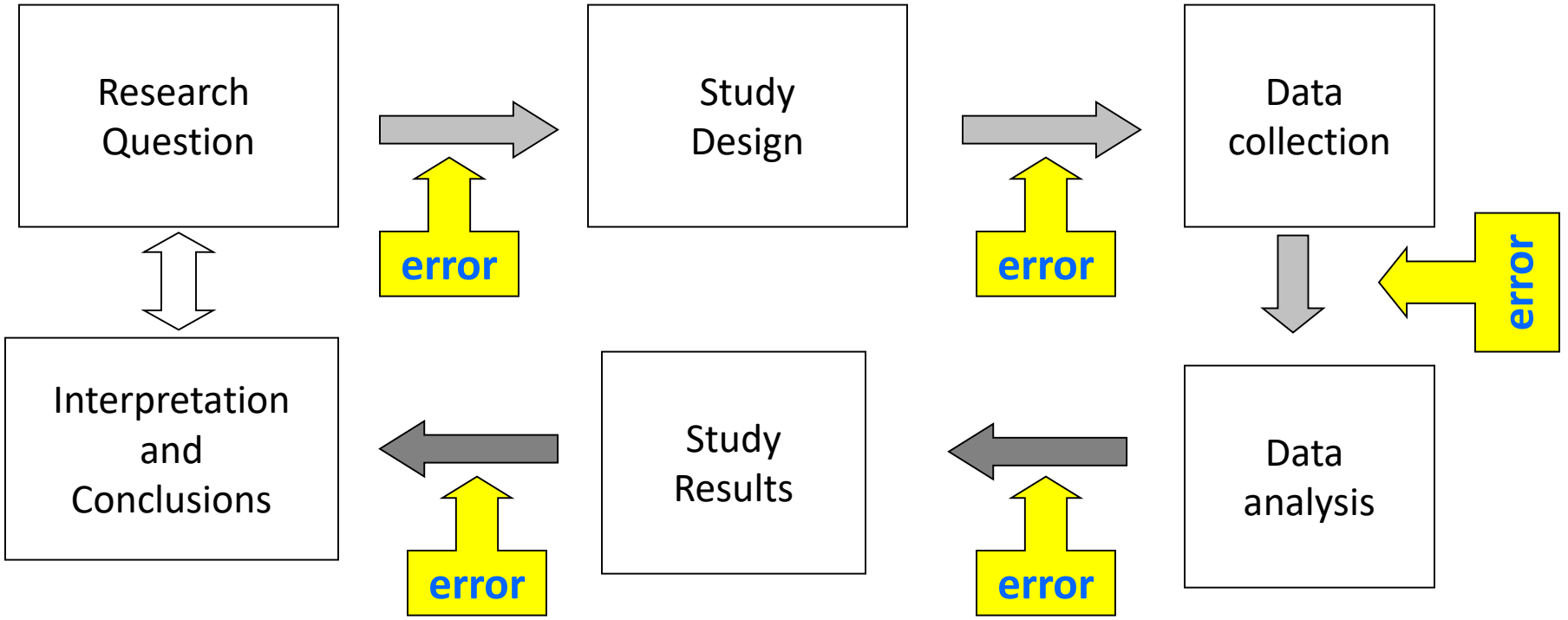
STROBE: Discussion

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
- Compare the study with other published studies regarding validity, generalizability, and precision

von Elm E, et al. PLoS Med 4(10): e296.

From research question to results



What kinds of bias are there in each step?
What are their direction and magnitude?
How are authors dealing with the potential bias?

Example #2

Comparison of Mortality and Costs at Trauma and Nontrauma Centers for Minor and Moderately Severe Injuries in California

Mark S. Zocchi, MPH*; Renee Y. Hsia, MD, MSc; Brendan G. Carr, MD, MS; Babak Sarani, MD; Jesse M. Pines, MD, MBA

*Corresponding Author. E-mail: mzocchi@gwu.edu.

