

观察性研究的报告规范STROBE

作者：李楠 赵一鸣 来源：临床流行病学和循证医学

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其实在
临床研究中，最常见的方案并不是RCT，根据临床研究的阶段划分，临床研究可以分为探索性研究、培育性研究和验证性研究，三个阶段对方案证据强度的要求逐渐递增，而RCT研究往往仅用于验证性研究中。反观一些基金，比如国家自然科学基金，往往更倾向于支持涉及诊断、治疗、预后、病因等问题的探索性和培育性研究，因此在设计中，我们最常用到的其实还是观察性研究这一大类研究。无论您是队列研究、病例对照研究还是这些研究的衍生类别，其实都属于观察性研究。

本文介绍观察性研究的报告规范——STROBE，供大家设计观察性研究方案的时候参考。与CONSORT标准不同，STROBE不仅针对一种研究方案，而是适用于队列、病例对照及其各种衍生研究设计方案，因此在STROBE官网上，我们既能看到通用的清单，也有用于各类观察性研究的分清单。

STROBE的全部信息和解读都可以从其官方网站(<http://www.strobe-statement.org/>)获取，目前最新版本清单是2007年确定的第4版。在此我们同样把最新的STROBE清单贴给大家参考，遗憾的是该清单并没有官方认可的中文翻译版。

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

	No	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	<p>(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</p> <p>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</p> <p>Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants</p> <p>(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed</p> <p>Case-control study—For matched studies, give matching criteria and the number of controls per case</p>
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
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
Statistical methods	12	<p>(a) Describe all statistical methods, including those used to control for confounding</p> <p>(b) Describe any methods used to examine subgroups and interactions</p> <p>(c) Explain how missing data were addressed</p> <p>(d) Cohort study—If applicable, explain how loss to follow-up was addressed</p> <p>Case-control study—If applicable, explain how matching of cases and controls was addressed</p> <p>Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy</p> <p>(e) Describe any sensitivity analyses</p>

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
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

*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.

更多 统计方法 请访问 <https://www.iikx.com/news/statistics/>

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