

Guidelines for the REporting of studies Conducted using Observational Routinely-collected health data (RECORD): An extension of the STROBE reporting guidelines

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BACKGROUND

- The increased availability of data generated while delivering healthcare (routinely collected data) transformed the landscape of research
- Challenge is understanding the strengths and limitations of individual data sources and associated biases
- Poor reporting can obscure sources of bias, reduce the usefulness of research by hampering efforts to undertake meta-analysis and lead to erroneous conclusions
- RECORD is an international collaborative process (involving >100 international stakeholders) to inform decision making

AIM

- To develop a reporting guideline for observational studies using health data routinely collected for non-research purposes as an extension of STROBE – the REporting of studies Conducted using Observational Routinely collected Data (RECORD) statement

METHODS

The approach to reporting guideline development involves five phases:

- Phase 1
Initial steps – including applications for external funding
- Phase 2
Pre-meeting activities – including identification of participants and stakeholders, conduct surveys and a systematic review of the literature based on survey results;
- Phase 3
Face-to-face consensus meeting - the Working Committee finalized the checklist of items prioritized
- Phase 4
Post-meeting activities – including formulation of final checklist phrasing, development of explanatory document and final publication
- Phase 5
Post-publication activities – including knowledge translation, encouragement of uptake and post-publication evaluation



Limitations:

- Both STROBE and RECORD are intended for application to observational research studies only
- As the field evolves, we expect to expand RECORD to other research designs

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RECORD CHECKLIST

	STROBE ITEMS	RECORD ITEMS
TITLE AND ABSTRACT	(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	1.1: The type of data used should be named in the title or abstract. Where possible, the name of the databases used should be included. 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract. 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.
INTRODUCTION		
Participants	(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	6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If codes used to select the population cannot be reported, an explanation should be provided. 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, its detailed methods and results should be provided. 6.3: Linkage: Consider the use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.
Variables	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these codes or algorithms cannot be reported, an explanation should be provided.
Data Access and Cleaning Methods	..	12.1: Authors should describe the extent to which the investigators had access to the database population in order to create the study population. 12.2: Authors should provide information on the data cleaning methods used in the study.
Linkage	..	12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.
RESULTS: Participants	(a) Report the numbers of individuals at each stage of the study (e.g. 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	13.1: Describe in detail the selection of the people included in the study (i.e. study population) selection including filtering based on data quality, data availability and linkage. These can be described in the text and/or by the study flow diagram.
DISCUSSION: Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time.
OTHER INFORMATION: Accessibility of protocol, raw data, and programming code	..	22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.

CONCLUSIONS

- RECORD will expand the STROBE criteria to observational studies conducted using routinely collected health data
- Implementation of the RECORD checklist by authors, journal editors, and peer reviewers will result in transparency, reproducibility, and completeness of reporting of research conducted using routinely collected health data

