**Better Research Reporting to Improve the Utility of Routine Data for Making Better Treatment Decisions**

Lars G. Hemkens, senior scientist1; Sinéad M. Langan, NIHR clinician scientist and senior lecturer2; Eric I. Benchimol, assistant professor and scientist3,4

*1 Basel Institute for Clinical Epidemiology and Biostatistics, University Hospital Basel, Basel, Switzerland*

*2 London School of Hygiene and Tropical Medicine, London, UK*

*3 Department of Pediatrics, Children’s Hospital of Eastern Ontario, and School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, Ottawa, Canada*

4 Institute for Clinical Evaluative Sciences, Ottawa, Canada

**Correspondence:**

RECORD Steering Committee

record@record-statement.org

Word count main text: 1240

Number of references: 14

**Keywords:**

Research Reporting, RECORD, Transparency, Routinely Collected Health Data, Comparative Effectiveness Research

**ABSTRACT**

The availability of routinely-collected health data, such as health administrative data, electronic health records, prescription records, and disease registries, has increased in the information age. This has led to an explosion of reports of comparativeness effectiveness research using such data. Guidelines for the **RE**porting of studies **C**onducted using **O**bservational **R**outinely-collected **D**ata (RECORD) will improve the completeness and transparency of reporting of research using routinely collected health data. The Journal of Comparative Effectiveness Research has endorsed these guidelines. In this commentary, the RECORD checklist is reprinted and members of the RECORD working committee reflect on the importance of these reporting guidelines for the field of comparative effectiveness research.

**COMMENTARY**

Comparing treatment effects in usual care settings and evaluating how they vary between specific patient groups is a key objective of comparative effectiveness research (CER)[[1](#_ENREF_1)]. “Real world” data collected during routine practice theoretically represents usual care and research conducted using extremely large databases (“Big data”) theoretically allows the exploration of treatment effects in patients with specific, and even rare, characteristics or conditions. Therefore, routinely collected health data such as electronic health records, prescription records, or health administrative data are promising and increasingly used data sources for CER.

The vast majority of CER using routinely collected health data is observational in research design. As such, it is subject to the inherent biases that inevitably affect any non-randomized research[[1](#_ENREF_1)]. These biases may be exponentially amplified by problems related specifically to the very nature of such data not being collected for research purposes, including misclassification of disease cohorts, missing data issues, linkage problems and other errors occurring when large datasets are collected, linked, processed, and retrospectively analyzed[[2](#_ENREF_2)]. Such research may be selectively analyzed, reported, discussed, and interpreted which further decreases the confidence in the comparative effectiveness estimates[[2](#_ENREF_2)]. Although the expectations in using routinely collected data to undertake observational CER to reliably assess treatment effects are probably exaggerated, several improvements to the current research agenda for the use of these data for CER have been proposed[[2](#_ENREF_2)].

An essential component of improving the CER research agenda is more complete and transparent reporting of research conduct and results[[2](#_ENREF_2)]. Poor reporting of research wastes efforts and resources[[3](#_ENREF_3)], and research-reporting using routinely collected data is often remarkably poor[[4](#_ENREF_4)]. A recent empirical analysis showed that readers of observational studies using routine health data were often unable to know which intervention was evaluated, in which population, and which outcome was measured[[4](#_ENREF_4)]. Minimal prerequisites for research replication (such as a full list of all variables used for modeling) are often missing. Methods and effectiveness of database linkage or the codes and classification algorithms used to identify subjects, exposures and outcomes are typically insufficiently described and statements about dataset availability or sharing are rare[[4](#_ENREF_4)].

Reporting guidelines, such as Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[[5](#_ENREF_5)], are widely used tools to improve research reporting and are associated with better reporting quality[[6](#_ENREF_6), [7](#_ENREF_7)]. While the STROBE guidelines represent a minimum requirement for reporting of all observation research (including observational CER), they are also general in nature. STROBE does not address issues that are specific to research conducted using routinely collected health data. Three checklists have been published that may aid in the conduct and ´critical appraisal´ of studies using routinely collected data for CER, one of which specifically addressed retrospective database research in the context of the STROBE guidelines[[8-10](#_ENREF_8)]. However, the following issues limit the usefulness of these checklists: a) they focus primarily on the methods of such research and less on transparency of reporting, b) they address specific research fields such as CER or drug research and do not apply to most observational research, c) they have not been widely endorsed by journal editors and d) they were not developed with international stakeholder consensus or as part of a formal extension of STROBE. The REporting of studies Conducted using Observational Routinely-collected Data (RECORD) statement was developed to fill these gaps[[11](#_ENREF_11)]. RECORD is a newly-published extension to the STROBE statement focusing on research conducted using routinely collected data.

RECORD was developed using the methods recommended for the development of reporting guidelines, produced by members of the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network[[12](#_ENREF_12)]. A three-stage development process was used to develop the RECORD statement[[13](#_ENREF_13)]. First, two modified electronic surveys of key stakeholders were undertaken. Stakeholders represented the diversity of the population who use research conducted using routine data in order to make decisions on health care, health policy, and research methods. Survey participants included clinicians, clinical and academic researchers, journal editors, policymakers, and pharmaceutical industry representatives. The first survey was qualitative in nature and sought to identify themes that were deemed important to include in a checklist of minimum requirements of reporting for studies using routinely collected data. In the second survey participants prioritised themes identified in the first survey for inclusion in the final RECORD checklist. The surveys were followed by a second stage consisting of a face-to-face meeting of the RECORD working committee members. Attendees reviewed the survey results and comments from stakeholders and created the checklist of items. The checklist was further refined and explanatory text was developed by a writing group. The third and final stage of the process involved further open comment on the draft checklist, conducted through an online message board on the RECORD website (record-statement.org). Using this rigorous approach, RECORD was designed to reflect the views of the diverse community of researchers, academics, clinicians, and policy-makers who conduct and use research using routinely collected health data. The final RECORD checklist is reprinted in Table 1, and the explanatory document is available online at record-statement.org or in print[[11](#_ENREF_11)].