LIMITATIONS

The study has several limitations. The primary one is that the Office of Statewide Health Planning and Development data sets are administrative and do not include several key variables, such as pl… pressure, Glasgow C… outcomes studied and could…o influence the choice that

Potential unmeasured bias

Our findings are not generalizable to the outpatient setting because costs could be observed only for admitted patients. This limitation is significant because some hospitals may be at… injuries by treating… opposed to an inpatient set…g. By limiting our cost

Generalizability

The exclusion of transfers may have affected trauma centers differently from nontrauma centers. Even though outcomes did not differ significantly from results of the main analysis when transfers were included, it is possible that costs were not fully captured for patients who were transferred. One st…

Data, Study population

Another limitation of the study was that injury severity scoring is calculated on postdischarge diagnostic coding. In practice, there may have been legitimate reasons for an emergency physician to suspect a more severe injury or illness that, after admission to the hospital and additional evaluation, was not found. This may have been especially

There were limitations in the outcome measures we used. In our estimate of mortality, all deaths were counted as we could not discern whether death was due to injury or other comorbid conditions. Inpatient mortality is a

The method we used to estimate costs from charges also has limitations. First, costs were derived with cost-to-charge ratios rather than the actual amount negotiated between hospitals and third-party payers. Cost-to-charge ratios are

Potential measurement bias

STROBE: Discussion

Interpretation (20)

- Give *a cautious overall interpretation* of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence

Generalizability (21)

- Discuss the *generalizability (external validity)* of the study results

von Elm E, et al. PLoS Med 4(10): e296.

STROBE Explanation

Interpretation (20)

- The heart of the discussion section
- Do not over-interpret
- Authors should put their results *in context with* similar studies and *explain how the new study affects the existing body of evidence*, ideally by referring to a *systematic review*

Vandenbroucke JP, et al. PLoS Med 4(10): e297.

STROBE Explanation

Interpretation (20)

- Do not ignore or omit references that are contrary to your thesis or findings
  - The peer reviewers will find them!
  - Need a balanced, unbiased discussion
- What future studies might shed further light on the issues you examined?
  - It is safe to mention studies that are planned or underway
  - Do not just say “further study is needed” – be specific about WHAT is needed

Vandenbroucke JP, et al. PLoS Med 4(10): e297.

Discussion: Interpretation

- The *purpose* of the discussion is
  - to interpret and describe the significance of your findings in light of what was already known about the research problem being investigated, and
  - to explain any new understanding or insights about the problem after you have taken the findings into consideration
- Do not restate content from background
- Discuss the real range of *uncertainty in the main results* (effect measure), which is larger than the statistical uncertainty reflected in confidence intervals

STROBE: Discussion

Interpretation (20)

- Give *a cautious overall interpretation* of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence

Generalizability (21)

- Discuss the *generalizability (external validity)* of the study results

von Elm E, et al. PLoS Med 4(10): e296.

STROBE Explanation

Generalizability (21)

- Called *external validity or applicability*, is the extent to which the results of a study can be applied to other circumstances
  - Can results be applied to an individual/ groups/ populations that differ from those enrolled in the study?*: Person*
  - Are the nature and level of *exposures* comparable, and the definitions of *outcomes* relevant to another setting or population?
  - Are data collected in many years ago still relevant today?*: Time*
  - Are results from one country applicable to other countries?*: Place*
- A matter of judgment depending on the study setting, the characteristics of the participants, the exposures examined, and the outcomes assessed

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Example #2

Comparison of Mortality and Costs at Trauma and Nontrauma Centers for Minor and Moderately Severe Injuries in California

Mark S. Zocchi, MPH*; Renee Y. Hsia, MD, MSc; Brendan G. Carr, MD, MS; Babak Sarani, MD; Jesse M. Pines, MD, MBA

*Corresponding Author. E-mail: mzocchi@gwu.edu.

