Objective

To develop reporting guidelines for observational studies using health data routinely collected for non-research purposes as an extension of STROBE – the **RE**porting of studies **C**onducted using **O**bservational **R**outinely-collected **D**ata (**RECORD**) statement.

Overview

The rapid entry of health care into the electronic age has led to a proliferation of large data repositories of health-related information. Such data are collected for administrative and clinical purposes, without specific *a priori* research questions. Examples of these "**routinely-collected health data**" include health administrative data, electronic medical records, primary care surveillance data and disease registries. These data are increasingly being used for observational, comparative effectiveness and health services research. This expanding research area and the growing numbers of publications have generated increasing interest in specific methodologic issues regarding the use of such data for research purposes. At present, there is a lack of clarity regarding the strengths and limitations of available electronic data sources. This confusion has been compounded by incomplete or inadequate reporting of research based on routinely collected health data in the literature. Formal reporting guidelines for studies using routinely-collected health data, with multi-disciplinary expert stakeholder involvement and collaboration from STROBE methodologists, will help ensure the transparency of the methods used in this growing field of research.

Call for Stakeholders

We are engaging stakeholders in the field of research using routinely-collected health data to participate in development of the RECORD statement. We are asking for the participation of researchers, database providers, journal editors and other interested parties in participating in a Delphi exercise. Should you be interested in becoming involved, you will be asked to provide suggested topics for inclusion in the RECORD statement (based on items specific to database research; see Appendix 2). Following this initial stage, you will be asked to rank statements of greatest importance from the most population themes and statements provided. The working committee will then use these suggestions for the final checklist creation process.

If you are interested in participating please email RECORD at record@record-statement.org or for specific queries, please contact Eric Benchimol (ebenchimol@cheo.on.ca) or Sinéad Langan (Sinead.Langan@lshtm.ac.uk). Please include your:
- Name
- E-mail address
- Primary affiliation
- Related experience and area of interest regarding routinely-collected health data (e.g. health administrative data, pharmacoepidemiology using primary care databases, cancer registries, etc.)

Appendix 1: Steering Committee

Name	Expertise	Affiliation	Country of Origin
Eric Benchimol, MD PhD FRCP(C)	Health Administrative Data, Chronic Disease Surveillance	Institute for Clinical Evaluative Sciences (ICES), Department of Epidemiology, University of Ottawa	Canada
Sinead Langan, MD MSc PhD MRCP(UK)	Primary Care Database Research, Pharmacoepidemiology	Department of Epidemiology and Population Health London School of Hygiene & Tropical Medicine	UK
Astrid Guttmann, MD MSc FRCP(C)	Health Administrative Data, Health Services Research	ICES, Department of Health Policy Management and Evaluation, University of Toronto	Canada
David Moher, PhD	Reporting Guideline Development, EQUATOR network	Ottawa Evidence-Based Practice Centre, Department of Epidemiology, University of Ottawa	Canada
Irene Petersen, MSc PhD	Primary Care Databases Methodological research	Department of Primary Care & Population Health, University College London	UK
Liam Smeeth, MBChB FRCGP FFPH MSc PhD	Primary Care Databases, Pharmacoepidemiology	Department of Epidemiology and Population Health London School of Hygiene & Tropical Medicine	UK
Henrik Toft Sørensen, MD, PhD, DMSc	Danish National Registries	Department of Clinical Epidemiology, University of Aarhus	Denmark
Fiona Stanley, AC	Health administrative data, population health, linkage studies	Telethon Institute for Child Health Research, University of Western Australia	Australia
Erik von Elm, MD MSc	Reporting Guideline Development, STROBE initiative	IUMSP University Hospital Lausanne & German Cochrane Centre, University Hospitals Freiburg / Germany	Switzerland

Appendix 2: Draft search strategy for systematic review

MEDLINE search strategy for systematic review of the literature. This strategy was adapted from a previous systematic review of the literature and will undergo peer review. The strategy will also be adapted for use in EMBASE.

1. databases, factual/ or geographic information systems/ or national practitioner data bank/ or databases as topic/
2. Medical Records Systems, Computerized/ or Electronic Health Records/
3. SEER Program/ or Registries/
4. (routine* adj2 (health or medical) adj2 data).mp. OR (routine* adj2 collect* adj2 (health or medical) adj2 data).mp. OR (routine* adj2 collect* adj2 (primary care) adj2 data).mp.
5. (health adj2 administrative adj2 data).mp. OR "administrative data".mp.
6. ((cancer adj2 regist*) or (disease adj2 regist*)).mp.
7. ("general practice research database" OR "clinical practice research datalink" OR "primary care databases").mp.
8. OR/1-7
9. disease notification/ or epidemiologic study characteristics as topic/ or epidemiologic studies/ or case-control studies/ or cohort studies/ or longitudinal studies/ or retrospective studies/ or cross-sectional studies/ or seroepidemiologic studies/
10. 8 AND 9

Appendix 3: Draft open text survey (in development)

1. Please provide specific themes that should be addressed in the RECORD guidelines? Examples of themes previously identified by the RECORD steering and working groups include: disease identification algorithms, code validation, and linkage between databases.

Please do not include items that are already covered in STROBE. Instead, items that would expand or enhance STROBE items are encouraged.

<free text response>

For each item, the following questions will be produced:
a. Which STROBE item would be expanded or enhanced for routine-data research based on your responses? <free text response>

b. Would this item be specific to a certain type of routine data (e.g. administrative data, disease registries, etc.) or would it apply to all types of routine data? <free text response>

2. In the following sections, please provide elements that should be reported in research using routinely-collected health data. Each element should be numbered and summarized in 1-2 sentences.

a. TITLE: <free text response>

b. ABSTRACT: <free text response>

c. INTRODUCTION: <free text response>

d. METHODS: <free text response>

e. RESULTS: <free text response>

f. DISCUSSION: <free text response>

g. OTHER: <free text response>

3. Name:

4. Age: (categories)

5. Current location (country)?

6. Duration of time using routine data or using the results of routine data research (categories)

7. Sex: (M/F)

8. Occupation:

9. Classification (may check multiple):

      a. Researcher, MD, MD/PhD

      b. Researcher, PhD/MSc/BS

      c. Journal editor, journal administrative support

      d. Public (non-medical, non-researcher) stakeholder

      e. Policy-maker

      f. Pharmaceutical industry (researcher)

      g. Pharmaceutical industry (administrative, business, marketing)

10. Type of data used for research (check all that apply):

      a. Researcher, but doesn't use routine data for research

      b. Non-research, but uses the below routine data for other purposes

      b. Health administrative data (government, hospitalization, outpatient, procedures)

      c. Health administrative data (insurance provider)

      d. Health administrative data (other)

      e. Cancer registry

      f. Disease registry   Specify _____

      g. Pregnancy/birth registry

      i. Other Registry   Specify _____

      g. Electronic health/medical records

      h. Government statistical databases (excluding health)

      i. Primary care databases (e.g. GPRD, CPRD, IPCI)

      j. Other _____

11. If necessary, may we contact you for a telephone interview to clarify any themes you mentioned above? YES/NO

12. If yes, telephone number (with country code): _____

      E-mail address: _____

      Days/hours of availability: _____

13. Do you have any comments on themes or topics that you wish to add?