One limitation of RECORD is the focus of the guidelines on observational research. A substantial and often underestimated potential of routinely collected health data for CER lies in its value for conducting large pragmatic clinical trials[[14](#_ENREF_14" \o "Vickers, 2014 #9)]. There are no guideline extensions specifically addressing issues of routine data for non-observational research. This would be a very valuable next step to further improve the utility of the increasing quantity and diversity of routinely collected data. However, RECORD might be used for non-observational research using routine data in combination with other reporting guidelines and may provide guidance with respect to reporting of the strengths and weaknesses of the data used, construction of the study population, research methods, and interpretation of results.

Publication of reporting guidelines and adoption by journals may not be sufficient to affect improvements in research transparency[[7](#_ENREF_7)]. We will work with the editors of the Journal of Comparative Effectiveness Research to efficiently implement the reporting guidelines, as well as evaluate the effectiveness of these guidelines in improving the quality of research reports. In so doing, RECORD will improve the completeness and transparency reporting of observational CER using routinely collected data in order to allow for better treatment decisions and improved patient care.

Table 1. The RECORD Checklist. Reprinted with permission from Benchimol EI, Smeeth L, Guttmann A, et al. *PLoS Med* 2015;12(10):e1001885 [[11](#_ENREF_11)].

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Item No.** | **STROBE items** | **Location in manuscript where items are reported** | **RECORD items** | **Location in manuscript where items are reported** |
| **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 |  | RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract. |  |
| **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 |  | RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 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, detailed methods and results should be provided.RECORD 6.3: If the study involved linkage of databases, consider 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 | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. |  | RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided. |  |
| 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 | (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 |  |   |  |
| Data access and cleaning methods |  | .. |  | RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.RECORD 12.2: Authors should provide information on the data cleaning methods used in the study. |  |
| Linkage |  | .. |  | RECORD 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 | 13 | (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 |  | RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram. |  |
| Descriptive data | 14 | (a) Give characteristics of study participants (*e.g.*, 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* - summarise follow-up time (*e.g.*, 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 (e.g., 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—e.g., 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 |  | RECORD 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, as they pertain to the study being reported. |  |
| 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 |  |  |  |
| Accessibility of protocol, raw data, and programming code |  | .. |  | RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code. |  |

**Literature**

1. Sox HC, Goodman SN. The methods of comparative effectiveness research*.* *Annu Rev Public Health* 33 425-445 (2012).

2. Hemkens LG, Contopoulos-Ioannidis DG, Ioannidis JPA. Routinely Collected Data and Comparative Effectiveness Evidence: Promises and Limitations*.* *CMAJ*  (In Press).

3. Glasziou P, Altman DG, Bossuyt P *et al*. Reducing waste from incomplete or unusable reports of biomedical research*.* *Lancet* 383(9913), 267-276 (2014).

4. Hemkens LG, Benchimol EI, Langan SM *et al*. Reporting of studies using routinely collected health data: systematic literature analysis (oral abstract presentation). *REWARD / EQUATOR Conference; Edinburgh, UK*  (2015. ).

5. Von Elm E, Altman DG, Egger M *et al*. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies*.* *PLoS medicine* 4(10), e296 (2007).

6. Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network Library 2015*.* (23 October 2015),

7. Turner L, Shamseer L, Altman DG *et al*. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals*.* *Cochrane Database Syst Rev* 11 MR000030 (2012).

8. Berger ML, Mamdani M, Atkins D, Johnson ML. Good research practices for comparative effectiveness research: defining, reporting and interpreting nonrandomized studies of treatment effects using secondary data sources: the ISPOR Good Research Practices for Retrospective Database Analysis Task Force Report—part I*.* *Value in Health* 12(8), 1044-1052 (2009).

9. Motheral B, Brooks J, Clark MA *et al*. A checklist for retrospective database studies—report of the ISPOR Task Force on Retrospective Databases*.* *Value in Health* 6(2), 90-97 (2003).

10. Peterson AM, Nau DP, Cramer JA, Benner J, Gwadry‐Sridhar F, Nichol M. A checklist for medication compliance and persistence studies using retrospective databases*.* *Value in Health* 10(1), 3-12 (2007).

11. Benchimol EI, Smeeth L, Guttmann A *et al*. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement*.* *PLoS medicine* 12(10), e1001885 (2015).

12. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines*.* *PLoS medicine* 7(2), e1000217 (2010).

13. Nicholls SG, Quach P, Von Elm E *et al*. The REporting of Studies Conducted Using Observational Routinely-Collected Health Data (RECORD) Statement: Methods for Arriving at Consensus and Developing Reporting Guidelines*.* *PLoS One* 10(5), e0125620 (2015).

14. Vickers AJ. Clinical trials in crisis: Four simple methodologic fixes*.* *Clinical trials* 11(6), 615-621 (2014).