Our findings are not generalizable to the outpatient setting because costs could be observed only for admitted patients. This limitation is significant because some hospitals may be able to decrease overall costs of treating injuries by treating them in the outpatient setting as opposed to an inpatient setting. By limiting our cost analysis to the inpatient setting, we could be discounting the value these hospitals are able to provide. In a secondary analysis, we compared the case mix of routine discharges at trauma and nontrauma centers. We found small differences in case mix and injury severity but, overall, they were similar (Table E7, available online at http://www.annemergmed.com). From this analysis, it does not appear that trauma centers treat a particularly different case mix in the outpatient setting than nontrauma centers. However, without cost data it is not possible to definitely determine what the difference in costs may or may not be.

Lack of generalizability

Authors' efforts

Example #3

Patient Outcomes at Urban and Suburban Level I Versus Level II Trauma Centers

Amy H. Kaji, MD, PhD*; Nichole Bosson, MD, MPH; Marianne Gausche-Hill, MD; Aaron J. Dawes, MD, PhD; Brant Putnam, MD; Tchaka Shepherd, MD; Roger J. Lewis, MD, PhD

*Corresponding Author. E-mail: akaji@emedharbor.edu.

LIMITATIONS

adjusted model did not change the results. Additionally, because our study included only trauma patients greater than or equal to 15 years and transported to a center within the regionalized system of Los Angeles County, the results may not be generalizable to other age groups or location. In

Lack of generalizability: Person and place

Thank you!


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Anytime | Anywhere | Anyone
SAFETY & HEALTH
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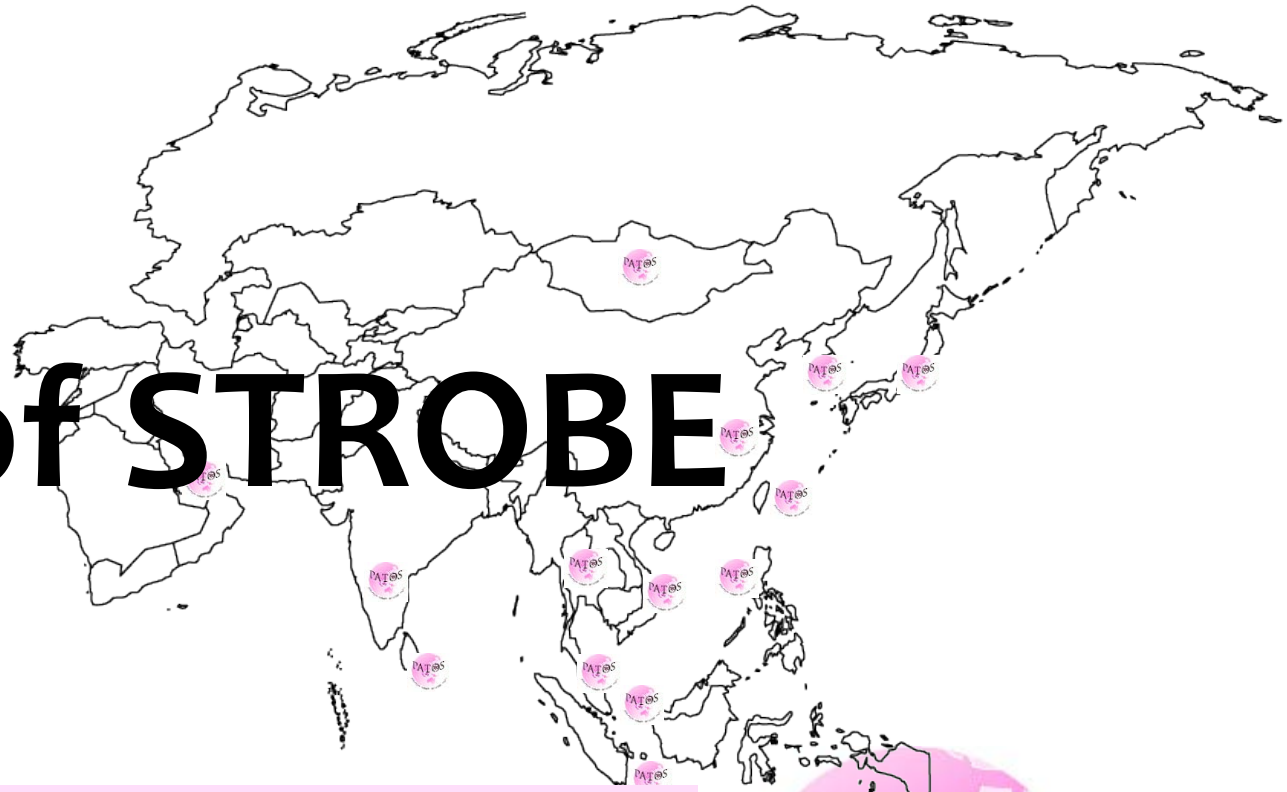
Remind of STROBE



