

The reporting of studies using routinely collected health data was often insufficient

Lars G. Hemkens^{a,*}, Eric I. Benchimol^{b,c}, Sinéad M. Langan^d, Matthias Briel^{a,e}, Benjamin Kasenda^a, Jean-Marie Januel^f, Emily Herrett^d, Erik von Elm^g

^aDepartment of Clinical Research, Basel Institute for Clinical Epidemiology and Biostatistics, University Hospital Basel, Spitalstrasse 12, CH-4031 Basel, Switzerland

^bDepartment of Pediatrics, Children's Hospital of Eastern Ontario, School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, 401 Smyth Road, Ottawa, ON K1H 8L1, Canada

^cInstitute for Clinical Evaluative Sciences, G1 06, 2075 Bayview Avenue, Toronto, ON M4N 3M5, Canada

^dDepartment of Non-communicable Disease Epidemiology, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, Keppel Street, London, WC1E 7HT, United Kingdom

^eDepartment of Clinical Epidemiology and Biostatistics, McMaster University, 1280 Main Street West, Hamilton, ON L8S 4K1, Canada

^fUniversity Institute of Higher Education and Research in Health Care (IUFERS), Faculty of Biology and Medicine, University of Lausanne, Biopole 2, Route de la Corniche 10, CH-1010, Lausanne, Switzerland

^gCochrane Switzerland, Institute of Social and Preventive Medicine, Lausanne University Hospital, Route de la Corniche 10, CH-1010, Lausanne, Switzerland

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Abstract

Objectives: To assess reporting quality of studies using routinely collected health data (RCD) to inform the REporting of studies Conducted using Observational Routinely collected health Data (RECORD) guideline development.

Study Design and Setting: PubMed search for observational studies using RCD on any epidemiologic or clinical topic. Sample of studies published in 2012. Evaluation of five items based on the STrengthening the Reporting of OBServational studies in Epidemiology (STROBE) guideline and eight newly developed items for RCD studies.

Results: Of 124 included studies, 39 (31.5%) clearly described its design in title or abstract. Complete information to frame a focused research question, that is, on the population, intervention/exposure, and outcome, was provided for 51 studies (41.1%). In 44 studies where definitions of codes or classification algorithms would be necessary to operationalize such a research question, only nine (20.5%) reported all items adequately. In 81 studies describing multivariable analyses, 54 (66.7%) reported all variables used for modeling and 34 (42.0%) reported basic details required for replication. Database linkage was reported adequately in 12 of 41 studies (29.3%). Statements about data sharing/availability were rare (5/124; 4%).

Conclusion: Most RCD studies are insufficiently reported. Specific reporting guidelines and more awareness and education on their use are urgently needed. © 2016 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Keywords: Routinely collected data; Observational studies; Research reporting; Guidelines; Research design; Bibliometrics

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the UK Department of Health.

* Corresponding author. Tel.: +41-61-265-3100; fax: +41 61 265 3109.

E-mail address: lars.hemkens@usb.ch (L.G. Hemkens).

What is new?**Key findings**

- Most studies using routinely collected health data (RCD) are insufficiently reported. For example, it is frequently impossible to know which exposure or intervention is associated with which outcome in which population or minimal prerequisites for replication/assessment of scientific validity are often lacking.

What this adds to what was known?

- Even years after introducing reporting guidelines for observational studies, many studies from various clinical and epidemiologic areas are poorly reported.

What is the implication and what should change now?

- Specific reporting guidelines for studies using RCD are necessary to address specific characteristics of such research.
- Authors, peer reviewers, and editors need training to apply both novel and established reporting guidelines to ensure better and more complete research reporting.

1. Introduction

Routinely collected health data (RCD) are defined as data collected for purposes other than research [1,2]. Examples include health administrative data, electronic health records, and disease or clinical registries. Increased ability to store, process, and quickly access large amounts of such data led to increasing collection and usage for health research. Using such novel data sources involves unique challenges for research reporting, for example, the description of database characteristics or record linkage methodology [3]. Poor reporting wastes efforts and resources [4]. Guidelines such as the STrengthening the Reporting of OBServational studies in Epidemiology (STROBE) statement have been developed and endorsed by many journals to improve reporting of biomedical research [5]. Inadequate or incomplete reporting has been shown in observational studies on general medical interventions that were published before introduction of STROBE [6] and in more recent evaluations that addressed specific research areas, including cancer [7], hand surgery [8], dermatology [9], plastic surgery [10], or magnetic resonance imaging [11].

We analyzed the reporting of any type of observational study using RCD in a randomly selected sample of studies published in 2012 which were identified in PubMed. We

focused on reporting domains that are central with regard to the study's design, its research question, and basic prerequisites for study results replication. We selected items addressing these reporting domains in STROBE, and we developed a set of new items deemed specifically important for reporting of research using RCD. This new set included items that directly correspond to the selected STROBE items and items that focus on selected specific characteristics of RCD research.

Using a sample of recent publications, we systematically evaluated these reporting items. In ancillary analyses, we explored if reporting affects both low- and high-impact journals and if better reporting is associated with more citations.

We aimed to assess the present state of reporting and provide a first empirical estimate of its quality to inform the development of a specific reporting guideline for RCD studies by the REporting of studies Conducted using Observational Routinely collected health Data (RECORD) working committee [12]. RECORD has recently been published as an extension of the STROBE guidelines and aims to enhance transparency of research reporting and provide guidance to adequately report methods and findings of research using RCD [13].

2. Methods*2.1. Eligibility of studies*

We selected a sample of English language studies that used RCD and reported outcomes related to the health status of persons or a population, such as mortality or morbidity. For example, we included publications detailing epidemiologic research on incidence and prevalence of diseases or risk factors or comparative effectiveness research studies measuring treatment effects. We did not consider studies on outcomes such as costs or care processes. We included nonexperimental studies in humans based on any type of health data that were routinely collected, that is, for purposes other than research. We also included analyses based on registries, albeit registries characteristically comprise at least one actively collected data element [14]. There were no restrictions with respect to characteristics of study participants.

2.2. Literature search

We searched PubMed for studies published in 2012 (search date June 6, 2013) using terms related to RCD, including constructs for “database,” “registries,” “electronic health records,” and “administrative data/routine data” (Webappendix 1 at www.jclinepi.com). We integrated the search strategy for electronic health records provided by the National Library of Medicine into our strategy [15]. An information specialist formally peer reviewed the strategy [16].

2.3. Study selection

The 24,929 hits in PubMed were exported to Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) and

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