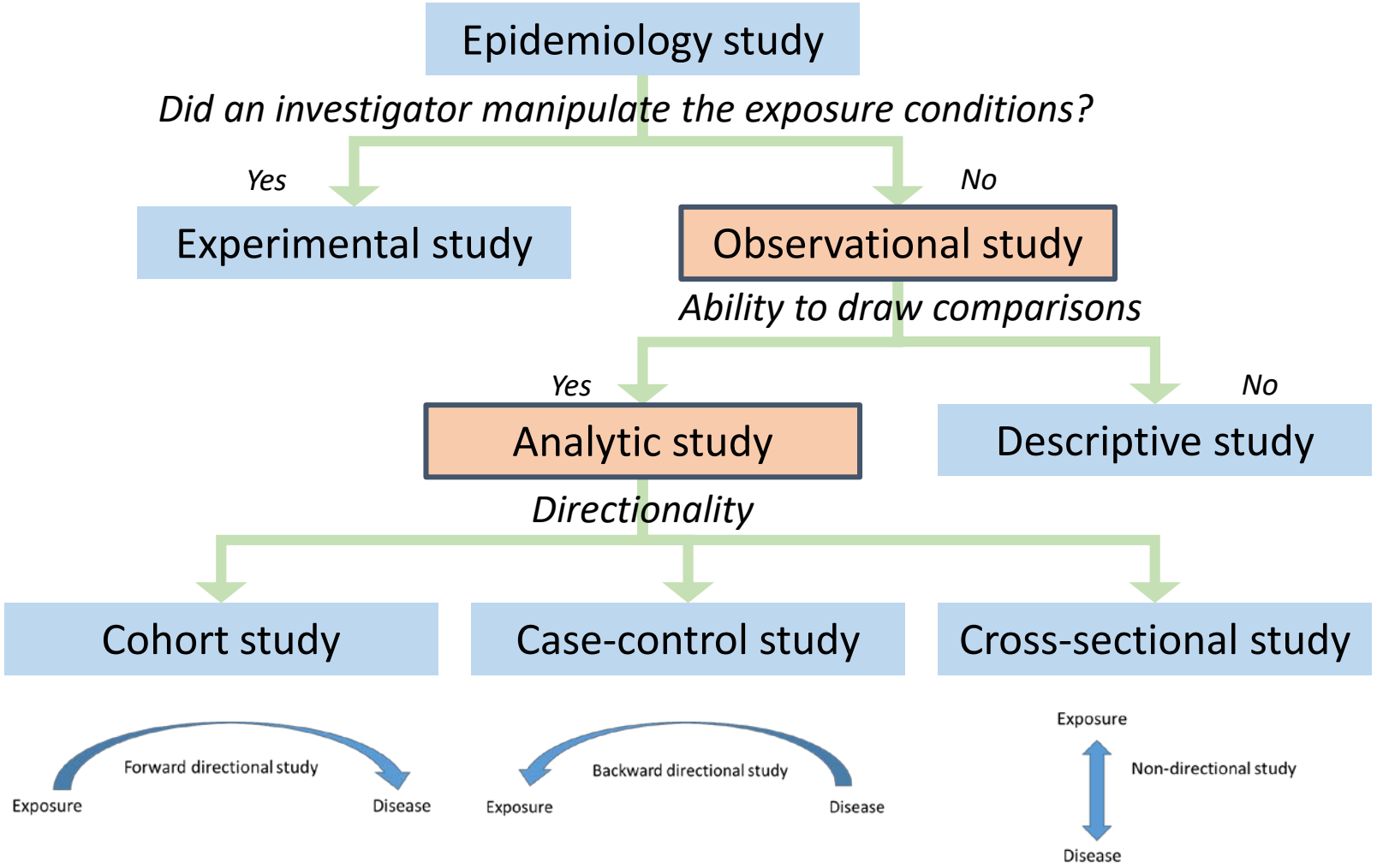
Anytime | Anywhere | Anyone
SAFETY & HEALTH
SNUH LEMS

The PATOS Research Workshop

How to write a paper?
Multicenter observational study

PATOS
PAN-ASIAN TRAUMA OUTCOMES STUDY

Epidemiologic study design



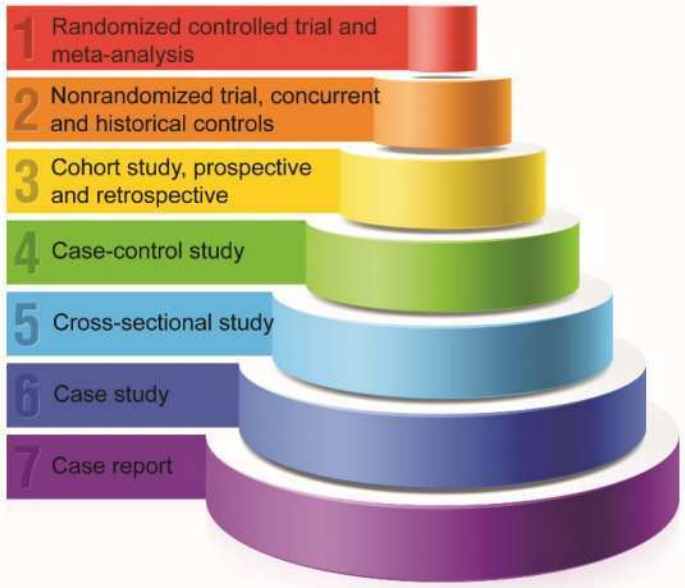
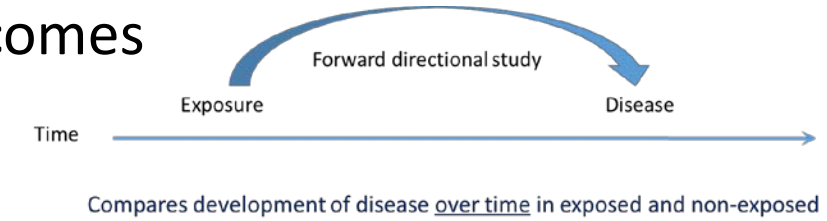


Figure. Hierarchy of Research Design

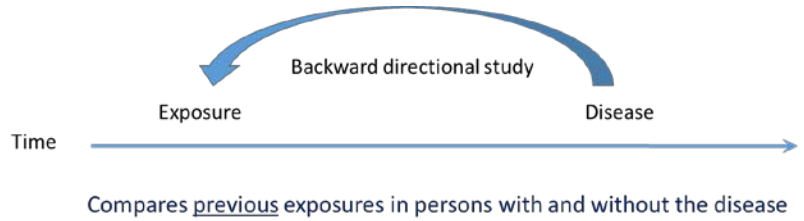
Analytic observational studies

- Relatively free from ethical issues
  - associations between measured exposures and outcomes
- Main categories analytic observational studies
  - Cohort
  - Case-control
  - Cross-sectional

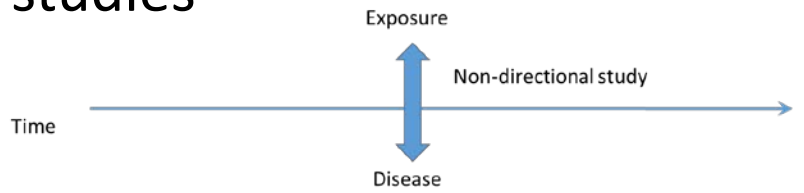
  ➔ ***Main target of STROBE statement***
- Critical design issue: Directionality
  - Forward: Observational cohort studies, Experimental studies
  - Backward: Case-control studies
  - Non-directional study: Cross-sectional studies



Compares development of disease over time in exposed and non-exposed



Compares previous exposures in persons with and without the disease



Compares presence of exposures in persons with and without existing disease

or

Compares presence of disease in persons with and without existing exposure

Remind of key study types

- Cohort: investigators follow people over time
  - *Think of the military definition of a "cohort"*
  - *A group of soldiers marching forward together*
- Case-Control: investigators compare exposures between people with a particular disease outcome ("cases") and those without ("controls")
  - *Key: controls must represent the population of people from whom the cases arose. If the cases were "males over age 60 years with prostate cancer", then the controls cannot be selected from "all persons who visited Tokyo in 2015"*
- Cross-Sectional: investigators assess all individuals in a sample, at the same point in time, to examine the prevalence of exposures, risk factors, or diseases
  - *The "point in time" could be an instant, a day, a week, even a month*

Remind of STROBE

- Checklist with 22 items
  - Heading (where in paper), item No
  - Recommendation, divided into: Cohort study, Case-control study, Cross-sectional study

➔ ***We discussed all of these items in this research workshop! Just yesterday! Remember??***

TABLE 1. The STROBE statement—Checklist of Items That Should be Addressed in Reports of Observational Studies

	Item Number	Recommendation
TITLE and ABSTRACT	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
INTRODUCTION		
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
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
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 (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	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
Bias	9	Describe any efforts to address potential sources of bias

Title and Abstract

Title and Abstract (1)

- (a) Indicate *the study's design* with a commonly used term in the title or the abstract
- (b) Provide in the abstract *an informative and balanced summary* of what was done and what was found

Introduction

Background/rationale (2)

- Explain *the scientific* background and rationale for the investigation being reported

Objectives (3)

- State *specific* objectives, including any *prespecified hypotheses*

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

Methods

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*

Methods

Participants (6)

- (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

Methods

Variables (7)

- *Clearly define* all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable

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

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

Methods

Bias (9)

➔ *Important in observational studies!*

- Describe any *efforts to address potential sources of bias*

Study size (10)

- Explain *how* the study size was arrived at

Quantitative variables (11)

- Explain *how* quantitative variables *were handled* in the analyses. If applicable, describe which groupings were chosen, and why

Methods

Statistical methods (12)

- (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 the 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, and analyzed
- (b) Give *reasons* for non-participation at each stage
- (c) Consider use of *a flow diagram*

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

Results

Descriptive data (14*)

- (a) Give *characteristics* of study participants (eg, demographic, clinical, social) and information on exposures and potential confounders
- (b) Indicate *the number of participants with missing data* for each variable of interest
- (c) *Cohort study*—Summarize *follow-up time* (eg, average and total amount)

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

Results

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

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

Results

Main results (16)

- (a) Give *unadjusted estimates* and, if applicable, *confounder-adjusted estimates* and *their precision* (eg, 95% confidence intervals). Make clear which confounders were adjusted for and why they were included
- (b) Report category boundaries when continuous variables were categorised
- (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

Discussion

Interpretation (20)

- Give *a cautious overall interpretation* of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence

Generalizability (21)

- Discuss the *generalizability (external validity)* of the study results

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

Thank you!

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PAN-ASIAN TRAUMA OUTCOMES STUDY

Anytime | Anywhere | Anyone

SAFETY & HEALTH

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